Evidence Report/Technology Assessment
Number 62

Diagnosis and Treatment of Worker-Related Musculoskeletal Disorders of the Upper Extremity

Agency for Healthcare Research and Quality

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome written comments on this evidence report. They may be sent to: Director, Center for Practice and Technology Assessment, Agency for Healthcare Research and Quality, 6010 Executive Blvd., Suite 300, Rockville, MD 20852.

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Structured Abstract

Objectives. We conducted a systematic review of published evidence on four common musculoskeletal disorders affecting workers; carpal tunnel syndrome (CTS), cubital tunnel syndrome, epicondylitis, and de Quervain's disease. This report is a "Best Evidence" synthesis in which we address the best available evidence, not the best possible evidence. We addressed 13 key questions regarding their diagnosis, treatment, and costs.

Search Strategy. To identify information for this report, we searched 31 databases, relevant web sites, four U.S. government datasets, hand-searched the reference lists of all studies retrieved for this evidence report, searched Current Contents-Clinical Medicine weekly, and reviewed over 1,600 documents maintained in ECRI's collections.

Selection Criteria. To be selected for evaluation, a published study had to enroll patients diagnosed with one of the four relevant disorders. All controlled trials were retrieved, regardless of year of publication or whether they were described as randomized or prospective. Other studies were evaluated only if they were published in 1980, or later, and included 10 or more patients. Only English-language articles were retrieved. After retrieval, documents were examined to ensure that they did not contain flaws (e.g. confounding, incomparable study groups) precluding interpretation of results.

Data Collection and Analysis. Data about trial design, patient signs, symptoms, comorbidities, characteristics, and treatments, treatment outcomes and diagnostic measurements were abstracted from articles meeting inclusion criteria using electronic forms. Data were meta-analyzed when possible. Other analyses included corrections for patient attrition, statistical power analyses, multiple regression analyses, effect size computation, determinations of statistically significant differences between patient characteristics and verification of diagnostic test characteristics.

Main Results

The literature describing these disorders is often of poor quality, with few studies addressing any given issue. The evidence currently available suggests the following tendencies:

Two diagnostic tests for CTS, distal motor latency and palmar sensory latency, appear to have high specificity and low-to-moderate sensitivity.

Patients who have undergone surgery for CTS are predominantly middle aged and female. It is not possible to determine the characteristics of those undergoing surgery for the other three conditions.

Studies comparing open and endoscopic carpal tunnel release show a small but statistically significant advantage for endoscopic release, despite a higher rate of complications and reoperation compared to open release.

CTS patients benefit, but may not recover fully or permanently after steroid injection into the carpal tunnel.

Published data do not support the use of neurolysis, ligament reconstruction, or ultrasound for most CTS patients.

Laser therapy does not appear to be an effective treatment for epicondylitis.

Patients with epicondylitis who were treated with acupuncture had better global outcomes and greater pain relief than patients given sham acupuncture.

Conclusions. Published literature describing the diagnosis, treatment and impact of worker-related upper-extremity disorders is diffuse and generally of low quality, making it difficult to come to firm evidence-based conclusions. There are trends in available data, but it is often difficult to quantify them.

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Contents

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Summary

Overview

This report is a systematic evaluation of the evidence pertaining to a broad range of issues related to the diagnosis and treatment of worker-related upper extremity disorders (WRUEDs). For the purposes of this report, "worker-related" is defined as a disorder that affects workers, not as a disorder necessarily caused by work. Four disorders are the focus of this report; carpal tunnel syndrome, cubital tunnel syndrome, epicondylitis, and de Quervain's disease.

The first two disorders are the result of nerve entrapment. Carpal tunnel syndrome is the result of increased pressure on the median nerve in the carpal tunnel of the wrist, resulting in sensory and motor disturbances in the parts of the hand innervated by this nerve. Cubital tunnel syndrome results from increased pressure on the ulnar nerve in the cubital tunnel of the elbow, resulting in sensory and motor disturbances in the parts of the forearm and hand innervated by this nerve. The second two disorders are the result of stress to the tendons of the elbow and wrist, respectively. All four disorders can lead to pain, loss of function, and long-term disability.

The overall prevalence of carpal tunnel syndrome in the United States may be as high as 1.9 million people, and each year there are 300,000–500,000 operations for the condition. Epicondylitis has been reported to affect 4.23 individuals per 1,000 adults per year in the U.S. The prevalence of cubital tunnel syndrome and de Quervain's disease has not been established.

In this evidence report, the Evidence-based Practice Center (EPC) assessed the published literature describing the effected of these disorders, before and after treatment, on patients, particularly workers. They did this by examining the literature pertaining to 13 key questions.

Reporting the Evidence

This report addresses 13 questions regarding worker-related disorders of the upper extremity. Eleven of these are condition-specific. Therefore, the EPC individually addressed them for each of the four above-mentioned disorders. Two questions are not condition-specific. Therefore, the EPC addressed them only once. The 11 condition-specific Key Questions addressed in this evidence report are:

Question 1: What are the most effective methods and approaches for the early identification and diagnosis of worker-related musculoskeletal disorders of the upper extremity?

Question 2: What are the specific indications for surgery for worker-related musculoskeletal disorders of the upper extremity?

Question 3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with worker-related musculoskeletal disorders of the upper extremity?

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Question 4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question 5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question 6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question 7: What are the surgical and nonsurgical costs or charges for treatment of worker-related musculoskeletal disorders of the upper extremity?

Question 8: For persons who have had surgery for worker-related musculoskeletal disorders of the upper extremity, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

Question 9: What instruments, if any, can accurately assess functional limitations in an individual with a worker-related disorder of the upper extremity?

Question 10: What are the functional limitations for an individual with a worker-related musculoskeletal disorder of the upper extremity before treatment?

Question 11: What are the functional limitations of an individual with a worker-related musculoskeletal disorder of the upper extremity after treatment?

The two Key Questions that are not condition-specific are:

Question 12: What are the cumulative effects on functional abilities among individuals with more than one worker-related musculoskeletal disorder of the upper extremity in the same limb?

Question 13: What level of function can patients achieve in what period of time when they are required to change hand dominance as a result of injury to their dominant hand?

Methodology

A panel of nine Technical Experts was employed to assist in defining the scope of this evidence report, developing its questions, and developing the criteria for retrieving and including articles.

To identify information for this evidence report, the EPC searched 31 electronic databases, the World Wide Web, and four U.S. Government databases. In addition to these searches, researchers also reviewed the bibliographies and reference lists of all studies included in this evidence report, searched Current Contents®/Clinical Medicine on a weekly basis, and routinely reviewed over 1,600 journals and supplements maintained in ECRI's collections.

To be included in this evidence report, an article had to meet a set of a priori retrieval criteria and a set of a priori question-specific inclusion criteria. The EPC designed broad retrieval criteria to ensure comprehensive retrieval. They retrieved an article whenever there was uncertainty about whether it met the retrieval criteria. They also retrieved articles when an abstract was not present in the search results, but when the title of the article suggested that it was relevant. The criteria for article retrieval are briefly summarized below:

- The patients had to have been diagnosed with a worker-related disorder of the upper extremity.
- All controlled trials, regardless of whether they were described as randomized or prospective, were retrieved, regardless of year of publication.
- Case series and other reports were evaluated only if published in 1980 or later and included 10 or more patients.
- Only English-language articles were retrieved.

Once an article was retrieved, it was examined to determine whether it met the question-specific criteria. The major criteria are briefly summarized below; additional question-specific inclusion criteria, which are not listed here, were also applied:

- The study could not have a serious design flaw that precluded interpretation of the results.
- The study must have addressed one of the key questions and have included patients with one of the WRUEDs of interest.
- For studies addressing Key Question 3, the study must have been a controlled trial.
- The study must have reported on at least one of the seven key outcomes addressed in this assessment. The outcomes are: pain, function, quality of life, ability to return to work, ability to return to activities of daily living, harms, and global outcome.

A global outcome is any score that attempts to encompass the overall success or failure of the treatment. It may be a numerical rating of overall symptom relief or patient satisfaction, a categorical rating such as excellent, good, fair or poor, or a dichotomous rating such as the answer to the question "Would you undergo this procedure again?"

Data from all articles that met our inclusion criteria were abstracted using electronic data abstraction forms. Separate data abstraction forms were designed for entering data about basic trial design information; patient signs, symptoms, comorbidities, characteristics, and treatments; reporting of treatment outcomes; surgical complications; and nerve conduction measurements.

The EPC employed a variety of statistical methods in this evidence report. Meta-analyses of studies of treatments were conducted using Hedges' d as a measure of each study's effect size, and then computing the precision-weighted summary d

from the combined results of all studies. Hedges' d is the difference between the means of any study's two groups expressed in standard deviation units. Researchers employed two tests for heterogeneity, the Q statistic and each study's standardized residual. The EPC researchers regarded the data as heterogeneous if the results of either test were statistically significant.

Diagnostic test meta-analyses were performed according to the method of Littenberg and Moses. The researchers took the mean threshold as the best estimate of a single threshold, and the values of sensitivity and specificity at the mean threshold as the single best global estimate of test effectiveness. Before using the results of a meta-analysis of diagnostics, they verified that there was no statistically significant heterogeneity among the results of the included articles using the Q statistic. If heterogeneity was detected, they removed any subgroups that caused the heterogeneity from the analysis. If there were no subgroups in the analysis, or those subgroups did not cause the heterogeneity, they looked for data points that were outliers, and reported the meta-analytic results with and without exclusion of these outliers.

The EPC performed numerous other statistical computations in addition to those involved in performing meta-analyses. Briefly, these were:

- Corrections for patient attrition.
- Statistical power analyses.
- Multiple regression for certain questions when such results were of interest.
- Computations of effect sizes for all studies, when possible, even when no meta-analysis was performed.
- Determinations of whether there were statistically significant differences between the characteristics of patients in any given study.
- Computation of pretreatment effect sizes.
- Verification of diagnostic test characteristics.

Findings

Carpal Tunnel Syndrome

Question 1: What are the most effective methods and approaches for the early identification and diagnosis of carpal tunnel syndrome?

- The evidence base on most individual diagnostic tests for carpal tunnel syndrome is small, even though the total number of articles on CTS diagnosis is large. This is because many different tests have been described. Nerve conduction tests are most frequently reported in the literature, but there is great diversity in their methods.
- The results of our analyses may overestimate the specificity of nerve conduction measurements in typical practice. This is because the trials we examined used healthy, asymptomatic persons as controls. In clinical practice, the test would be used on workers believed to be at risk for CTS or persons suspected of having CTS. Under these conditions, the false positive rate would be higher, and the specificity correspondingly lower.
- The most frequently reported nerve conduction tests were distal motor latency and palmar sensory latency. For both tests, clinicians chose thresholds that yielded high specificity (a low incidence of false-positive results). The EPC's meta-analyses of distal motor latency studies found the sensitivity of the test to be 57% to 66% and the specificity to be 98%. Meta-analysis of palmar sensory latency studies found a sensitivity of 76% and a specificity of 98%.
- Clinical signs and symptoms are also used in the diagnosis of CTS. They attempted to use their meta-analysis techniques to obtain summary values for the sensitivity and specificity of two such signs: Tinel's sign and Phalen's maneuver. In both cases, there was heterogeneity in the published results that could not be explained by differences in patient selection or by single outlier studies. Therefore, they did not calculate summary measurements for sensitivity or specificity. The sensitivity of Phalen's maneuver was lower than its specificity, and two trials reported sensitivity of 80% to 90%. All of the studies of Tinel's sign found that its sensitivity was lower than its specificity, and none found a sensitivity of 75 percent or greater. There was too much heterogeneity in the results for them to conclude that one test was superior to the other, or to compare these tests to nerve conduction testing.
- Regarding sensory tests, composite nerve conduction tests, and imaging tests, there was insufficient evidence for the EPC to perform meta-analyses of clinical trial results.
- Their well-designed study suggests that nerve conduction measurement may be able to identify some workers at risk of developing CTS in the future. By itself, this evidence is not sufficient for the EPC to conclude that nerve conduction screening for CTS is effective.

Question 2: What are the specific indications for surgery for carpal tunnel syndrome?

- Patients who have undergone surgery for carpal tunnel syndrome are predominantly middle aged and female.
- Because of underreporting, no firm evidence-based conclusions can be drawn regarding the signs, symptoms, neuroelectrical characteristics, and comorbidities of these patients.

Question 3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with carpal tunnel syndrome?

- Meta-analysis of studies comparing open and endoscopic carpal tunnel release show a small but statistically significant advantage to endoscopic release in global

treatment outcome. In addition, the data show a trend toward faster return to work and to activities of daily living among patients receiving endoscopic release. However, these findings must be viewed only as trends in currently available data. This is because they are based on a meta-analysis that contained a number of non-randomized, non-blinded studies. Data from these studies also suggests that endoscopic release has a higher complication rate and a higher rate of reoperation compared to open release. The higher reoperation rates likely arise because of incomplete transection of the transverse carpal ligament. Exact complication rates cannot be determined from presently available data. Presently available data also do not allow one to reach firm evidence-based conclusions about the relative effects of open and endoscopic surgery on the ability of patients to perform daily functions.

- Meta-analysis of global outcomes demonstrates a potential benefit from not performing neurolysis. Available return to work data also shows a trend toward an advantage to not performing neurolysis. There is insufficient data to determine the effect of neurolysis on pain and function. The available evidence suggests there is little or no benefit from performing neurolysis along with surgical release of the carpal tunnel. The possibility remains that neurolysis may be helpful in special cases, such as in the presence of marked scarring or neural adhesion, but no available evidence specifically documents the benefits and harms of neurolysis among such patients.
- Results of four studies suggest that injection of steroid into the carpal tunnel yields superior global outcomes compared to no treatment, placebo, or oral steroids. However, relief from steroid treatments is not complete. Carpal tunnel injection was significantly better than intramuscular injection at a 1 month followup time. Because no further time points were reported, researchers are unable to determine whether this difference persists beyond this time. There are no data available that indicate whether any type of steroid may be superior to any other, or whether any particular dose is optimum. Although the effects of steroid injection may wear off over time, there is no information indicating the expected duration of relief for the average patient, or whether any patients can expect to experience permanent relief.
- Two double-blinded randomized controlled trials suggest that oral steroids may lead to a reduction in symptoms of CTS. However, the effects of oral steroids are short-lived and may not be sufficient for patient satisfaction. The effects of higher steroid doses or longer treatment regimens have not been examined in published controlled trials.
- A single published randomized controlled trial indicates that oral tenoxicam (a NSAID) and trichlormethiazide (a diuretic) do not reduce the symptoms of CTS under the dosing regimens described. Further trials are needed to confirm this observation, and to test the effects of additional drugs and dosing regimens.
- Results of a single study suggest that manual therapy may have some use in the treatment of carpal tunnel syndrome. This study suggests that carpal bone mobilization provides pain relief, improves function, and delays or eliminates the need for surgery among patients with carpal tunnel syndrome. However, this small study was unblinded. Results from neurodynamic mobilization show a similar trend, but because of a lack of statistical power one cannot conclude that this trend is real. For the same reason, differences in effectiveness between these two treatment groups cannot be determined. A large, blinded, randomized controlled trial is necessary to confirm these results.
- A larger, more statistically powerful study found no difference between the effects of a physical therapy program and home exercise instructions on pain or function. However, patients receiving physical therapy returned to work faster than those instructed to exercise at home.
- Although these studies indicate a trend toward some forms of physical therapy having an effect on carpal tunnel syndrome, their small size and design difficulties make it difficult to arrive at a firm evidence-based conclusion.
- Only one study meeting inclusion criteria addresses the use of ultrasound for carpal tunnel syndrome. Because of this, and because of its associated design and analysis difficulties, one cannot reach a firm evidence-based conclusion.
- Splint use was addressed only by a single trial that had design difficulties. Because of this, one cannot reach a firm evidence-based conclusion about splint use. There may be conditions under which splints offer an advantage and conditions under which they do not, but this is not addressed by available evidence.
- The results of one study suggest that suboptimal outcomes are obtained when patients receive ligament reconstruction. However, this trial was neither randomized nor blinded, so one cannot draw firm evidence-based conclusions from it.
- Although the low statistical power of the one relevant study prevents any solid conclusion from being drawn, this study does not support the therapeutic effectiveness of Vitamin B6. This is because it showed a trend toward a greater percentage of improved patients in the placebo group.

Question 4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with carpal tunnel syndrome?

- The only clinical finding variable shown by more than one study to significantly predict treatment outcomes was electrodiagnostic testing. Patients with mildly impaired or normal results of electrodiagnostic tests had longer sick leaves and were less likely to be satisfied with the results of treatment. This finding was statistically significant in three of the four studies examining this relationship.
- This apparent lack of consistency of results could indicate that, although the relationship between electrodiagnostic tests and treatment outcomes is statistically significant, it may not be substantial. The possibility that this relationship is small is supported by the results of stratified studies that examined the relationship between electrodiagnostic test results and global outcomes. Six of seven studies did not find a statistically significant relationship.

Question 5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with carpal tunnel syndrome?

- The majority of available evidence is less than optimal because it consists primarily of retrospective studies. The highest quality study (prospective with multiple regression analysis) suggested that there was no statistically significant correlation between duration of symptoms and global outcome after surgery. One prospective and two retrospective stratified studies found similar results. Two retrospective studies (one performing multiple regressions, one stratified) found a statistically significant relationship between shorter duration of symptoms and symptom resolution or patient satisfaction after surgery. The retrospective nature of these trials could have created bias that influenced these findings. An additional high quality prospective study is needed before firm conclusions can be reached.

Question 6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with carpal tunnel syndrome?

- The available evidence suggests that patients who are not receiving workers' compensation tend to return to work faster than those receiving such compensation. This is suggested by one of two "multiple regression" studies of this relationship and by a combination of 10 prospective and retrospective stratified studies. Evidence of a relationship does not constitute evidence of causality.
- Some evidence also suggests that patients who are not receiving workers' compensation have better global outcomes, but this evidence is derived exclusively from retrospective studies. Therefore, these latter findings require confirmation.
- Available evidence suggests that there is no strong relationship between gender, employment status, or hand dominance and return to work or global outcomes.
- There is insufficient evidence to arrive at a firm evidence-based conclusion on the relationship between type of work, presence of diabetes, or age and patient outcomes.

Question 7: What are the surgical and nonsurgical costs or charges for treatment of carpal tunnel syndrome?

- According to the Medicare Provider Analysis and Review (MEDPAR) database, which covers hospital inpatient services, average total charges per patient for the DRG (diagnosis-related group) of carpal tunnel release are $8,185.24 (calculated by dividing total charges by number of discharges). This DRG includes open and endoscopic release.
- The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for endoscopic release of the transverse carpal ligament is $849.84 (cost of open release was not reported by this database). The reported median cost for application of a short arm static splint is $72.69.

Question 8: For persons who have had surgery for carpal tunnel syndrome, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

- No controlled trials have been published that report on the efficacy or effectiveness of any technique for the prevention of recurrence of carpal tunnel syndrome. In the absence of controlled trials, no analysis may be performed and no evidence-based conclusions may be drawn.

Question 9: What instruments, if any, can accurately assess functional limitations in an individual with carpal tunnel syndrome?

- Three prospective cohort trials have indicated that the SF-36 is not a useful instrument for assessing functional limitations in individuals with carpal tunnel syndrome. The SF-36 was reported to be unresponsive to treatment and unable to predict ability to work.
- Four prospective cohort trials have indicated that the Levine CTS-I may be a useful instrument for assessing functional limitations in individuals with carpal tunnel syndrome. This instrument was reported to be responsive to treatment, and to have concurrent validity as measured by grip and pinch strength. However, the studies that addressed the Levine CTS-I did not examine

its internal reliability, content validity, or its ability to predict how well patients could perform activities of daily living. In addition, the Levine CTS-I has been reported by one study to be unable to predict ability to work.

- No other instrument has been evaluated by more than one study. It is difficult to reach an evidence-based conclusion as to the usefulness of the other instruments evaluated in this report due to the limited evidence base.

Question 10: What are the functional limitations for an individual with carpal tunnel syndrome before treatment?

- There is some evidence to suggest that most untreated patients with carpal tunnel syndrome have mild to moderate functional difficulties before treatment. However, this evidence is derived from only two studies comprised of a total of 51 patients. This is too few patients and too few studies to allow one to reach a firm evidence-based conclusion.

Question 11: What are the functional limitations of an individual with carpal tunnel syndrome after treatment?

- Although studies of non-surgical therapies suggested that most patients experience only mild difficulty with functional activities after treatment, it is unclear whether the results of these two studies are generalizable to the larger patient population.
- Studies with surgical outcomes suggested that most patients report no-to-moderate difficulty with functional activities (mean 1.4-2.6 on the Levine CTS-I) after surgery.
- Although there were no statistically significant differences between specific patient groups, there was a trend toward more difficulty with functional activities among workers' compensation patients in surgical studies. This trend was based on the results of two studies.
- The available data are insufficient to determine a cutoff point on measuring scales above which patients are unable to work.

Cubital Tunnel Syndrome

Question 1: What are the most effective methods and approaches for the early identification and diagnosis of cubital tunnel syndrome?

- One test for cubital tunnel syndrome, ulnar motor nerve conduction velocity at the elbow, was commonly mentioned by reviewers. Three studies reported high specificity and low sensitivity for this test. Due to the small number of studies, however, one cannot draw quantitative conclusions about the effectiveness of the test. There are insufficient data to permit firm evidence-based conclusions about the effectiveness of this or any other tests for cubital tunnel syndrome.

Question 2: What are the specific indications for surgery for cubital tunnel syndrome?

- Thirty-two studies of patients who received surgery for cubital tunnel syndrome were identified. The mean age of patients who received surgery for cubital tunnel syndrome was 46 years.
- The patients were slightly more likely to be male (62% male).
- On average, patients had symptoms 10 to 24 months before receiving surgical treatment.

Question 3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with cubital tunnel syndrome?

- One randomized controlled trial of 52 patients found that medial epicondylectomy was superior to anterior transposition in relieving pain and in improving global outcome scores. The results of this study are suggestive, but one cannot arrive at a strong conclusion from the results of only one trial. There is insufficient evidence to determine the relative effectiveness of other surgical treatments.
- There are insufficient data available to determine the rates of surgical complications for any of the described surgical procedures.

Question 4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with cubital tunnel syndrome?

- The only clinical finding variable shown by more than one study to significantly predict treatment outcomes was severity of symptoms. This correlation was statistically significant in four out of seven studies that examined it. The studies that did not find a statistically significant correlation may have been underpowered. Therefore, currently available evidence tentatively suggests that there is a correlation between having less severe symptoms and having a higher global outcome score after surgical treatment for cubital tunnel syndrome.
- There are insufficient data to reach evidence-based conclusions about the relationships between other clinical findings and treatment outcomes.

Question 5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with cubital tunnel syndrome?

- Currently available evidence does not suggest a clear-cut relationship between the duration of symptoms before treatment and the success of surgery.
- There are insufficient data available to reach evidence-based conclusions about the relationship between symptom duration and other treatment outcomes.

Question 6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with cubital tunnel syndrome?

- The available data do not suggest a substantial correlation between the age, sex, or workers' compensation status of the patient and the success of surgery.
- Two studies that used multiple regression to examine relationships between patient characteristics and treatment outcomes found that patients whose cubital tunnel syndrome is caused by an acute trauma have better outcomes after surgical treatment than patients with cubital tunnel syndrome from other causes. However, three studies that stratified by etiology found no statistically significant relationship between cause and patient outcomes. The studies that used multiple regression techniques are of better quality than the stratified studies. Thus, current data suggest that there may be a correlation between etiology and patient outcomes, but this cannot be regarded as definitive.

Question 7: What are the surgical and nonsurgical costs or charges for treatment of cubital tunnel syndrome?

- According to Medicare Provider Analysis and Review (MEDPAR), average total charges per patient for the DRG (diagnosis-related group) of major shoulder/elbow procedures with comorbidities or complications are $9,008.94 (calculated by dividing total charges by number of discharges).
- For the DRG shoulder, elbow or forearm procedures, except major joint procedures, without comorbidities or complications, average total charges per patient are $7729.16.
- For the DRG peripheral and cranial nerve and other nerve procedures without complications or comorbidities, the average total per patient charges are $14,357.65 (with complications or comorbidities the charges are $24,288.00).
- The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for a decompression fasciotomy of the forearm and/or wrist is $603.85. The reported median cost for application of a long-arm splint is $80.48.

Question 8: For persons who have had surgery for cubital tunnel syndrome, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

- None of the included studies addressed this question.

Question 9: What instruments, if any, can accurately assess functional limitations in an individual with cubital tunnel syndrome?

- None of the included studies addressed this question.

Question 10: What are the functional limitations for an individual with cubital tunnel syndrome before treatment?

- None of the included studies addressed this question.

Question 11: What are the functional limitations of an individual with cubital tunnel syndrome after treatment?

- None of the included studies addressed this question.

Epicondylitis

Question 1: What are the most effective methods and approaches for the early identification and diagnosis of epicondylitis?

- There are insufficient data to permit evidence-based conclusions about the effectiveness of any tests for epicondylitis. This is because the evidence base is small and heterogeneous.

Question 2: What are the specific indications for surgery for epicondylitis?

- Nineteen studies of patients who received surgery for epicondylitis were identified. Due to a lack of reported data, few trends or characteristics of patients who received surgery could be identified. A typical patient who received surgery for epicondylitis was middle-aged and equally likely to be male or female.

Question 3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with epicondylitis?

- Seven double-blinded randomized controlled trials compared laser therapy to sham laser therapy as treatment for epicondylitis. A meta-analysis of the results of the four studies that reported "success of treatment" did not reveal a statistically significant difference in outcome between laser and sham-treated patients.
- The four studies that reported the effect of laser treatment on pain also did not find a statistically significant difference in outcome between laser and sham treated patients. However, EPC researchers were unable to perform a meta-analysis of the outcome pain and, because all of these studies were small, their individual results cannot be taken as definitive proof that laser therapy has no effect on the pain of epicondylitis.
- Only one study examined work status of patients after laser treatment. This study was also small, and it failed to find a statistically significant effect of laser treatment on work status. The results of all seven small randomized double-blinded controlled trials are consistent with the

results of our meta-analysis, and suggest that if there is an effect of laser therapy on epicondylitis, it is not large.

- Two randomized controlled trials of a total of 62 patients compared oral naproxen to oral diflunisal. One study reported no statistically significant difference in outcomes when comparing patients treated with the two different drugs, and did not find a consistent trend in favor of one drug. The other study reported that diflunisal treatment consistently resulted in better outcomes. For two outcomes, pain and function, the difference reached statistical significance. Further studies are necessary to resolve discrepancies between these studies.
- Two randomized controlled trials of 82 patients in total compared ultrasound treatment to phonophoresis of hydrocortisone as a therapy for epicondylitis. Neither study found a statistically significant difference between treatment groups for any of the outcomes. When interpreting these results, it is important to keep in mind that both studies may have been too small to be able to detect clinically relevant differences between treatment groups.
- Three randomized controlled trials of 220 patients in total compared ultrasound treatment to sham ultrasound treatment or no treatment as a therapy for epicondylitis. All three of the studies reported a trend towards better outcomes in the groups treated with ultrasound. However, this difference reached statistical significance in only one of the studies. Although low statistical power may explain the negative results of the two "nonsignificant" studies, further research is required to demonstrate this.
- Simply wearing an elbow brace is reported by two crossover studies to have no effect on pain. Because these two studies were of less than optimal design, further studies are necessary before a conclusion may be reached.
- Two randomized controlled trials of a total of 134 patients evaluated the effect of acupuncture on epicondylitis. Both studies reported patients treated with acupuncture had better global outcomes and greater pain relief than patients treated with sham acupuncture at relatively short (2 weeks) followup times. Although only two studies evaluated this treatment, both were well-designed. It is possible to tentatively conclude that acupuncture is an effective palliative treatment for epicondylitis.
- Two randomized controlled trials of a total of 203 patients compared oral NSAIDs to injections of corticosteroids. One study did not find a statistically significant difference between the groups. The other study reported that patients treated with injections of corticosteroids had better outcomes than the patients treated with oral NSAIDs. Design differences may explain the discrepancy between these studies' results, and further study is required to resolve this issue.
- One double-blinded randomized controlled trial reported that patients treated with placebo had a trend towards better outcomes than patients treated with topical DMSO; however, this trend did not reach statistical significance. This study also reported that topical DMSO application caused clinically significant skin irritation. However, this trial was based on only 51 patients, so further studies are necessary before a definitive evidence-based conclusion can be reached.
- One randomized controlled trial of 128 patients compared oral diclofenac to placebo. The group treated with diclofenac had statistically significantly less pain than the placebo group, but the NSAID treatment had no statistically significant effect on hand/arm function, number of days of missed work, or global outcome. Oral NSAIDs were reported to occasionally cause gastrointestinal side effects. In the absence of a very large effect, it is difficult to reach a firm evidence-based conclusion from the results of a single trial of moderate size.
- One double-blinded randomized controlled trial and one double blinded randomized crossover trial, of a total of 47 patients, compared topical diclofenac to placebo. One of the studies reported no statistically significant differences between the two groups for any of the outcomes. The other study reported that the group treated with the NSAID may have had some statistically significant benefit from the treatment. Researchers were unable to determine whether the differences in results between studies were due to differences in statistical power. Further studies are necessary to resolve discrepancies between these studies.
- One randomized controlled trial of 40 patients compared topical diclofenac to topical salicylate, and reported that diclofenac was more effective for treating epicondylitis. Topical NSAIDs were reported to occasionally cause mild skin rashes. Further studies are necessary before a definitive evidence-based conclusion can be reached.
- One randomized double-blinded study reported that injections of glucosamines are effective in treating the symptoms of epicondylitis in the short term (less than 6 months) as measured by global outcome and patient-reported pain. However, injections of glucosamines were found to have a high rate of side effects—40% of patients experienced pain at the site of injection, and 6% developed hematomas at the site of injection. Further studies are necessary before a definitive evidence-based conclusion about the clinical utility of this treatment can be reached.
- One randomized double-blinded study reported that injections of methylprednisolone plus lidocaine were

statistically significantly more effective at treating pain than injections of lidocaine. Further studies are necessary before a definitive evidence-based conclusion can be reached.

- One randomized double-blinded study reported that injections of lignocaine plus triamcinolone were statistically significantly more effective at treating pain than injections of lignocaine or injections of lignocaine plus hydrocortisone. Further studies are necessary before a definitive evidence-based conclusion can be reached.
- One randomized double-blinded study reported that injections of triamcinolone plus bupivacaine were more successful at treating epicondylitis than injections of triamcinolone plus lidocaine. Further studies are necessary before a definitive evidence-based conclusion can be reached.
- One study reported a trend towards more successful treatment of epicondylitis after injections of methylprednisolone than after injections of hydrocortisone. However, this study was of less than optimal design, which makes it problematic to come to a definitive evidence-based conclusion on the basis of its results.
- One study reported no difference in rates of successful treatment or number of work-days missed after treatment with injections of methylprednisolone as compared to injections of betamethasone plus lidocaine. This study had sufficient statistical power to have detected relatively small differences between treatment groups. However, design flaws in this study make it problematic to come to a definitive evidence-based conclusion on the basis of its results.
- One study reported that wearing a brace regularly over the course of several months is not as effective in treating epicondylitis as is physiotherapy, but a different study reported that wearing a brace regularly in addition to physiotherapy may be more effective than physiotherapy alone. Further studies of these therapies are necessary before one can reach definitive evidence-based conclusions.
- One retrospective case-controlled study compared fasciectomy, wide fasciectomy plus anconeus transfer, and re-operation of failed fasciectomy to include an anconeus transfer. However, because this was a single study of suboptimal design, one cannot reach a firm evidence-based conclusion about the relative efficacy of these procedures.
- One non-parallel historically controlled trial reported that simple denervation led to statistically significantly better global outcome and greater pain relief than denervation plus decompression. However, because this was a single study of suboptimal design, one cannot reach a firm evidence-based conclusion about the relative efficacy of these procedures.
- A single double-blinded randomized controlled trial of 30 patients reported that there were no statistically significant differences in the signs and symptoms of epicondylitis between patients treated with pulsed electromagnetic field therapy and patients receiving sham treatment. When interpreting the results of this trial, it must be kept in mind that the small size of the trial may have prevented the results from reaching statistical significance.
- One randomized controlled trial reported that patients treated with extracorporeal shock wave therapy had statistically significantly greater improvements in pain and arm function than patients given sham treatment. However, it is difficult to reach firm evidence-based conclusions from the results of this trial because the lack of blinding and lack of intent-to-treat analysis of this trial may have affected its results.
- One randomized controlled trial reported that patients treated with injections of corticosteroids had better outcomes than patients treated with manipulations and deep friction massage. Incomplete data and methods reporting from this trial make it problematic to reach any definitive evidence-based conclusions from its results.
- One randomized controlled trial of 76 patients reported that patients treated with injections of corticosteroids had better outcomes than patients treated with braces or immobilization. Partly because of the small size of this trial, further studies are necessary before a definitive evidence-based conclusion can be reached.
- One randomized controlled trial of 63 patients reported that patients treated with acupuncture had better outcomes than patients treated with corticosteroid injections. However, the results of this study may have been affected by patient selection bias because it enrolled only patients previously found to be unresponsive to injections of corticosteroids.

Two randomized controlled trials, one comparing transcutaneous electrical nerve stimulation, ultrasound, phonophoresis, and injections of steroids, the other comparing physical therapy to ultrasound, reported no statistically significant differences between treatment groups. However, both trials may have been too small to be able to have detected clinically meaningful differences between treatment groups.

- Five randomized controlled trials evaluated various combinations of therapies for the treatment of epicondylitis. One trial of 18 patients found that patients treated with manipulation plus a home exercise program had fewer difficulties in performing activities of daily living than patients treated with a combination of ultrasound, physiotherapy, and home exercise. The other

four trials did not find statistically significant differences between treatment groups. However, these studies were small, which may have prevented them from detecting clinically important differences between the treatment groups.

Question 4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with epicondylitis?

- One study reported that the site of pain could be used to predict response to treatment, one reported that the severity of pain could be used to predict response to treatment, and one reported that the timing of onset of symptoms (acute vs. gradual) did not correlate with the response to treatment. Because only one study addressed each outcome, it is difficult to reach firm evidence-based conclusions from the available data.

Question 5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with epicondylitis?

- Seven studies examined whether duration of symptoms correlated with treatment outcomes. Only one of the four studies that employed multiple regression found a statistically significant relationship between symptom duration and outcomes, and this study was retrospective. One of three studies that stratified patients according to their duration of symptoms found a statistically significant correlation with treatment outcomes. As this study was also retrospective, evidence suggesting a relationship is contradictory and weak. Two prospective studies that employed multiple regression did not find such a relationship. Both were of patients who had received ultrasound. However, currently available evidence about use of ultrasound in patients with epicondylitis or de Quervain's disease does not allow firm evidence-based conclusions. A lack of treatment effectiveness could obscure potential relationships between symptom duration and treatment-related outcomes. Therefore, one cannot draw firm evidence-based conclusions from currently available data.

Question 6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with epicondylitis?

- Three studies that used multiple regression found no statistically significant correlation between gender or age and response to treatment, suggesting that there is no strong relationship between these variables and patient outcomes.
- One study found no statistically significant correlation between certain hobbies and response to treatment. However, it is difficult to reach evidence-based conclusions from the results of a single study.
- The only study that examined co-morbidities reported that patients with co-existent ulnar neuropathy had significantly poorer outcomes than patients without ulnar neuropathy. However, it is difficult to reach evidence-based conclusions from the results of a single study.

Question 7: What are the surgical and nonsurgical costs or charges for treatment of epicondylitis?

- According to Medicare Provider Analysis and Review (MEDPAR), average total charges per patient for the DRG (diagnosis-related group) of major shoulder/elbow procedures with comorbidities or complications are $9,008.94 (calculated by dividing total charges by number of discharges).
- For the DRG shoulder, elbow or forearm procedures, excepting major joint procedures, without comorbidities or complications, average total charges per patient are $7729.16.
- The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for strapping of the elbow or wrist is $62.61 (cost of open release was not reported by this database).

Question 8: For persons who have had surgery for epicondylitis, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

- No controlled trials addressed this question. Therefore, it was not possible to perform a reliable analysis, and one cannot draw firm evidence-based conclusions from the available data.

Question 9: What instruments, if any, can accurately assess functional limitations in an individual with epicondylitis?

- Three studies evaluated two different instruments (PRFEQ and F-VAS) as ways to measure functional limitations of patients with epicondylitis. Neither assessment instrument has been shown to be a useful instrument for evaluating functional limitations in persons with epicondylitis. However, it is difficult to reach firm evidence-based conclusions about the instruments evaluated in this report due to the limited evidence base.

Question 10: What are the functional limitations for an individual with epicondylitis before treatment?

- This question is addressed by only two studies comprised of a total of 82 patients. Although these studies suggest that epicondylitis patients have an average level of functional difficulty between 30% - 40% (mild to moderate) on functional status scales, the low number of studies and patients makes it difficult to arrive at an evidence-based answer to this question.

Question 11: What are the functional limitations of an individual with epicondylitis after treatment?

- There were no studies that met the inclusion criteria for this question. Therefore, it cannot be answered in an evidence-based fashion.

De Quervain's Disease

Question 1: What are the most effective methods and approaches for the early identification and diagnosis of de Quervain's disease?

- None of the included studies addressed this question.

Question 2: What are the specific indications for surgery for de Quervain's disease?

- Two of the three studies that addressed this question reported that surgery was performed only on patients who did not benefit from conservative (non-operative) treatment. However, with so few studies and so many unreported patient characteristics, one cannot assume that the present data are representative of the larger patient population with de Quervain's disease.

Question 3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with de Quervain's disease?

- Although one study found that corticosteroid plus lidocaine injection produced more treatment success than immobilization splints among de Quervain's patients, there were design problems with this study. Because of these problems, and because only one study addressed this question, it is difficult to reach firm evidence-based conclusions concerning the effectiveness of any treatment for de Quervain's disease.

Question 4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with de Quervain's disease?

- This question was addressed by only one relatively small retrospective study. This study found no relation between presence of a septated first dorsal compartment and treatment outcome. However, it is difficult to reach evidence-based conclusions from the results of a single study of suboptimal design.

Question 5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with de Quervain's disease?

- This question was addressed by only one relatively small retrospective study. This study found no relation between duration of symptoms and treatment outcome. However, it is difficult to reach evidence-based conclusions from the results of a single study of suboptimal design.

Question 6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with de Quervain's disease?

- This question was addressed by only one relatively small retrospective study. This study found no relation between age, gender, or occupational status and treatment outcome. However, it is difficult to reach evidence-based conclusions from the results of a single study of suboptimal design.

Question 7: What are the surgical and nonsurgical costs or charges for treatment of de Quervain's disease?

- According to the Medicare Provider Analysis and Review (MEDPAR) database, which covers hospital inpatient services, average total charges per patient for the DRG (diagnosis-related group) of hand or wrist procedures (excepting major joint procedures) without complications or comorbidities are $7,408.14 (calculated by dividing total charges by number of discharges).
- The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for application of a short arm static splint is $72.69.

Question 8: For persons who have had surgery for de Quervain's disease, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

- None of the included studies addressed this question.

Question 9: What instruments, if any, can accurately assess functional limitations in an individual with de Quervain's disease?

- None of the included studies addressed this question.

Question 10: What are the functional limitations for an individual with de Quervain's disease before treatment?

- None of the included studies addressed this question.

Question 11: What are the functional limitations of an individual with de Quervain's disease after treatment?

- None of the included studies addressed this question.

Non-Treatment-Specific Questions

Question 12: What are the cumulative effects on functional abilities among individuals with more than one worker-related musculoskeletal disorder of the upper extremity in the same limb?

- There were no studies that met the inclusion criteria for this question. Therefore, it cannot be answered in an evidence-based fashion.

Question 13: What level of function can patients achieve in what period of time when they are required to change hand dominance as a result of injury to their dominant hand?

- The studies of the ability of training to improve use of the non-dominant hand do not allow one to determine the degree to which this training provides the patient with employment opportunities or allows resumption of normal activities. These studies also lack long-term followup data. Evidence from two studies suggests that some learning and training in the use of the non-dominant hand is possible, and statistically significant improvement can be accomplished in 2 to 6 months of training. For some activities, statistically significant improvement can be accomplished within 1 week.

Future Research

In general, the literature addressing WRUEDs is of uneven quality. Well-designed studies on many aspects of WRUEDs are needed. Prospective, randomized double-blinded controlled trials are widely considered to provide the highest quality of evidence for treatment effectiveness. Results of non-randomized trials can be affected by differences in the characteristics of the patient groups, rather than the treatment applied. Uncontrolled trials do not allow one to ascertain whether patients improve in the absence of treatment, and they do not allow one to accurately gauge the magnitude of any change that occurs after treatment. Blinding of patients and evaluators to treatments avoids the potential for placebo effects and previously held beliefs about the effectiveness of treatments to impact on the results of trials.

Studies of diagnostic tests do not necessarily need not be randomized or contain control groups. In the absence of a "gold standard" test, longitudinal studies are the most desirable for assessing diagnostic tests for WRUEDs. In these studies, patients are first given the diagnostic test, and then they are followed for a period of time to determine whether they develop symptoms of a WRUED. Repeating the tests at regular intervals during the trial could yield insights into the etiology of the conditions as well as measure test-retest variability. If a "gold standard" test were developed, then single-arm cross-sectional studies that compared the results of the "gold standard" test to the results of the test under investigation would be appropriate. In such studies, in order to obtain the most useful information, it is important to select a patient population that closely resembles the general population on whom the diagnostic test would ultimately be used.

Availability of Full Report

The full evidence report from which this summary was derived was prepared for AHRQ by ECRI's Health Technology Assessment Group under contract number 290-97-0020. It is expected to be available in the Winter of 2002. At that time, printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requestors should ask for Evidence Report/Technology Assessment No. 62, *Diagnosis and Treatment of Worker-Related Musculoskeletal Disorders of the Upper Extremity.*

Internet users will be able to access the report online through AHRQ's Web site at: www.ahrq.gov.

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Chapter 1. Introduction

Scope and Objectives

Worker-related upper-extremity disorders (WRUEDs) result in pain, disability, and loss of productivity. This report is a systematic analysis of the evidence pertaining to thirteen key questions and four specific disorders. These disorders are considered worker-related not because they are necessarily caused by working, but because they effect workers.

Conditions of Interest

Although a wide variety of WRUEDs have been described in the medical literature, this report is limited to four. They are:

- Carpal tunnel syndrome
- Cubital tunnel syndrome
- Epicondylitis
- De Quervain's disease

Key Questions

This report addresses 13 questions regarding worker-related disorders of the upper extremity. Eleven of these are condition specific. Therefore, we individually address them for each of the disorders we consider. Questions 12 and 13 are not condition-specific. Therefore, they are answered only once. The questions we address are:

Condition-Specific Questions:

Question #1: What are the most effective methods and approaches for the early identification and diagnosis of worker-related musculoskeletal disorders of the upper extremity?

Question #2: What are the specific indications for surgery for worker-related musculoskeletal disorders of the upper extremity?

Question #3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with worker-related musculoskeletal disorders of the upper extremity?

Question #4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question #5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question #6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question #7: What are the surgical and nonsurgical costs or charges for treatment of worker-related musculoskeletal disorders of the upper extremity?

Question #8: For persons who have had surgery for worker-related musculoskeletal disorders of the upper extremity, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with a worker-related disorder of the upper extremity?

Question #10: What are the functional limitations for an individual with a worker-related musculoskeletal disorder of the upper extremity before treatment?

Question #11: What are the functional limitations of an individual with a worker-related musculoskeletal disorder of the upper extremity after treatment?

Non-Condition-Specific Questions:

Question #12: What are the cumulative effects on functional abilities among individuals with more than one worker-related musculoskeletal disorder of the upper extremity in the same limb?

Question #13: What level of function can patients achieved in what period of time when they are required to change hand dominance as a result of injury to their dominant hand?

Worker-Related Upper-Extremity Disorders

Carpal Tunnel Syndrome

Carpal tunnel syndrome (CTS) results from compression of the median nerve as it passes through the carpal tunnel from the wrist to the hand. This leads to progressive sensory and motor disturbances.

Signs and Symptoms

Symptoms of CTS include paresthesia (tingling), anesthesia (numbness), diminished or altered sensation (hypoesthesia or dysesthesia) in the affected area of the hand; pain in the hand and arm, and/or the impairment of motor function, particularly of the abilities to grip and grasp.[2] Usually the symptoms appear first (and worst) at nighttime.[3] In about 1% of cases, permanent nerve damage results, resulting in impaired use of the hands.[4] Continued denervation can lead to atrophy of the innervated muscle.[5]

Anatomy

The median nerve is a mixed sensory and motor nerve that supplies the thumb, all of the index and middle fingers, and part of the ring finger. It enters the hand on the palmar side of the wrist, through a narrow, rigid, osteoligamentous passageway (the carpal tunnel, see Figure 1) that is bordered on three sides by the carpal bones and on the other by the flexor retinaculum (or transverse carpal ligament). The median nerve shares the carpal tunnel with nine flexor tendons that displace the nerve to the superficial (palm-most) side of the tunnel, directly against the transverse carpal ligament (See figure 2). The nerve is the softest and most sensitive element in the tunnel. Anything that decreases the size of the tunnel or increases the size of its contents can cause CTS. This may include space-occupying lesions, arthritis, trauma, edema, and dislocation of the lunate bone.

Figure 1. Location of the carpal tunnel

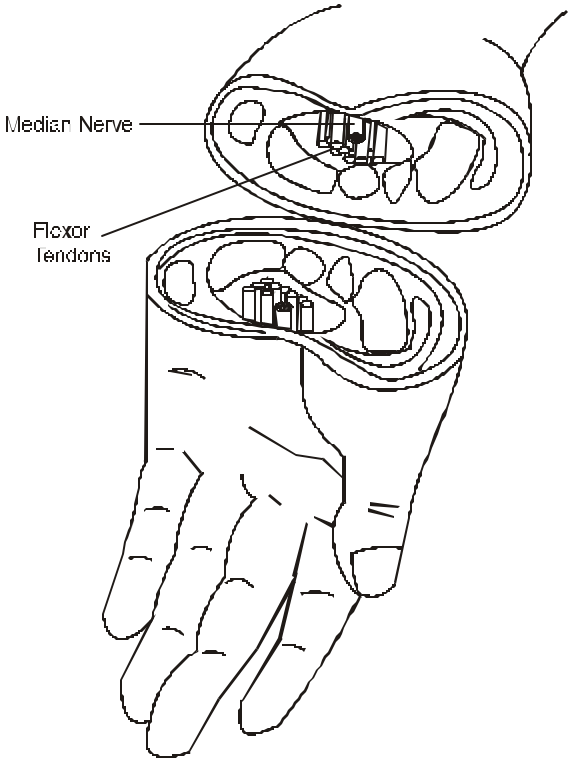
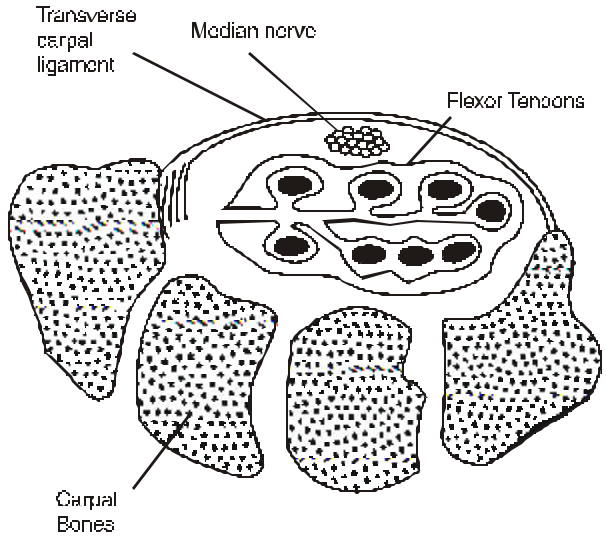


Figure 2. Structures associated with carpal tunnel syndrome



Etiology

Carpal tunnel syndrome is often idiopathic. The most common attributed cause of CTS is tenosynovitis or hypertrophy of the tendon sheaths of the finger flexor tendons due to overuse, often from the repetitive hand motions associated with

certain occupations.[6,7] Assemblers, cashiers, and secretaries are among those most prone to the disease, with data-entry keyers, typists, and office clerks also at high risk.[4] It is not clear, however, whether occupational activities cause or merely contribute to development of CTS.[8] Female sex, middle age, diabetes, alcoholism, hypothyroidism, obesity, pregnancy, menopause, and the use of birth control pills are all associated with CTS.[9]

CTS is associated with several conditions. Rheumatoid involvement in the wrist joint may lead to carpal tunnel compression.[3] Bone growth due to acromegaly may lead to shrinking of the carpal tunnel and median nerve compression.[10] Patients receiving hemodialysis may develop CTS because of edema or amyloid deposits in the carpal tunnel.[7,11] Tissue deposits due to gout may also cause or exacerbate CTS.[12]

Carpal tunnel syndrome may be exacerbated by other nerve injuries, such as at the neck, shoulder, elbow, or by generalized peripheral neuropathies. This phenomenon, known as double-crush syndrome,[13] has not been definitively established to exist, and remains controversial.[14] Comorbidities causing peripheral neuropathy such as diabetes or thyroid disturbances may both exacerbate CTS and interfere with its diagnosis.[15-18] CTS associated with pregnancy, childbirth and lactation may resolve spontaneously.[19]

Epidemiology

The overall prevalence of CTS in the United States may be as high as 1.9 million people, and each year there are 300,000–500,000 operations for the condition, at a total cost of more than $2 billion.[20] There are no widely accepted figures for the fraction of cases requiring surgery. Estimates range from nearly half of all CTS patients with occupational disease to a "small percentage" of all patients.[20]

The incidence of CTS is higher in women than in men, and differences in carpal tunnel volume between men and women may contribute to these differences.[21] Idiopathic CTS occurs in women three to five times more frequently than in men.[22] Many of the occupations associated with CTS are held disproportionately by women, and several of the causal medical conditions are found more often in women than in men.[20] In addition, the prevalence for men generally increases steadily with increasing age while, for women, the prevalence peaks dramatically during middle age (45-55 years of age) and then levels off.[23,24]

About 60% of cases are seen in patients between 40 and 60 years of age.[25] Whites have been reported to have a 1.8 times higher prevalence of carpal tunnel syndrome than do non-whites.[26]

The U.S. Bureau of Labor Statistics reported 29,937 cases of CTS that resulted in work days lost in 1996, and the National Institute of Occupational Safety and Health (NIOSH) reported that, in 1993, CTS occurred at a rate of 5.2 per 10,000 full-time workers. This syndrome required the longest recuperation period of all conditions

that result in lost work days, with a median of 30 work days lost.[4] A study of all surgeries performed to treat carpal tunnel syndrome in Wisconsin from July 1990 to March 1993 found that 75% of the individuals had only one surgery, 24.7% had two surgeries, and 0.3% had three or more surgeries. Workers' Compensation paid for 26.1% of these surgeries.[23]

Diagnosis

Diagnosis of carpal tunnel syndrome is complicated by the fact that there is no "gold standard" method for verifying its presence or absence.[27] A variety of diagnostic instruments have been used by investigators including clinical signs, sensory tests, nerve conduction studies, and imaging tests. It is not known which modality or combination of modalities are optimal for the diagnosis of carpal tunnel syndrome.

Most clinical tests to diagnose carpal tunnel syndrome involve specific maneuvers that elicit pain, numbness, or tingling in the median-nerve portion of the wrist. For example, in Phalen's test, the patient places both elbows on a horizontal surface with the forearms vertical, and allows the wrists to flex by gravity. If the patient feels numbness or tingling within one minute, the test is positive.[28] In Tinel's test, the examiner taps lightly on the palmar aspect of the wrist, over the carpal tunnel. If the patient feels tingling, the test is positive.[29]

Sensory tests for carpal tunnel syndrome typically involve measurement of a patient's threshold for detection of a sensory stimulus. For example, in the Semmes-Weinstein test, the examiner touches the patient with monofilaments, and the test is positive if the patient's sensitivity to the monofilaments falls outside normal limits.[30] Another example is the two-point discrimination test in which the examiner touches two closely-spaced prongs to the patient's fingers. The test is positive if the patient cannot discriminate the prongs when they are 5 millimeters apart.[31]

Nerve conduction tests are also used to diagnose CTS. In such tests, electrodes are placed in two locations along a nerve; the nerve is stimulated from one electrode, and the impulse is recorded from the other electrode. Tests can be performed on either the median nerve, ulnar nerve, or radial nerve, and can assess either motor or sensory function. The placement of electrodes in sensory nerve conduction tests can be either orthodromic (in which stimulating electrodes are placed distal to recording electrodes) or antidromic (in which stimulating electrodes are placed proximal to recording electrodes). Other aspects of the nerve impulse can also be measured such as latency, amplitude, and velocity. Some investigators compare two or more nerve conduction tests in an attempt to assist the diagnosis of carpal tunnel syndrome (e.g., compute a difference between two latencies). We refer to these comparisons as composite nerve conduction tests.

Imaging tests for carpal tunnel syndrome include magnetic resonance imaging (MRI), computed tomography (CT), scan x-ray film, and ultrasound. Using these

methods, investigators attempt to measure the size of anatomical areas within the carpal tunnel or other areas that may be affected by carpal tunnel syndrome.

Treatment

Conservative treatment

Nonsurgical interventions that have been used to treat CTS include wrist splints, avoidance of precipitating activities, anti-inflammatory drugs, vitamin B_6, diuretics, ultrasound, injection of anti-inflammatory steroids and physical therapy.[17,32-36] Treatment of comorbid conditions contributing to CTS may also be effective.[37,38]

Surgical treatment

The standard surgery for CTS is the transection of the transverse carpal ligament.[39] This transection may be accomplished by endoscopic or open surgery. For virtually all patients it is an outpatient procedure performed in an ambulatory surgical center under regional anesthesia, but a few patients request general anesthesia. A variety of endoscopic techniques have been reported.[40-46] Variations in technique include the specific types of equipment used and whether the technique requires one or two incisions. No published evidence is available quantifying the relative advantages and disadvantages of the various methods.

Additional procedures, such as ligament repair or neural surgery may also be used. Ligament reconstruction involves the reattachment of the transected ends of the transverse carpal ligament in such a way that the overall ligament is lengthened. This results in an enlargement of the carpal tunnel and relief of the pressure on the median nerve.[47-49]

Neural surgery for CTS (external or internal neurolysis or epineurotomy) is generally performed immediately following the division of the transverse carpal ligament. The term "neurolysis" is used to encompass several different procedures.[50] These include removal of adhesions from the connective tissue surrounding the nerve (the epineurium), relieving pressure within the epineurium by means of a longditudinal incision, or removal of a segment of epineurium. There is confusion due to the nonstandard usage of terms, compounded by the different subspecialties and nationalities of surgeons. The common goal in all techniques is to remove adhesions and scar tissue to decompress the nerve and allow it to glide freely.

Cubital Tunnel Syndrome

Patients with cubital tunnel syndrome are affected by a weak grip, lack of hand coordination, hand clumsiness, and numbness, paresthesia, and pain in the hand, particularly in the fourth and fifth digits. These symptoms are thought to be caused by compression of the ulnar nerve at multiple sites in the area of the elbow, where the nerve passes through an anatomically restricted area called the cubital tunnel.

Signs and symptoms

Patients presenting with cubital tunnel syndrome usually complain of a weak grip, hand clumsiness and lack of coordination, and dropping of objects. Numbness and paresthesia in the fourth and fifth digits may also be present, in particular after prolonged flexion of the elbow.[51] Pain in the hand may be present, but is neither as severe or as common as in carpal tunnel syndrome.[52] The medial aspect of the elbow may be painful.[53] Severe cases may present with atrophy of the intrinsic muscles and clawing of the fourth and fifth fingers.[51]

Diagnosis

Upon examination, patients with cubital tunnel syndrome are positive for Tinel's sign (tingling in the fingers after tapping over the ulnar nerve at the elbow), and the ulnar nerve may feel swollen and hard upon palpation.[52] In addition, patients have diminished sensation in the fourth and fifth digits (pin-prick or Semmes-Weinstein monofilament testing), weak intrinsic hand muscles, a progressive inability to separate the fingers, and a loss of power grip and dexterity.[53] Patients with more advanced cases may exhibit a positive Wartenberg's sign (upon extension of the fingers abduction of the fifth digit occurs) and/or a positive Froment's sign (patient cannot pinch between the index finger and thumb without flexion of the distal phalanx of the thumb).[53]

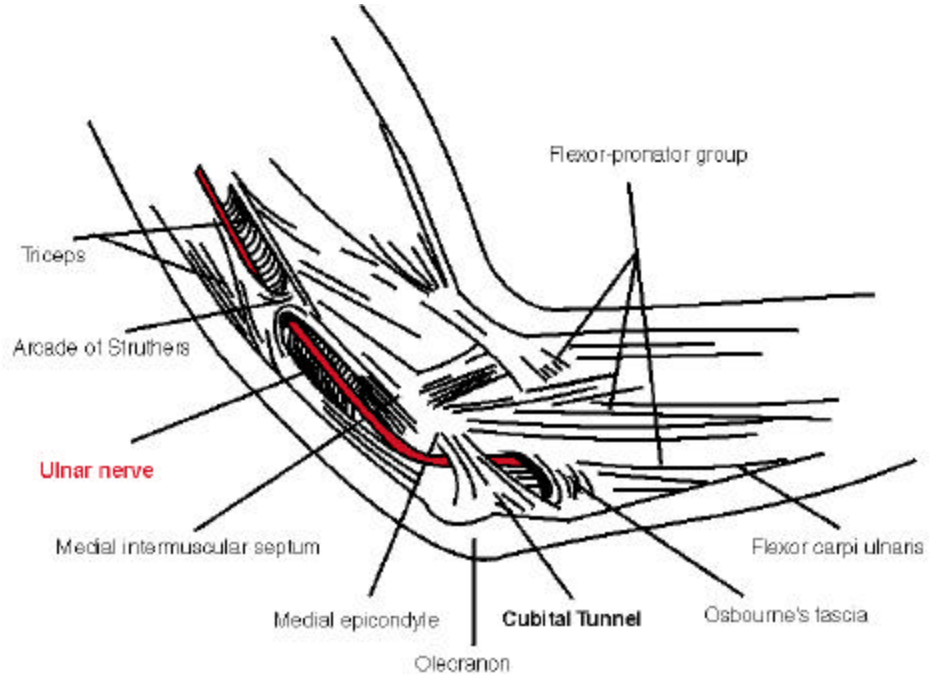
Electrodiagnostic tests can be used to confirm a lesion of the ulnar nerve, and to help locate the exact site of compression. Two examples of such tests are motor and sensory conduction velocities across the elbow.[54,55] For motor conduction velocity, stimulating electrodes are placed above and below the elbow, and a recording electrode is placed on the abductor digit minimi (a muscle in the hand that is innervated by the ulnar nerve).[54] The measured latencies, along with the measured distances between stimulating and recording electrodes, are used to compute the motor conduction velocity in the across-elbow portion.[54] For sensory conduction velocity, the ulnar nerve can be stimulated below the elbow and recorded above the elbow (this placement of electrodes is termed orthodromic because the stimulating electrode is distal to the recording electrode).[54] Alternatively, the electrodes can be reversed to yield an antidromic sensory measurement.[55] Regardless of whether orthodromic or antidromic placement is employed, the latencies and distances are used to calculate the sensory conduction velocity across the elbow.[54,55]

Cubital tunnel syndrome can be confused with compression of nerves at other points. Cervical root lesions, such as compression of the eighth cervical root by a bulging disc, may produce symptoms similar to that of cubital tunnel syndrome.[56] Other nerve compression disorders that may produce symptoms similar to that of cubital tunnel syndrome included compression of the medial components of the brachial plexus (thoracic outlet syndrome), compression of the ulnar nerve at the wrist in Guyon's canal (ulnar tunnel syndrome), and compression of the ulnar nerve at more than one point.[56]

Anatomy

The ulnar nerve carries nerve fibers from the eighth cervical and first thoracic nerves. It passes down the upper arm medial to the brachial artery, then passes through the intermuscular septum and travels towards the elbow near the medial head of the triceps. At the elbow, the ulnar nerve passes behind the medial epicondyle of the humerus in a groove between it and the heads of the flexor carpi ulnaris, the cubital tunnel. The ulnar nerve then enters the forearm between the two heads of the flexor carpi ulnaris muscle and enters the hand.[57-59] It is not until the ulnar nerve passes between the two heads of the flexor carpi ulnaris muscle that it begins supplying motor and sensory innervation. It supplies motor innervation to the muscles of the forearm and hand, and sensory innervation to the medial half of the hand, the palm, and the fourth and fifth digits.[57]

Figure 3. The cubital tunnel and associated structures



The groove that the ulnar nerve passes through at the elbow is referred to as the cubital tunnel. This tunnel is bounded by the medial epicondyle of the humerus anteriorly (See Figure 3), the ulnohumeral ligament laterally, and posteromedially, a fibrous arcade of fascial strands that extends from the olecranon to the medial epicondyle, bridging the two heads of the flexor carpi ulnaris muscle.[57,58] Under normal conditions, the capacity of the ulnar tunnel is greatest during elbow extension. Flexion of the elbow decreases the volume of the cubital tunnel by tightening the arcuate ligament, bulging of the medial elbow ligament, and contraction of the flexor carpi ulnaris muscle.[58]

Inside the cubital tunnel, the motor fibers to the flexor carpi ulnaris and flexor digitorum profundus are located deep inside the ulnar nerve, while the motor fibers to the hand muscles and sensory fibers to the fingers are located more superficially. This peripheral location places these fibers to the hand at increased risk of damage from compression, and accounts for their early involvement in the development of cubital tunnel syndrome.[56]

Etiology

Cubital tunnel syndrome is caused by compression of the ulnar nerve within or near the cubital tunnel. The site of entrapment of the ulnar nerve in the region of the elbow can occasionally occur in locations other than the cubital tunnel, including proximal to the elbow by the medial head of the triceps (the arcade of Struthers), at the elbow by the arcuate ligament, or in the mid-forearm by the flexor carpi ulnaris muscle.[53] Chronic reduction in volume of the cubital tunnel results in compression damage and focal ischemia of the nerve. Compression of the ulnar nerve within the cubital tunnel is most often due to constriction of the nerve by the overlying fibrous arcade. Compression can be caused by repetitive trauma, inflammation, idiopathic thickening of Osborne's band, arthritis, hematomas, tumors, bone fragments, and idiopathic persistent epitrochleoanconeus muscle.[57,59] Fractures, dislocations, and direct blunt trauma near the elbow can cause acute compression of the ulnar nerve.[59] Cubital tunnel syndrome can be precipitated by general anesthesia, and is thought to be related to compression of the ulnar nerve caused by poor limb positioning, tourniquets, and/or blood pressure cuffs.[58,59] Systemic diseases such as diabetes, kidney disease, amyloidosis, acromegaly, alcoholism, hemophilia, and leprosy can contribute to the development of cubital tunnel syndrome.[58]

In many patients, no precipitating event can be identified. Compression of the ulnar nerve can be the end result of a pathological cycle of chronic irritation of the nerve. Mild irritation of the nerve can causeinflammation and swelling. These processes restrict movement of the nerve through the cubital tunnel. Failure of the ulnar nerve to slide smoothly during elbow flexion and extension causes the nerve to be stretched, and to rub against surrounding surfaces, damaging the nerve and surrounding tissues, leading to more inflammation, swelling, and the formation of adhesions between the nerve and surrounding tissues, which further restricts nerve movement. Eventually this process leads to chronic compression of the nerve.[59] Activities thought to result in repetitive trauma to the ulnar nerve include habitual leaning on the elbow, sleeping with the arms flexed, or performing repetitive elbow flexion-extension motions.

Epidemiology

The incidence and prevalence of this disorder has not been established. In Connecticut, 3% of claims for Workers' Compensation for occupational disorders of the upper extremity were reported to be for cubital tunnel syndrome.[60] Cubital tunnel syndrome affects men 1.3 to 3 times more often than women.[61,62] Thin

women (BMI<22) are reported to have a greater prevalence of cubital tunnel syndrome than heavier women. No association between BMI and cubital tunnel syndrome has been reported for men.[61]

Treatment

Conservative treatment

The choice of how to treat cubital tunnel syndrome is based upon the severity of symptoms upon presentation. Mild cases are usually treated by minimizing elbow flexion through behavioral changes and splinting, minimizing direct pressure on the elbow using pads and pillows, and reducing inflammation with non-steroidal anti-inflammatory drugs (NSAIDs). If symptoms are severe, or do not respond to conservative treatment, then surgery may be performed.[63]

Surgical treatment

Surgical techniques used to relieve the compression of the ulnar nerve can be divided into three categories: decompression, epicondylectomy, and transposition of the ulnar nerve.

Decompression is the simplest of the procedures and usually involves cutting the tissues that form the roof of the cubital tunnel.[64] The tissues commonly cut during decompression are the medial intermuscular septum, the arcade of Struthers, the superficial fascia, and the deep flexor pronator aponeurosis. Decompression can be performed through an open incision or by endoscopic techniques.[65] Cutting the tissues in this fashion is thought to relieve the compression on the nerve that is causing the problem.

Medial epicondylectomy consists of removal of the medial epicondyle, and reattachment of the flexor-pronator muscle groups to the site of removal.[66] Decompression is usually performed at the same time. Removal of the epicondyle is thought to allow greater anterior migration of the ulnar nerve upon elbow flexion.[63]

Transposition of the ulnar nerve describes several different procedures, all of which reposition the ulnar nerve outside of the cubital tunnel, anterior to the medial epicondyle.[67] Moving the nerve in this fashion is thought to decrease or eliminate nerve tension and avoid further irritation and compression of the nerve.[67] Subcutaneous transposition refers to shifting the ulnar nerve and forming a sling of fascia to hold it in place.[68] The nerve can also be placed in a trough inside the flexor-pronator muscle mass (intramuscular transposition). Submuscular transposition (the Learmonth procedure) involves detaching the flexor-pronator muscle mass from the medial epicondyle, moving the ulnar nerve anteriorly and underneath the flexor-pronator muscle to lie on the brachialis fascia near the median nerve, and then re-attaching the flexor-pronator muscles to the epicondyle. Sometimes when using this technique the flexor-pronator muscle is elongated to prevent tension from being placed on the underlying ulnar nerve.[69]

Epicondylitis

Patients with epicondylitis experience pain at the elbow. The pain is localized over the affected epicondyle, and becomes severe upon use of the affected muscles when grasping objects.

Signs and symptoms

The chief complaint of patients affected by epicondylitis is an insidious onset of elbow pain. The pain is described as dull and aching when at rest, but becomes sharp and severe upon use of the affected muscles when grasping objects.[70] There is tenderness upon palpation over the affected epicondyle. In severe cases, the afflicted person may complain of grip weakness. Upon resisting wrist extension (flexion, for medial epicondylitis), severe pain occurs at the affected epicondyle.[53]

Diagnosis

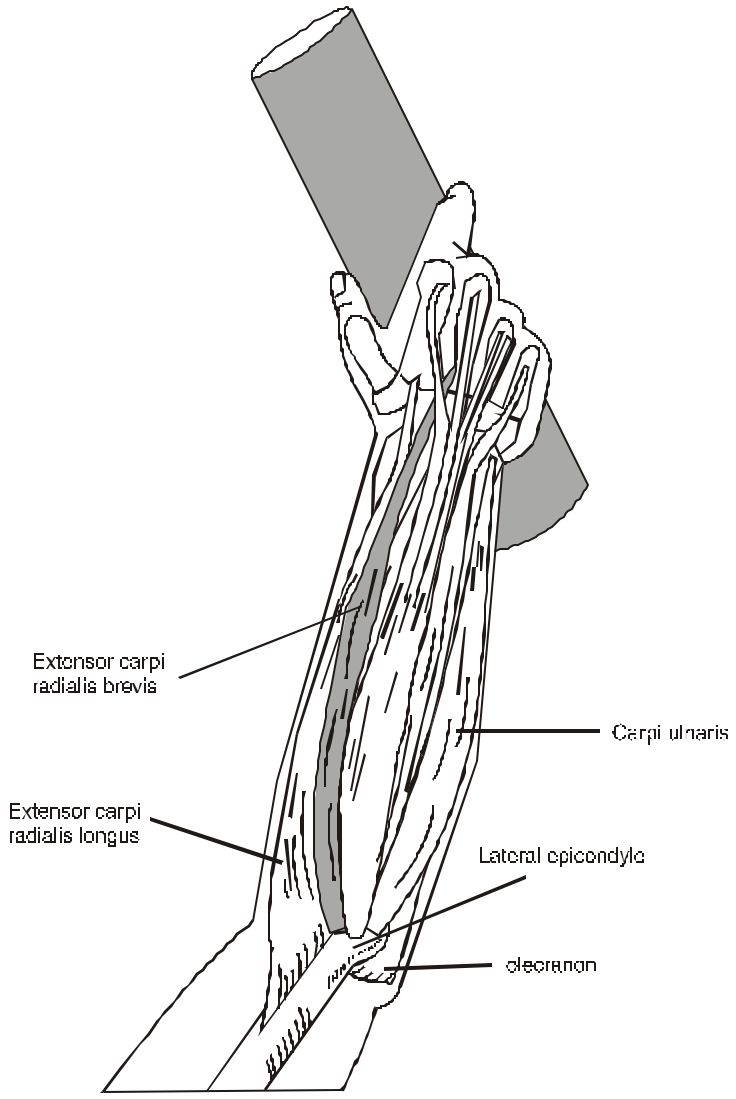
Diagnosis of epicondylitis is reached by clinical exam and history. In addition to pain upon resisted wrist extension, other clinical signs of epicondylitis include pain upon resisted supination of the forearm, reduced grip strength, and pain upon resisted extension of the middle finger.[71-73] In clinically diagnosed cases that do not improve with conservative management, MRI of the elbow has been used to clarify the diagnosis and assess the degree of tendon disease.[74]

Anatomy

Epicondylitis refers to pain in the area where the muscles of the forearm attach to the epicondyle of the elbow, pain that is worsened by use of these muscles. Epicondylitis is divided into two distinct syndromes: lateral and medial epicondylitis. Lateral epicondylitis, also referred to as tennis elbow, refers to pain in the attachment of the extensor muscles, most commonly the insertion of the extensor carpi radialis brevis tendon, into the lateral epicondyle. Medial epicondylitis, also referred to as golfer's elbow, refers to pain in the attachment of the flexor muscles of the forearm to the medial epicondyle. Lateral epicondylitis is more common than medial epicondylitis.[75]

A tendon attaches muscle to bone or fascia. The power of the muscle contraction is transmitted down the tendon and causes the attached bone to move. The site of attachment of the tendon to the bone is thus subject to considerable force with each contraction of the muscle.[76] Tendonitis and tenosynovitis refer to disorders of the tendon and the synovial membrane of the tendon sheath, respectively. Although historically inflammation was thought to be the pathology underlying tendonitis, chronic degenerative changes in the tendon and synovial tissue appear to be the predominant pathological processes.[53,77]

Figure 4. Structures associated with lateral epicondylitis



The exact pathology that underlies epicondylitis is not known.[70] The problem appears to be confined to the tendinous and fascial attachments to the bone (See Figure 4). The tendons become dull, gray, friable, and edematous. The normal tendon fibers become disrupted by invading fibroblasts and granulation tissue.[78] Adhesions may form between the tendon and surrounding tissues. The extensor carpi radialis brevis tendon appears to be most often affected because it is intimately attached to the joint capsule, and because of this proximity adhesions readily form between it and the joint.

Etiology

Lateral epicondylitis is thought to be a degenerative process caused by overuse of the wrist extensors. Repetitive strong synergic and fixator action of the wrist extensors during gripping are believed to result in minor trauma to the muscle attachment to the epicondyle.[75] Continued muscle use prevents healing. Medial epicondylitis is thought to be a similar process affecting the flexor, rather than the extensor, muscles. Forceful, repetitive motions of the forearm are thought to be the initial precipitating factor.[79]

Epidemiology

Epicondylitis has been reported to affect 4.23 individuals per 1000 adults per year in the U.S.[80] The mean age of diagnosis is 45 years, and men and women appear to be equally affected.[80] Lateral epicondylitis is six times more common than medial epicondylitis.[80] Individuals who have been diagnosed with carpal tunnel syndrome have a greater prevalence of lateral epicondylitis than do those without carpal tunnel syndrome.[81] Persons who engage in forceful, repetitive forearm work such as mechanics, butchers, and construction workers have a higher prevalence of the condition than the general population.[82]

Treatment

Conservative treatment

Initial treatment of epicondylitis usually involves rest and massage. In addition, a number of conservative therapies are used to treat epicondylitis. These are briefly described below.

Pharmacologic treatments for epicondylitis include NSAIDs, either taken orally or applied topically, topical dimethyl sulfoxide (DMSO), injections of glucocorticoid steroids, injections of anesthetics, and oral glucosamines.

Rest, ice, massage, physiotherapy, manipulations, splints, braces, and exercise programs are commonly used when treating epicondylitis.

Other treatments for epicondylitis include acupuncture, low level red or infrared lasers, ultrasound, phonophoresis, transcutaneous electrical nerve stimulation (TENS), extracorporal shock-wave therapy (ESWT), and pulsed electromagnetic fields (PEMF).

Surgical treatment

Surgery is not generally a first-line treatment for epicondylitis. However, in cases that are resistant to more conservative treatments, a variety of surgical techniques have been used. Some of the techniques are listed in Table 1. They can be broken down into four broad categories: denervation, nerve decompression, excision of various tissues, and lengthening of the extensor tendon (ERCB).[83]

Table 1. Surgical procedures used to treat epicondylitis[a]

Category	Type of surgery
Denervation	Complete denervation
	Partial lateral denervation
	Partial ventral denervation
Nerve decompression	Decompression of thePIN
	Decompression of the radial nerve
	Combination of denervation and decompression of the PIN
Lengthening of the ERCB	Distal lengthening of the ECRB
	Proximal lengthening of the ERCB
Removal of tissues	Incision of the ERCB
	Partial resection of the annular ligament (Bosworth technique)
	Epicondylar osteotomy
	Epicondylectomy and excision of the distal portion of the annular ligament
	Excision of subtendinious pathological tissue
	Excision of the subcutaneous tissue
	Excision of the radiohumoral bursa
	Fasciectomy of the common extensor origin
	Fasciectomy plus anconeous transfer
	Debriding of the elbow join

[a] Adapted from Wilhem et al.[84]
PIN = posterior interosseus nerve
ERCB = extensor carpi radialis brevis tendon

De Quervain's Disease

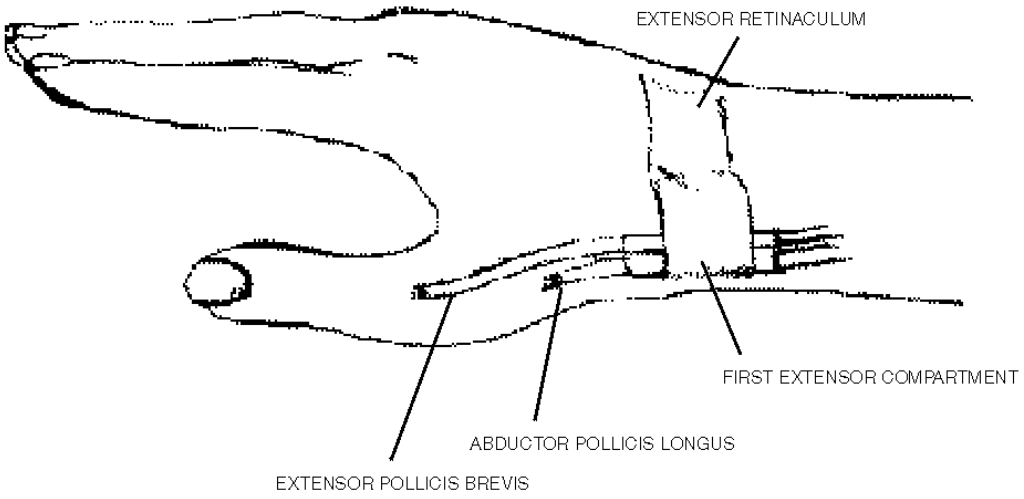
Signs and Symptoms

De Quervain's disease is characterized by pain localized on the radial border of the wrist that may also radiate into the thumb and forearm.[85] The pain is usually worsened by abduction and/or extension of the thumb.[53] Other symptoms may include weakness of the thumb and loss of grip. Range of motion of the wrist and thumb is usually unaffected or only slightly limited.[85]

Anatomy

De Quervain's disease is a stenosis (thickening) of the fibrous sheath of the first extensor compartment of the extensor retinaculum.[86] This compartment surrounds two tendons, the extensor pollicis brevis and the abductor pollicis longus (See Figure 5). In the past, de Quervain's disease has been described as a type of stenosing tenosynovitis of the hand and wrist. Because recent studies have shown that there is no inflammatory process associated with de Quervain's disease, some experts believe that the term tenosynovitis is not accurate for describing this condition.[53,86]

Figure 5. Structures associated with De Quervain's disease



Etiology

Possible etiologic factors include acute trauma, recurrent trauma, or an underlying collagen disease.[87]

Epidemiology

De Quervain's disease appears most frequently in the 30 to 50 year age group and has been reported to be 10 times more common among women than men.[85] Work occupations commonly associated with this condition include musicians, weavers, typists, nurses, knitters, golfers, switchboard operators, and manual workers.[53,85] However, there is disagreement among experts as to whether these types of work cause de Quervain's disease or merely exacerbate the symptoms.[53,86] Anatomic variations of the first extensor compartment have also been reported to be associated with de Quervain's disease.[86]

Diagnosis

Diagnosis of de Quervain's disease is usually accomplished by the Finkelstein test. While the patient flexes the thumb within the palm while holding it tightly with the other fingers, the examiner performs an ulnar deviation of the patient's wrist. Intense pain on the styloid process of the radius indicates a positive test. The pain disappears after the thumb is released and extended.[85] Additional diagnostic criteria include patient-reported pain at the radial wrist and tenderness to palpation at the radial wrist.[53]

Treatment

Conservative treatment

A number of conservative therapies have been used to treat de Quervain's disease. These include workplace modification, hand rest, neutral wrist splinting with a thumb spica, anti-inflammatory medication, and iontophoresis.[53] If these therapies fail, injection of cortisone may be used to supplement splinting and anti-inflammatory medication.

Surgical treatment

Persistent pain after four to six weeks of conservative therapy is usually considered an indication for surgery.[85,87] This procedure consists of unroofing the retinaculum to release the abductor pollicis longus and extensor pollicis brevis tendon sheaths.[87] As noted earlier, anatomic variation exists in that these tendon sheaths may be contained in one or two compartments. Reported complications of surgery include radial sensory nerve injury and painful surgical scarring.[88]

Chapter 2. Methodology

Conditions of Interest

This evidence report is concerned with worker-related upper extremity disorders. The term "worker-related" implies a disorder that affects workers, not a disorder caused by work. In this report, we address four specific disorders: (1) carpal tunnel syndrome, (2) cubital tunnel syndrome, (3) epicondylitis, and (4) de Quervain's disease. This list of disorders was determined during discussions among ECRI, the Agency for Healthcare Research and Quality (AHRQ), the organizations that nominated this topic to AHRQ, and a panel of technical experts. Below, we provide further details about the nominating organizations and technical experts.

Technical Experts

Technical Experts were employed to assist in defining the scope of this evidence report, developing its questions, and developing the criteria for retrieving and including articles. Seven organizations were solicited to nominate individuals who could serve as Technical Experts. All solicitations were pre-approved by AHRQ. All seven organizations nominated an individual. Thus, the Expert Panel was comprised of individuals from the American Association of Electrodiagnostic Medicine, the American Academy of Neurology, the American Academy of Physical Medicine and Rehabilitation, the American Physical Therapy Association, the Association for Repetitive Motion Syndromes, the American Association of Neurological Surgeons, and the American Academy of Orthopedic Surgeons. The participation of these individuals and organizations does not imply their endorsement of the findings of this evidence report.

Key Questions

To determine the specific questions that this evidence report would address, a multidisciplinary team was assembled. This team included ECRI research staff, AHRQ project staff, representatives from the organizations that nominated this topic to AHRQ (the Social Security Administration and the American College of Occupational and Environmental Medicine), and the Technical Experts. The key questions for this report were decided during three conference telephone calls between ECRI, AHRQ, the experts, and the nominating organizations, as well as subsequent discussions between ECRI, AHRQ, and the nomination organizations.

The final set of key questions is comprised of 13 questions, 11 of which are separately addressed for the four above-mentioned disorders. The remaining two questions are not disorder specific. This evidence report is correspondingly organized. Thus, we first

address each of the 11 questions for each disorder, beginning with carpal tunnel syndrome, and conclude by addressing the two questions that are not disorder-specific.

Condition-Specific Questions

The 11 condition specific questions that we address in this report are:

Question #1: What are the most effective methods and approaches for the early identification and diagnosis of worker-related musculoskeletal disorders of the upper extremity?

Question #2: What are the specific indications for surgery for worker-related musculoskeletal disorders of the upper extremity?

Question #3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with worker-related musculoskeletal disorders of the upper extremity?

Question #4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question #5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question #6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

Question #7: What are the surgical and nonsurgical costs or charges for treatment of worker-related musculoskeletal disorders of the upper extremity?

Question #8: For persons who have had surgery for worker-related musculoskeletal disorders of the upper extremity, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with a worker-related disorder of the upper extremity?

Question #10: What are the functional limitations for an individual with a worker-related musculoskeletal disorder of the upper extremity before treatment?

Question #11: What are the functional limitations of an individual with a worker-related musculoskeletal disorder of the upper extremity after treatment?

Non-Condition-Specific Questions

The two questions that are not condition specific are:

Question #12: What are the cumulative effects on functional abilities among individuals with more than one worker-related musculoskeletal disorder of the upper extremity in the same limb?

Question #13: What level of function can one achieve in what period of time when one is required to change hand dominance as a result of injury to his or her dominant hand?

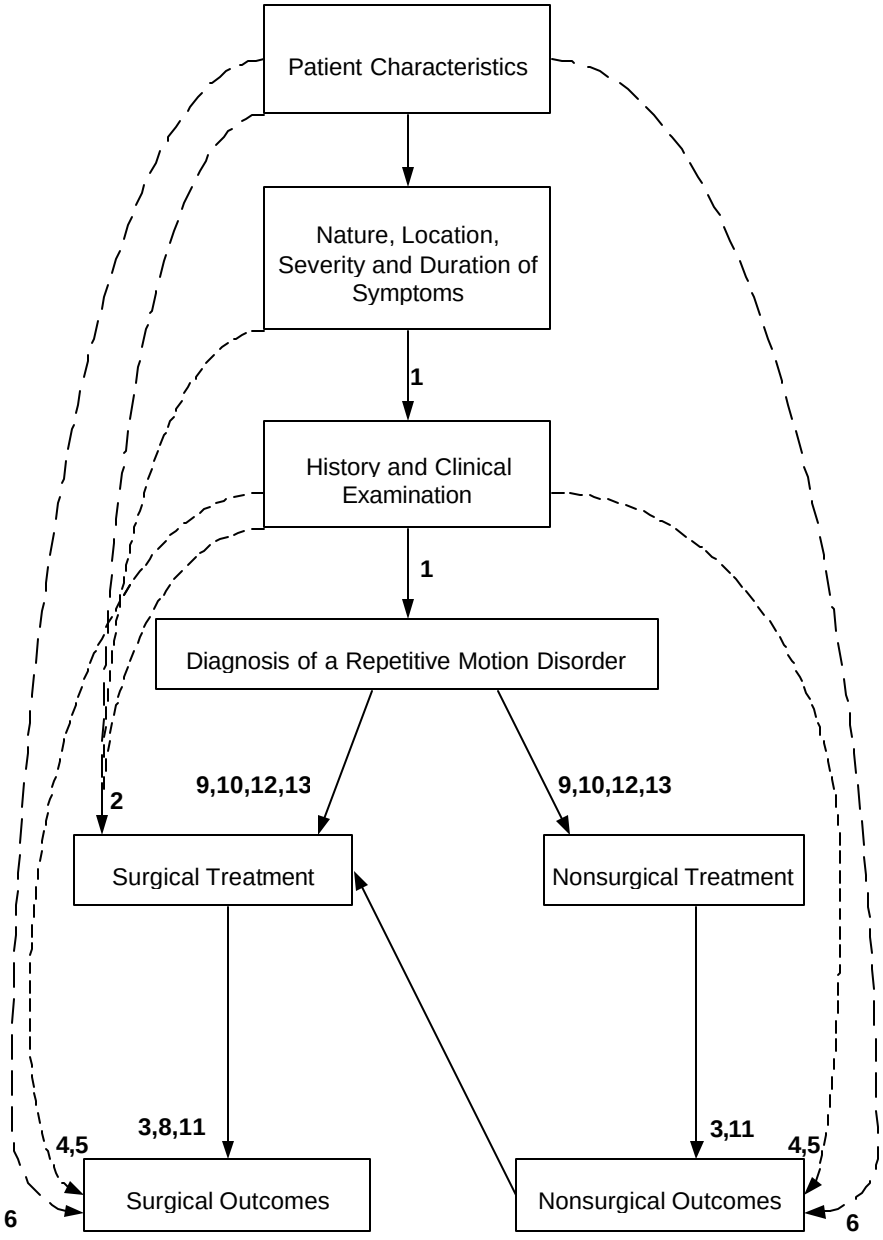
Causal Pathway

The scope of this report can be illustrated by a causal pathway. More specifically, this pathway illustrates the key questions and the relationships among them. It also illustrates items that are beyond the scope of this evidence report. This pathway is shown in Figure 6. The rectangles in this figure depict the primary clinical "events", from presentation of a patient (who has certain characteristics that may be at least partly diagnostic and/or prognostic) to the outcomes that the patient experiences (e.g., improves/does not improve). That this, in fact, is a pathway that proceeds in a certain chronological order is depicted by solid arrows that connect the rectangles in Figure 6. Because these arrows connect two rectangles, they are termed "links." The numbers next to each link represent the numbers of the Key Questions that address that link. Key Question 7 is not shown in the pathway because it is concerned with costs and, therefore, is not part of the clinical pathway.

The dashed lines in the figure "overarch" several rectangles. We have drawn these lines as dashed because they do not depict the sequence of events in the clinical pathway. In general, these lines portray Key Questions about how patient characteristics (including clinical findings) may influence a patient's movement through the clinical pathway or whether these characteristics influence outcomes.

Theoretically, one can derive a key question by drawing a line between any two rectangles in Figure 6. Therefore, rectangles not connected by solid or dashed lines are beyond the scope of this evidence report.

Figure 6. Causal Pathway



Literature Searches

Our searches for information were designed to produce a comprehensive dataset. Therefore, we searched a number of electronic databases and other sources. These are described below.

Electronic Database Searches

We searched 31 electronic databases. These databases were:

CISILO Database (International Occupational Safety and Health Information Centre) (through November 2000)

The Cochrane Database of Systematic Reviews (through 2000, Issue 4)

The Cochrane Registry of Clinical Trials (through 2000, Issue 4)

The Cochrane Review Methodology Database (through 2000, Issue 4)

CRISP (Computer Retrieval of Information on Scientific Projects) (through November 16, 2000)

Cumulative Index to Nursing and Allied Health (CINAHL) (1988 through September 29, 2000)

Current Contents (through December 2000)

The Database of Reviews of Effectiveness (Cochrane Library) (through 2000, Issue 4)

DIRLINE (through September 27, 2000)

ECRI Health Devices Alerts (1977 through January 2001)

ECRI Health Devices Sourcebase (through January 2001)

ECRI Healthcare Standards (1975 through January 2001)

ECRI International Health Technology Assessment (IHTA) (1990 through January 2001)

ECRI Library Catalog (through January 2001)

ECRI TARGET (ECRI's database of emerging technologies; through January 2001)

Embase (Excerpta Medica) (1974 through December 12, 2000)

ERIC (Educational Resources Information Center) (searched June 28, 2000)

Health and Psychosocial Instruments (HAPI) (through January 30, 2001)

Health Services Research Projects (HSRPROJ) (through September 27, 2000)

HealthSTAR (Health Services, Technology, Administration, and Research) (1990 through September 26, 2000)

LocatorPlus (through January 2001)

NIOSHTIC (through November 3, 2000)

Old Medline (1957 -1965) (searched September 27, 2000)

PsycINFO (1967 through January 22,2001)

PubMed (1966 through January 22, 2001)

Rehabdata (through November 2000)

SciSearch (through November 13, 2000)

U.K. National Health Service (NHS) Economic Evaluation Database (NHS EED) (through January 2001)

U.S. Health Care Financing Administration (HCFA) (through January 2001)

U.S. National Guidelines Clearinghouse (NGC) (through January 2001)

U.S. National Institutes of Health Web site (NIH) (through January 2001)

World Wide Web Searches

To further ensure that this evidence report was comprehensive, we also searched the World Wide Web using various resources and search engines including AltaVista, NorthernLight, and Google. These resources included:

American Academy of Orthopedic Surgeons http://www3.aaos.org

American College of Occupational and Environmental Medicine (ACOEM) http://www.acoemwebapps.org/gov/welcomeNS.asp

Association for Repetitive Motion Syndromes (ARMS) http://www.certifiedpst.com/arms/

Canadian Centre for Occupational Health and Safety (CCOHS) http://www.ccohs.ca/

Centre for Clinical Effectiveness http://www.med.monash.edu.au/publichealth/cce/

Development Evaluation Committee http://www.hta.nhsweb.nhs.uk/rapidhta/main.htm

ErgoWeb http://www.ergoweb.com/

HCUPnet http://www.ahcpr.gov/data/hcup/hcupnet.htm

Medscape http://www.Medscape.com

National Institute for Occupational Safety and Health (NIOSH)
http://www.cdc.gov/niosh/homepage.html

NHS Centre for Reviews and Dissemination http://www.york.ac.uk/inst/crd/welcome.htm

Safety and Health Statistics, Bureau of Labor Statistics http://stats.bls.gov/oshhome.htm

SUM Search http://sumsearch.uthscsa.edu/searchform4.htm

TRIP Database http://www.tripdatabase.com/

Other Sources

In addition to the above searches, we also reviewed the bibliographies and reference lists of all studies included in this evidence report, searched Current Contents—Clinical Medicine on a weekly basis, and routinely reviewed over 1,600 journals and supplements maintained in ECRI's collections.

United States Cost/Reimbursement Data

We searched four additional U.S. government datasets solely to obtain information about costs. These were:

2001 Physician Fee Schedule. This Health Care Financing Administration (HCFA) dataset contains fees and limiting charges for physician services under Medicare in 2001.

Median Costs for Hospital Outpatient Services Dataset. This HCFA dataset contains median costs, by HCPCS codes, for services reimbursed under the hospital outpatient prospective payment system. The data are calculated based on 1996 hospital outpatient claims.

Medicare Provider Analysis and Review (MEDPAR). This HCFA dataset contains information for 100% of Medicare beneficiaries using hospital inpatient services. The data are provided by state and then by diagnostic related group (DRG) for all short stay and inpatient hospitals for fiscal years 1990-1996. Data include total charges, covered charges, Medicare reimbursement, total days, number of discharges, and average total days.

Hospital Outpatient Prospective Payment System. This HCFA dataset contains rules for payment of outpatient services provided by hospitals or affiliated organizations under hospital control. The system is based on ambulatory payment classifications (APCs). This classification system groups services both clinically and by resource utilization.

Search Strategies

The systematic nature of the searches for information for an evidence report is a means of diminishing reviewer bias during the preparation of a report. This systematic nature is reflected in our strategies for searching PubMed/Medline and HCUPnet for ICD-9 procedure codes and CPT codes, diagnostic related groupings (DRGs), ambulatory related groupings (ARGs), and HCPS codes. These strategies are detailed in Appendix A.

Article Retrieval Criteria

To be included in this evidence report, an article had to meet two sequentially applied sets of *a priori* criteria. The first set determined whether a full article would be retrieved. The second set, which was based on major study design flaws and certain elements specific to each question, determined whether a retrieved article would be included in the report. To facilitate comprehensive article retrieval, the retrieval criteria were designed to be broad.

The abstracts of articles identified by our searches were reviewed against the retrieval criteria to determine whether we would retrieve an article identified by our searches. This task was independently performed by six research analysts, each of whom individually worked on different questions. We retrieved an article whenever there was uncertainty about whether it met the retrieval criteria. We also retrieved articles when an abstract was not present in the search results, but when the title of the article suggested that it was relevant.

The criteria for article retrieval were:

- All patients, or a separately reported subset of patients in any given article, had to be diagnosed with a worker-related disorder of the upper extremity. No restrictions were placed on the patient populations in clinical trials of conservative or surgical treatments that were retrieved for this analysis. For studies addressing condition-specific key questions, patients had to be diagnosed with the specific disorder of interest.

- All controlled trials were retrieved, regardless of whether they were described as randomized or prospective. There was no cutoff date for year of publication. Included in the retrieved articles were those that compared a treatment to a placebo, sham, or untreated group and those that compared two or more treatments.

- Case series and other reports were evaluated only if published in 1980 or later. This was an arbitrary cut-off date set to exclude case series using obsolete techniques and outdated patient selection criteria.

- Case series had to enroll 10 or more patients. Studies with less than 10 patients are unlikely to be representative of the range of patients with the disorder being evaluated.

- Only English-language articles were retrieved.

Inclusion Criteria

Once an article was retrieved, it was examined to determine whether it suffered from a major design flaw and whether it met certain question-specific criteria. When an article was excluded, the research analysts entered a unique article identifier and the reason(s) for exclusion into an electronic data abstraction form (DAF).

When an article was included, the unique identifier and details about the studies results, design, and enrolled patient population were entered in these forms. Additional details about the DAFs are provided below.

Many of our exclusions were made because an article contained a significant design flaw. To avoid redundancy, we do not list these flaws here. Rather, we provide a listing of the major design flaws used to exclude articles in the sections of this report in which we evaluate the quality of the literature. Below, we provide the inclusion criteria that are unique to each question:

Question 1. What are the most effective methods and approaches for the early identification and diagnosis of worker-related musculoskeletal disorders of the upper extremity?

Studies meeting the retrieval criteria were included:

- Only if they reported sensitivity and specificity or provided sufficient data to allow us to compute these measures of test performance.

- If they did not use obsolete tests (e.g., first- and second-generation CT scanners).

- Regardless of whether they were prospective or retrospective.

- Regardless of whether they contained a concurrent control group. Use of controlled and particularly randomized controlled studies is exceedingly rare in the evaluation of any diagnostic test. Often, such controls are not needed because the patients can validly serve as their own controls.

Question 2. What are the specific indications for surgery for worker-related musculoskeletal disorders of the upper extremity?

To address this question, we tabulated the characteristics of patients enrolled in clinical studies. Doing so does not require any particular study design, and this is reflected in our inclusion criteria. Thus, among the studies that met the retrieval criteria, we included:

- Controlled trials and case series of surgical patients

- Studies in which not all patients received surgery were included, but only if characteristics of patients receiving surgery were reported on separately.

- Studies that did not exclusively enroll patients with co-morbidities not routinely encountered during routine clinical practice (e.g., patients with amyloidosis).

Question 3. What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with worker-related musculoskeletal disorders of the upper extremity?

Among studies meeting the retrieval criteria we included:

- Controlled studies, regardless of whether they were randomized or blinded.

- Studies that were not exclusively dedicated to comparing highly similar treatment variations (such as incision shape).

- Studies that reported on at least one of the seven key outcomes addressed in this assessment. The outcomes are: pain, function, quality of life, ability to return to work, ability to return to activities of daily living, harms, and global outcome.

Question 4. Is there a relationship between specific clinical findings and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

We evaluated controlled trials and case series that attempted to correlate patient-oriented outcomes with specific clinical findings, patient characteristics or duration of symptoms. It is not feasible to conduct randomized controlled trials that address this question because, by definition, one cannot fully randomize patients with different pretreatment clinical findings into different groups. Therefore, the inclusion criteria adopted for this question were:

- Studies that evaluated the relationship of pretreatment clinical findings and outcomes using multiple linear or logistic regression.

- Studies that statistically compared the outcomes of patients stratified across some pretreatment clinical finding.

- Studies reporting patient-level data were included when the data were presented in enough detail to allow us to perform independent multiple regression analyses.

- Studies that reported on at least one of the seven key outcomes addressed in this assessment. The outcomes are: pain, function, quality of life, ability to return to work, ability to return to activities of daily living, harms, and global outcome.

- Studies that examined a simple correlation between a given pretreatment variable and outcomes were included, even if they did not attempt to control for the effects of other predictor variables. However, we only included such studies if there were at least three studies that attempted to correlate the same outcome with the same predictor variable. We adopted the arbitrary criterion of requiring three correlational studies because, when taken individually, interpretation of such studies is difficult. This is because they do not contain information about potential inter-variable multicolinearity.

Question 5. Is there a relationship between duration of symptoms and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

The criteria used for this question were identical to those used for Question 4.

Question 6. Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with worker-related musculoskeletal disorders of the upper extremity?

The criteria used for this question were identical to those used for Question 4.

Question 7. What are the surgical and nonsurgical costs or charges for treatment of worker-related musculoskeletal disorders of the upper extremity?

Cost and charge information from large national databases was included.

Question 8. For persons who have had surgery for worker-related musculoskeletal disorders of the upper extremity, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

- Controlled trials of any design (RCTs, prospective non-randomized, and retrospective) were included.

Question 9. What instruments, if any, can accurately assess functional limitations in an individual with a worker-related disorder of the upper extremity?

For inclusion in this question, a study meeting the retrieval criteria had to be:

- A case series or controlled study that measured the validity, response to treatment, or test-test reliability of the assessment instrument.

- A study not exclusively devoted to measuring the internal consistency of an instrument. Although internal consistency is important in instrument development, it does not directly address the ability of an instrument to predict functional limitations.[89]

- A study of an instrument designed to evaluate patient function. Instruments that only evaluated symptoms or that were primarily designed to aid in diagnosis were not included.

- A study of an instrument that enrolled patients with one of the four specific disorders of interest.

Question 10. What are the functional limitations for an individual with a worker-related musculoskeletal disorder of the upper extremity before treatment?

In addressing this question, we tabulate functional limitations. Answering this question does not require randomized controlled trials. Therefore, our inclusion criteria for studies meeting the retrieval criteria were:

- All studies, regardless of design

- Studies that measured functional disability using one of the instruments identified in Question 9

- Studies that exclusively enrolled patients with one of four conditions of interest.

- Studies reporting on functional ability using portions of these instruments or minor variations of these instruments were included as well.

- Study must not have enrolled patients who received prior treatment.

Question 11. What are the functional limitations of an individual with a worker-related musculoskeletal disorder of the upper extremity after treatment?

This question is similar to Question 10 and, therefore, identical inclusion criteria were employed except for the one requiring that patients must not have had prior treatment. To be included for Question 11, the study must have been of patients who received prior treatment.

Question 12. What are the cumulative effects on functional abilities among individuals with more than one worker-related musculoskeletal disorder of the upper extremity in the same limb?

The criteria for this question were identical to those used for Question 11, except that the study must have reported data on the patient population relevant to Question 12.

Question 13. What level of function can one achieve in what period of time when one is required to change hand dominance as a result of injury to his or her dominant hand?

This question also does not depend on randomized controlled trials. Therefore, we included any retrieved study, regardless of design, that employed any test of functional

ability in patients required to change hand dominance as a result of injury to the dominant hand.

Electronic Data Abstraction Forms

Data from all articles that met our inclusion criteria were abstracted using electronic data abstraction forms. These forms were created using Microsoft Access. Using this software, separate data abstraction forms were designed for entering data about basic trial design information; patient signs, symptoms, comorbidities, characteristics, and treatments; reporting of treatment outcomes; surgical complications; and nerve conduction measurements. The data abstraction forms are presented in the appendix B.

The abstraction form for trial information contained information on trial design, purpose, author, year of publication, general diagnosis of patient condition, a specific description of the treatment outcomes examined, inclusion and exclusion criteria, and other important information with which to judge the quality of the trial. One record containing a unique trial identification number appears for each trial entered in the database.

The abstraction form for patient characteristics and treatments was designed to contain information on each patient group within a trial. A separate record containing a unique patient group identification number appears for each patient group within a trial. This form contained entries for treatment given to the patient group, stratification of patient groups based on pretreatment characteristics, number of patients in the group, specific descriptions of patient treatment, and patient characteristics such as age, dropouts, signs, symptoms, disease severity and duration of symptoms prior to treatment.

Abstraction forms with similar design were created to contain information on treatment outcomes. Separate abstraction forms were needed for dichotomous, categorical and continuous outcome data. These forms contained entries for the patient group identification number, number of patients reporting the outcomes, and time the outcome was measured. A separate record was entered for each patient group and each follow up time for which an outcome was reported.

Special forms were designed for symptoms, comorbidities, complications, and results of diagnostic tests.

Because diagnostic trials differ from treatment trials in many important ways, several special forms were used in the abstraction of diagnostic data, and irrelevant sections of the other data abstraction forms were not completed.

One clinical trial information form and one diagnostic clinical trial information form were completed for each study; not all of the fields in the clinical trial information form were relevant to the diagnostic studies. One patient groups—diagnostics and characteristics form was completed for each patient group or subgroup in each study. Most articles from which we abstracted data reported on two groups; some reported more. One diagnostic test information form was completed for each diagnostic test result

reported in each study. Because separate forms were completed for each test parameter reported (e.g. distal motor latency v. distal sensory latency), most studies required more than one form and several required 30 or more forms. One study reported 57 different tests.[90]

Articles Identified

Our searches identified 7,312 articles. Of these, 1270 were clinical trials. The number of articles included for each question is shown in Table 2.

Table 2. Number of articles Included for Each Key Question

Question #	Carpal Tunnel	Cubital Tunnel	Epicondylitis	De Quervain's
1	189	20	10	0
2	145	32	19	3
3	44	3	50	1
4	12	11	3	1
5	5	14	7	1
6	21	15	6	1
8	0	0	0	0
9	8	0	3	0
10	2	0	2	0
11	12	0	0	0

For the two questions that were not condition specific, Questions 12 and 13, we included 0 and 2 articles, respectively. Question 7 is not depicted in the above table because we addressed it using information from a national database, not published articles.

Evaluating Literature Quality

Because this is a "best evidence" synthesis, we incorporated studies that represented the best available evidence, not the best possible evidence. Therefore, not all evidence that we included is of equal quality.

The quality of studies of treatments that we evaluated can be ranked according to the following hierarchy:

Randomized controlled trials

Other prospective controlled trials

Retrospective controlled trials, including those with historical control groups

Prospective case series

Retrospective case series

The hierarchy, like any evidence hierarchy, is only a rough guide. As noted above, randomized controlled trials are not necessary for some of the questions (among which are questions about diagnostics) that we addressed. In such cases, this hierarchy is not applicable. Therefore, for these questions, we discuss the dimensions along which we evaluated the quality of the literature when we address that question. These discussions appear in the appropriate Internal Validity sections under each of these questions.

Statistical Methods

Meta-Analysis of Studies of Treatment

Meta-analyses of studies of treatments were conducted using Hedges' d as a measure of each study's effect size, and then computing the precision-weighted summary d from the combined results of all studies.[91] Hedges' d is the difference between the means of any study's two groups expressed in standard deviation units. We performed meta-analyses on data from studies of treatments only when four or more controlled studies of a given treatment reported the same outcome. We did not perform meta-analyses of smaller data sets because of the high potential for publication bias to affect their results.

For computation of effect sizes derived from dichotomous outcomes, we converted the odds ratio to Hedges' d as described by Hasselblad and Hedges.[92] For computation of effect sizes derived from rating scale data, we calculated a mean for each group as described by Torgenson (his equations 71-78).[93] An advantage of this method is that it does not assume that all patients employ exactly the same boundaries for each category in a rating scale.

We employed two tests for heterogeneity, the Q statistic and each study's standardized residual. We regarded the data as heterogeneous if the results of either test was statistically significant. When we detected heterogeneity, we analyzed the data for sources of heterogeneity. It was not always possible to find a source, particularly when there were only a small number of studies in the meta-analyses. These models were computed using a modified method of moments.[94] To further assist in interpreting the results of our meta-analyses, we present the results of our fixed effects models in terms of Forrest plots and as a pair of normal curves. Each curves represents the distribution of results in a study's two groups. The difference between the means of these two normal curves represents d, the effect size. We quantified the degree of the non-overlap of these two curves using the $\cup$ statistics described by Cohen[95], and have expressed these results in terms of the overlap between these curves.

Meta-Analysis of Diagnostic Studies

Diagnostic test meta-analyses were done according to the method of Littenberg and Moses.[1] Meta-analyses of diagnostic studies were performed only when there were 10 or more retrieved trials of a given test. We adopted this criterion to ensure that this

evidence report would focus on the tests for which there is the greatest research interest. We have taken the mean threshold as the best estimate of a single threshold, and the values of sensitivity and specificity at the mean threshold as the single best global estimate of test effectiveness.

Before using the results of a meta-analysis, we verified that there was no statistically significant heterogeneity among the results of the included articles. This was accomplished, using the Q statistic, as described by Hasselblad and Hedges.[92] The presence of heterogeneity indicates that something other than threshold is affecting sensitivity and specificity, and that the points on an ROC curve are not derived from the same population of sensitivity/specificity pairs. If heterogeneity was detected, we removed any subgroups that caused the heterogeneity from the analysis. If there were no subgroups in the analysis, or those subgroups did not cause the heterogeneity, we looked for data points that were outliers, and reported the meta-analytic results with and without exclusion of these outliers.

Meta-analysis results of diagnostic tests are reported both in table and graphical form. Tables list each study in the meta-analysis, its 2 x 2 data, and any special steps ECRI had to take in abstracting that data. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) are also reported in those tables, along with confidence intervals on each of these ratios, calculated according to Wilson's method.[96] Finally, the prevalence of WRUED cases in each study is reported. The last row of the results table provides the sensitivity/specificity at mean threshold results of the meta-analysis, along with the sensitivity and specificity of the points representing the 95% confidence interval on the mean threshold point. Summary values for PPV and NPV are not calculated in the meta-analysis because they are dependent on disease prevalence. Meta-analysis results graphs include the summary ROC itself, the confidence interval and the sensitivity/specificity data points for each included article. The diagonal line in each graph represents the performance of a test that worked no better than chance.

Some investigators based their diagnostic thresholds on results obtained in a control population of individuals without the condition, typically setting a threshold at 2.0 or 2.5 standard deviations from the mean test score of the controls. When the actual number of positive and negative results in the control subjects was reported in the article, we used that data in the meta-analysis. In cases where these numbers were not reported, we assumed a normal distribution of test results in the control subjects, and calculated the theoretical number of false positives and true negatives based on the one-tailed normal distribution. If the threshold was two standard deviations from the mean, one expects false positive results in 2.275% of controls; if the threshold was 2.5 standard deviations, then false positives should make up 0.621% of the control group. The appropriate percentage was multiplied by the number of control subjects and rounded to the closest whole number of patients to get counts for the 2 x 2 table. If the number of controls given the study test was not reported, the article was excluded from analysis even though we knew test specificity from the reported threshold. This is because actual counts of false positives and true negatives are needed to obtain confidence intervals on specificity and the predictive values.

Other Computations

We performed numerous other statistical computations in addition to those involved in performing meta-analyses. We describe these calculations and the logic behind them in our considerations of the appropriate questions. Briefly, these calculations included:

1. Corrections for attrition; Following all patients for the duration of a study is difficult, particularly when the study is relatively long term. It is possible that in some studies, poor outcomes among patients lost to followup could overturn the results of a study, including those of a well-designed randomized controlled trial. Therefore, wherever possible, we made conservative assumptions about outcomes in patients who were not accounted for in an effort to determine how robust reported results were. This approach is preferable to one that ignores attrition and to one that discards such studies that exceed an arbitrary attrition level. The former approach could lead to incorrect conclusions and the latter can lead to information loss.

2. Statistical power analyses; Studies that do not contain a sufficient number of patients cannot detect statistically significant differences between groups, even when these differences are clinically meaningful. Therefore, whenever possible, we computed the minimum between-group difference that any given controlled study had the power to detect.

3. Multiple regression; For certain questions, the results of multiple regressions were of interest, but such analyses were not conducted by the authors. We therefore conducted these analyses when t-patient-level data were available.

4. Computations of effect sizes for all studies, when possible, even when no meta-analysis was performed. Results of statistical tests (p-values) do not convey information about the magnitude of an effect. To provide an idea about this magnitude, we computed effect sizes for all controlled studies, wherever such computations were possible.

5. Determinations of whether there were statistically significant differences between the characteristics of patients in any given study. Although studies may report that they were randomized, it is sometimes the case that the randomization protocol was not adequately followed or the study was not truly randomized. These departures from randomization can manifest themselves in pretreatment between-group differences in patient characteristics.

6. Computation of pretreatment effect sizes. Departures from randomization can also manifest themselves as a statistically significant difference in the outcome between groups prior to the administration of treatment. For example, if the pain levels experienced by patients were significantly different before treatment, one might suspect that the study was not truly randomized.

7. Verification of 2 x 2 tables reported in studies of diagnostic tests. Because peer-reviewed published articles often contain errors in reported results, we attempted to verify the calculations in each article. If an error was found, we corrected the data and included it in the analysis. If we could not verify the 2 x 2 table, the article was excluded. These exclusions are documented in the text of this report.

Table 3. Coding of Patient Inclusion Criteria

Code	Definition
WRUED groups	
Symptoms/presented	Patients had unspecified symptoms of the disorder being studied, or were referred for diagnosis of suspected WRUED
Simple signs/symptoms	Patients included if they had specified symptoms of the disorder, but other tests such as nerve conduction tests were not used for patient selection
Simple NCS	Patients included if they had abnormal results in a specific nerve conduction test or tests (no more than three tests in selection algorithm)
Complex objective standard	A specified algorithm with more than three nerve conduction studies or combining specific NCS tests with specific symptoms
Unspecified (diagnosed)	Authors reported that all patients had been diagnosed with the disorder in question, but did not detail how the diagnosis was defined
Other	Details reported in separate database field
Control groups	
Healthy volunteers	Subjects drawn from hospital or community populations, and not being evaluated for other upper extremity disorders
Workers at risk	Asymptomatic individuals considered to be at risk for WRUED
Unrelated disease	Subjects were being evaluated or treated for known abnormalities of the hand or wrist unrelated to WRUEDs
Contralateral arm	Unaffected contralateral extremity of persons with diagnosed WRUED
Other	Details reported in separate database field

Table 4. Coding of Diagnostic Test Groups

Test group	Included tests
Imaging tests	Radiography (film x-ray), computed tomography, MRI, ultrasound
Nerve conduction	Amplitude, latency, and velocity of signal conduction in median and ulnar nerves
Composite nerve conduction	Differences and ratios of nerve conduction test results
Signs and symptoms	Phalen's maneuver, reverse Phalen maneuver, Tinel's sign, Durkin (carpal compression) test, sensory diagrams
Sensory tests	Semmes-Weinstein monofilament test, vibrometry, current perception threshold

Table 5. Coding of Results Reporting Level

Reporting level	Definition
Patient-level	Results for each patient reported individually. This includes studies where patient-level results were reported in a graph rather than a table. Where possible, ECRI research analysts
Counts	Sufficient data to yield a two-by-two truth table relating test results to another condition (usually patient's assignment to disease or control group)
Summary statistics	Mean and standard deviation of results for all patients in the group
Agreement or difference	Statistics reporting agreement or difference between results of one test and another, but not the results themselves
Technical criteria	Accuracy, precision, and reproducibility of the test results, but not the results themselves.

Table 6. Coding of Studies of Special Interest

Characteristic	Definition
Longitudinal data	Study reported repeated measurements on the same subjects, from which information on the progression of the condition can possibly be derived
Early diagnosis	Study reported that it was intended to identify early-stage disease. For purposes of this assessment, we relied on the authors' own definitions of "early diagnosis" and did not try to validate that validate that description.
Screening study	Study included at least one group of subjects that can be considered a screening population (e.g. asymptomatic individuals whose work entails repetitive movements).

Peer Review

To select peer-reviewers for the draft evidence report, ECRI prepared a list of 30 potential reviewers. This list was submitted to AHRQ, which approved all reviewers. Letters inviting these individuals to review were then mailed. Fifteen individuals responded to these letters, 12 individuals agreed to review the draft evidence report, and 9 individuals returned reviews.

Upon receipt of reviews, ECRI revised the draft report accordingly. ECRI also prepared a document describing the disposition of all substantive reviewer comments and supplied this document to AHRQ for review and approval.

Chapter 3. Results

Carpal Tunnel Syndrome

Question #1: What are the most effective methods and approaches for the early identification and diagnosis of carpal tunnel syndrome?

Our response to this question is comprised of a subsection on early diagnosis and a subsection on studies of diagnosis of carpal tunnel syndrome, in general. These two subsections follow our evaluation of the internal validity and generalizability of the available relevant literature. Following these two subsections, is a subsection on screening.

The subsection on early diagnosis is the most direct answer to this question, and in it we examine all articles described by their authors as pertaining to early diagnosis of these conditions. However, there are only a few such articles, and we therefore expand our response to diagnosis in general on the grounds that a "good" diagnostic method may also be a "good" method for making an early diagnosis. Ultimately, though, this reasoning is inferential, and conclusive evidence about whether a "good" diagnostic method is also useful for making an early diagnosis can only be derived by studies that directly address this issue.

The evaluation the diagnostic tests we consider is, as with any such test, greatly complicated by the absence of an independent "gold standard" test for any of the upper extremity disorders we address .[27] With no independent reference standard whose results are definitive, clinical trials of diagnostic tests for these disorders generally report differences in test results between a group of patients believed to have the condition and a group believed not to have it. Because determinations of who has and does not have the disorder are imperfect (for example, persons who do not have CTS may have symptoms of another condition that mimics CTS), it is impossible for such studies to draw accurate conclusions on how well any test performs.

The definitions of the groups being compared in these studies can also affect results by introducing spectrum effects to the study population. Criteria for selecting patients withWRUEDs may result in inclusion of only clear-cut cases of the condition, thus excluding mild cases that would be harder to diagnose. Selection criteria for patients without WRUEDs may result in inclusion of only those in ideal health, excluding those with early-stage cases of an upper extremity disorder. Together, these spectrum effects amplify the differences that are found in these studies. Thus, their results may not be applicable to the population most likely to get a test in routine practice: persons in high risk groups or with questionable symptoms.

A variety of diagnostic modalities have been reported in the carpal tunnel syndrome literature, including clinical signs (Table 7), sensory tests (Table 8), nerve conduction studies (Table 9), and imaging tests (Table 10). Furthermore, within each testing

modality, there are many specific tests and test variations, and there is little consensus about which tests are useful.

Most clinical tests to diagnose CTS (Table 7) involve specific maneuvers that elicit pain, numbness, or tingling in the median-nerve portion of the wrist. For example, in Phalen's test, the patient places both elbows on a horizontal surface with the forearms vertical, and allows the wrists to flex by gravity. If the patient feels numbness or tingling within one minute, the test is positive.[28] In Tinel's test, the examiner taps lightly over the median nerve at the wrist. If the patient feels tingling, the test is considered positive.[29]

Sensory tests for carpal tunnel syndrome (Table 8) typically involve measurement of a patient's threshold for detection of a sensory stimulus. For example, in the Semmes-Weinstein test, the examiner touches the patient with monofilaments, and the test is considered positive if the patient's sensitivity to the monofilaments falls outside normal limits.[30] Another example is the two-point discrimination test in which the examiner touches two closely-spaced prongs to the patient's fingers. The test is considered positive if the patient cannot discriminate the prongs when they are 5 millimeters apart.[31]

Nerve conduction testing for carpal tunnel syndrome can involve several variables (Table 9). Electrodes are placed in two locations along a nerve; the nerve is stimulated from one electrode, and the impulse is recorded from the other electrode. Tests can be performed on either the median nerve, ulnar nerve, or radial nerve, and can assess either motor or sensory function. The placement of electrodes can be either orthodromic (in which stimulating electrodes are placed distal to recording electrodes) or antidromic (in which stimulating electrodes are placed proximal to recording electrodes). Furthermore, many aspects of the nerve impulse can be measured such as latency, amplitude, and velocity.

Some investigators compare two or more nerve conduction tests in an attempt to assist the diagnosis of CTS (e.g., compute a difference between two latencies). We refer to these comparisons as *composite nerve conduction* tests. One potential advantage of composite nerve conduction tests is that they can compare two measurements in the same individual, thereby controlling for the effect of age on single nerve conduction tests.[97]

Imaging tests for carpal tunnel syndrome include radiography (conventional film x-ray), computed tomography (CT) scan, magnetic resonance imaging (MRI), and ultrasound. Using these methods, investigators attempt to measure the size of anatomical features such as the carpal tunnel or the median nerve. Radiologists may also look for qualitative signs of CTS, such as bowing of the flexor retinaculum or a flattened shape of the carpal tunnel.[98] CTS may also manifest itself through changes in the appearance of the image, such as changes MR signal intensity of the median nerve. One cannot generalize that CTS will always be represented by an increase in signal intensity, because the relative contrast of different tissues is a function of the specific MR pulse sequence used.[99] Within a given study, if the same pulse sequence is used, the effect on appearance of normal and abnormal tissue is expected to be consistent.

Many different measurements are possible from a single image. Some of them may be useful in diagnosis of CTS while others are of no use at all. Furthermore, radiologists may take several of these measurements into account when judging an image as positive or negative for CTS. When assessing imaging tests for CTS, one must be specific as to the particular image parameter or combination of parameters being used, and avoid generalization from effectiveness of one imaging measurement to effectiveness of another. Because they were so numerous, we did not tabulate all imaging measurements reported in clinical trial articles, but instead we tabulated the use of each imaging modality (x-ray, CT, MRI, or ultrasound).

Imaging tests, particularly film radiography, may be used to rule out other causes of hand and wrist symptoms, such as fractures or osteoarthritis [100] and thus may have a role in differential diagnosis of CTS, even if they are not themselves tests for CTS.

As noted above, the vast majority of CTS diagnostic trials compared groups of patients with known or suspected disorders and groups of healthy normal controls. Therefore it is worth summarizing the difficulties with such studies:

- Potential spectrum bias because the controls are required to be asymptomatic, and subjects with unrelated upper extremity disorders are excluded. In routine practice, the spectrum of negative cases is likely to include patients with abnormalities that might mimic the condition being tested for, thereby reducing test specificity and positive predictive value.

- Potential spectrum bias when severe or obvious cases are selected for in patient inclusion criteria, and patients with mild disorders are excluded. In routine practice, the spectrum of patients with CTS is likely to include mild cases that may not be detected by the diagnostic test, thereby reducing sensitivity and negative predictive value.

- The converse of the above spectrum bias, where inclusion criteria are designed to study patients with mild disorders. Studies of patients with only mild disease will underestimate test performance.

- Potential age bias arising from selection of young hospital or laboratory workers as controls rather than persons of the same ages as CTS sufferers. Where possible, we recorded mean ages of CTS and control groups in each study, and identified studies in which the mean ages of the groups differed by 5.0 years or more.

Potential sex bias arising from different sex distributions in the patient group and the control group. Where possible, we recorded the sex distributions of CTS and control groups in each study, and identified studies in which the percentage of females differed by 20 percentage points or more.

Table 7. Clinical Signs and Symptoms Used to Diagnose CTS

Test	Definition
Closed fist test[101]	The patient makes a fist. If the patient feels tingling within one minute, the test is positive.
Combined Phalen's and Durkan's test[102]	With the patient's elbow extended, the forearm in supination, and the wrist flexed to 60 degrees, the examiner uses one thumb to apply pressure over the carpal tunnel. If the patient feels tingling or numbness within 30 seconds, the test is positive.
Decreased muscle strength[103]	Maximum force exerted by the patient on a measurement device.
Durkan compression test[104]	This test is also called the carpal compression test. With the patient's wrist in a neutral position and the forearm supinated, the examiner uses his/her thumbs to compress the wrist at the median nerve. If the patient feels numbness or tingling within 30 seconds, the test is positive.
Flick test[105]	The patient is asked: "What do you do with your hands when your symptoms are at their worst?" If the patient shakes or flicks the hands, the test is positive.
Gilliat tourniquet test[106]	The examiner inflates a blood pressure monitor on the patient's arm proximal to the elbow. If the patient feels numbness or tingling within one minute, the test is positive.
Grip strength[107]	Force measured when patient squeezes a measurement device using the whole hand.
Hypesthesia[103]	Also called hypoesthesia. It refers to decreased sensitivity to touch.
Pain on VAS[108]	Pain as measured by a visual analog scale in which the patient rates the subjective degree of pain by placing a mark on a graphical bar.
Paresthesia in APB[109]	Tingling in the abductor pollicus brevis muscle of the hand.
Phalen's test[28]	This test is also called the wrist flexion test. The patient places both elbows on a horizontal surface with the forearms vertical, and allows the wrists to flex by gravity. If the patient feels numbness or tingling within one minute, the test is positive.
Pinch strength[107]	Force measured when patient squeezes a measurement device using the thumb and a finger
Symptoms measured systematically[29]	Any symptoms of carpal tunnel such as pain, tingling, or numbness, as measured by a questionnaire or a hand diagram.
Symptoms during ultrasound[110]	Whether the patient experiences carpal tunnel symptoms when the wrist is stimulated with an ultrasound transducer.
Reverse Phalen's test[111]	This test is also called the wrist extension test. The patient extends both wrists and fingers. If the patient feels numbness or tingling within two minutes, the test is positive.
Thenar atrophy[103]	The degree of wasting in the thenar muscle of the hand.
Thenar weakness[31]	The degree of weakness in the thenar muscle of the hand.
Tinel's test[29]	This test is also called Hoffman-Tinel's test. The examiner taps lightly on the medial aspect of the wrist. If the patient feels tingling, the test is positive.

Sources: Massy-Westrop[112] and ECRI review of clinical trial articles

Table 8. Sensory tests for Diagnosis of CTS

Test	Definition
Current perception[113]	Whether the patient's threshold for perception of electrical current is within normal limits.
Moving two-point discrimination[107]	The examiner touches two closely-spaced prongs to patient's fingers and moves them distally. The test is positive if the patient cannot discriminate the prongs when they are 4-6 millimeters apart.
Object identification[114]	The patient blindly feels wooden shapes and is asked to identify them.
Pinprick sensation[109]	Whether the patient has normal pinprick-induced sensation.
Pressure measurement[115]	Whether the patient's threshold for perception of pressure is within normal limits.
Ridge threshold[116]	The patient places an index finger on a circular disc that has a small ridge. If the patient's threshold for detection of the ridge is abnormal, the test is positive.
Semmes-Weinstein monofilament[30]	This test is also called the von Frey hairs test. The examiner touches the patient with a series of standardized nylon monofilaments, and records the smallest monofilament the patient can detect the presence of.
Static two-point discrimination[31]	The examiner touches two closely-spaced prongs to patient's fingers and holds them still. The test is positive if the patient cannot discriminate the prongs when they are 5 millimeters apart.
Temperature measurement[117]	Whether the patient's threshold for perception of temperature, heat pain or cold pain is within normal limits.
Tuning fork[30]	The examiner hits a metal tuning fork which vibrates, and the patient's threshold for detection of vibration is determined. If the threshold falls outside of normal limits, the test is positive.
Vibrometer[118]	An instrument vibrates at varying frequencies, and the patient's threshold for detection of vibration is determined. If the threshold falls outside of normal limits, the test is positive

Sources: Massy-Westrop[112] and ECRI review of clinical trial articles

Table 9. Definitions of Nerve Conduction Parameters

Test	Definition
Nerves tested	
Median nerve	The central nerve that is believed to be impaired in carpal tunnel syndrome. It innervates the thumb, index, middle, and ring fingers.
Ulnar nerve	The nerve on the medial side of the arm that innervates the ring and little fingers. Some researchers compare median and ulnar nerve conduction tests to diagnose carpal tunnel syndrome.
Radial nerve	The nerve on the lateral side of the arm that innervates the thumb. Some researchers compare median and radial nerve conduction tests to diagnose CTS.
Motor or sensory	Whether the test assesses motor or sensory nerve function.
Orthodromic or antidromic	The relative placement of the stimulating and recording electrodes. If the stimulating electrode is distal to the recording electrode (i.e., the stimulator is further from the torso), the test is orthodromic. Conversely, if the stimulating electrode is proximal to the recording electrode, (i.e., the stimulator is closer to the torso), the test is antidromic. These terms apply to sensory tests but not to motor tests.
Electrode placement sites	
Abductor pollicus brevis muscle (APB)	A muscle in the hand that is used to record median motor parameters.
Abductor digiti minimi (ADM)	A muscle in the hand that is used to record ulnar motor parameters.
Parameters Measured	
Latency	The time in milliseconds (ms) between stimulation and recording of an electrical impulse.
Onset latency	The time in milliseconds (ms) between stimulation and recording of an electrical impulse when measured to the beginning of the action potential.
Peak latency	The time in milliseconds (ms) between stimulation and recording of an electrical impulse when measured to the largest amplitude of the action potential.
Velocity	Speed of nerve conduction in meters per second (m/s)
Amplitude	Size of the action potential in microvolts (uV)
Presence/absence	Whether the nerve action potential was recordable. In severe cases, some action potentials may not be recordable.
Inching test	A series of nerve conduction tests designed to locate specific areas of nerve slowing. It can be performed orthodromically or antidromically. Electrodes are placed in 9-12 locations which are each a small distance (e.g., 1 cm) apart. By stimulating a fixed site (e.g., the middle finger) and recording at several locations (e.g., 9 evenly-spaced locations along the wrist), researchers can measure the nerve latencies and velocities for each segment along the nerve.

Table 10. Imaging Modalities for the Diagnosis of CTS

Test	Definition
Film	Plain film radiograph (x-ray).
CT	Computed tomography scan. No articles reported use of obsolete (first- or second-generation CT scanners).
MRI	Magnetic resonance imaging scan. No articles reported use of obsolete or prototype MR scanners
Ultrasound	Ultrasonic imaging

Evidence Base

Articles were included in this analysis if they reported counts of positive and negative test results for at least one test, and they included ten or more patients. Having sufficient data from each included study to complete the 2 x 2 diagnostic truth table is important, because sensitivity and specificity must be measured simultaneously, using the same diagnostic threshold. Otherwise, the threshold could be shifted to favor the reported statistic at the expense of the unreported one.

Not all of the articles we examined are addressed in this evidence report. However, data from the articles we did not address are provided in the evidence tables in the appendix. We included articles in these evidence tables, regardless of their level of reporting, if their authors described them as screening studies or studies on "early diagnosis" of CTS.

The evidence tables thus list 205 articles that met our *a priori* inclusion criteria. We subsequently excluded 16 of them. Each of these excluded articles is listed in Table 11 along with its reason for exclusion. Some articles were excluded for more than one reason, but only the first reason is listed in the table. Therefore, this table cannot be used to determine what percentage of the literature suffered a specific flaw. The reasons for exclusion of each study in the table were each confirmed by a second analyst. In case of disagreement, the study was not excluded.

After these exclusions, 189 articles remained for analysis, with a total of 38,087 participants in these studies. The majority of studies (110 or 58%) were conducted outside the United States, and almost all of the studies (184 or 97%) were done at a single center.

In order to be included in meta-analyses of diagnostic trial results, articles had to report sufficient data to permit calculation of sensitivity and specificity for the test in question. In other words, counts of positive and negative test results had to be reported, percentages had to be reported with sufficient data on numbers of patients and controls for us to recalculate the 2 x 2 table, or results for each individual patient had to be reported. Patient-level data were reported in 19 of the 189 articles, and counts for at least some patient groups were reported in 131. Only summary statistics (typically group means) were reported in 39 articles. Even though sensitivity and specificity were not reported in

these articles, they were included in the analysis because they met other criteria, such as reporting "early diagnosis" of CTS or an intent to evaluate diagnostic tests in a screening population. In 129 of the articles (68%), it was possible to determine sensitivity and specificity for at least one test from the reported data; in 79 of the articles, the authors themselves reported sensitivity and specificity.

Table 11. Excluded Studies

Author	Reason for Exclusion
Ikegaya[119]	Special patient population (dialysis)
Tackmann[120]	No diagnostic data
Jordan[121]	Reported only statistical significance of results
Sivri[122]	Special patient population (arthritis), only 2 cases of CTS
Stolp-Smith[123]	Special patient population (pregnant women), only 5 cases of CTS
Dlabalová[124]	All patients post-surgery for CTS
Lazaro[125]	All patients post-surgery for CTS
Nakamichi[126]	All patients post-surgery for CTS
Williams[127]	Discrepancies in reported results; 2 x 2 table could not be accurately reproduced by ECRI.
Mossman[128]	Published as letter rather than full paper; 2 x 2 table could not be accurately reproduced by ECRI.
Westerman[129]	Discrepancies in reported number of patients, unexplained exclusions of patients.
Herrick[130]	Combined results from CTS patients and patients with other conditions.
MacDermid[131]	Combined results from CTS patients and patients with other conditions.
Gerrning[132]	Combined results from CTS patients and patients with other conditions.
Byl[133]	Combined results from CTS patients and patients with other conditions.
Palmer[134]	Combined results from CTS patients and patients with other conditions.

Internal Validity of Results

To evaluate the quality of this literature base, we determined what proportion of articles reported various details of study methods or results. Reporting of these details is necessary to verify the internal validity and generalizability of study results. Reporting of characteristics affecting the internal validity of the results (the degree to which the reported results reflect the true performance of the test in the conditions of the particular study) is summarized in Table 12; this table includes all 189 articles on CTS diagnosis that were abstracted into the database. Details of the studies eventually included in quantitative analyses are listed in Table 13.

The design of most studies raised the possibility of age bias in which patients were markedly older than controls. Some nerve conduction measurements become slower as people age,[97] thus if patients are older than controls, the study will overestimate the

effectiveness of some nerve conduction tests. For this analysis, we defined age bias as a difference of five years or more between the mean age of patients and the mean age of controls. If a study reported ages of more than one group of carpal tunnel patients or more than one group of controls, we used the ages that implied the least amount of age bias in the study. This conservative approach tends to underestimate the amount of age bias in the studies.

Of 189 carpal tunnel studies we examined, 35 did not include a separate control group and 65 failed to report mean or median ages for one or both groups. That left 89 studies for which we could determine whether there was an age bias. Of these 89 studies, 52 had no age bias according to our definition. In 36 studies, patients were five years or more older than controls, while in one study[135], controls were five years or more older than patients. In only 12 articles were all patient groups within one year of the controls in mean age. This suggests that there is little use of age-matching to ensure that age bias does not affect results, even though it is known that results of some diagnostic tests are affected by age.

Figure 7 plots each study using the mean age of controls on the horizontal axis and the mean age of patients on the vertical axis. The solid diagonal line represents the points at which patients and controls had the same age. The dashed diagonal lines represent the points at which patients and controls were five years apart. The plot shows that patients tended to be older than controls. Whereas patients were older than controls in 76 studies, the reverse was true in only 11 studies (in the remaining two studies, the group means were the same).

A similar analysis was done for possible sex bias. We arbitrarily defined potential sex bias as a difference of 20 or more percentage points in the proportions of females in the patient group and in the control group. As with the age bias analysis, when a study had more than one carpal tunnel group or more than one control group, we used a conservative approach by selecting groups that minimized potential sex bias. This approach will underestimate the amount of potential sex bias.

Of 189 carpal tunnel diagnostic studies recorded in the database, 35 did not contain a separate control group, and 65 did not report the sex distribution for one or both of the CTS and control groups. There were 89 studies for which we could determine whether there was a sex bias. Note that these were not the same 89 studies for which we could determine age bias; 21 studies reported age but not sex, and 21 studies reported sex but not age.

Of these 89 studies, 65 did not meet our definition of possible sex bias. In 21 studies, the percentage of females in the CTS group was 20 or more percentage points higher than the control group. In 3 studies, the percentage of females in the CTS group was 20 or more percentage points lower than in the control group.

Figure 8 plots the sex distribution of each study, using the percentage of females in the control group on the horizontal axis and the percentage of females in patient group on the

vertical axis. The plot shows that the percentage of females tended to be higher in patient groups than in control groups. The percentage of females in the patient group was greater than the percentage of females in the control group in 63 of the 89 studies. The reverse was true in only 13 studies. There were 13 studies in which the percentages were equal.

We defined studies as sex-matched if the proportion of women in each patient groups differed two percentage points or less from the proportion of women in the control group. Using this definition, 20 of the 89 studies (22%) could be called sex-matched. To the extent that sex affects the diagnostic tests for CTS, there is a potential for sex bias in the results. Despite this possible bias, few studies controlled for differing proportions of men and women in their CTS and control groups. These differences, and age differences in patient and control group, are components of the evaluation of diagnostic clinical trial results.

Other study and patient characteristics that potentially affect diagnostic results are just as poorly reported in the clinical trial articles on CTS diagnosis. Patient inclusion criteria were reported in nearly all studies (98%), but exclusion criteria were reported in less than half (48%, Table 12). Lack of reporting does not necessarily mean that studies are free of selection bias. Patients' comorbidities were reported in only 24% of articles even though some may affect test results. Methods for evaluating the diagnostic tests were also rarely reported.

Blinding of test operators and readers to whether a subject was in the CTS or control group was reported in 7-12% of articles, and only 2 of the 29 articles included in our analyses (7%, Table 12). Blinding protects against the potential for intentional or unintentional bias in performing and interpreting the test. Groups of workers in the same hospital or university as the investigators were often used as a convenient source of asymptomatic control subjects. Without blinding, the persons evaluating those subjects would know that familiar persons from around the institution are likely to be controls who do not have CTS, and could consciously or unconsciously bias their findings toward the negative. While some studies may have used blinding without reporting it, one cannot assume that this is so.

Use of multiple readers was not widely reported, and where there were multiple readers reported, only 4 of 7 articles reported how they arrived at conclusions. This could affect the internal validity of the conclusions in studies where multiple readers interpreted each test and then met with each other to resolve their differences in interpretation. This practice can reduce interobserver variability and thus may overestimate the true performance of tests which normally are interpreted by just one person.

Generalizability

Reporting statistics on characteristics pertaining to the generalizability of each article's results on them are found in Table 14. Details of the studies in the quantitative analyses are reported in Table 15. Some of these characteristics, like age and sex, can affect both internal validity and generalizability. Even if a study is free of age bias (the ages of the

control subjects are similar to the ages of the CTS patients), it is possible that the results may not be generalizable because the ages of the patients in a clinical trial of a test are different from the ages of patients encountered in routine use of the test.

In this literature, reporting of patient comorbidities was particularly bad. Only 46 of the articles (24%) reported any comorbidities at all. Duration of patients' conditions was reported in only 18 studies (10%) even though this variable is an indicator of condition severity.

Ninety-eight CTS diagnostic articles (52%) reported patient selection criteria that had the potential to bias studies towards including more easy cases (e.g. including only cases of severe CTS) or more difficult cases to diagnose (e.g. including only cases where other diagnostic tests were equivocal). These criteria represent potential for bias but not conclusive proof of bias, thus we did not exclude such studies. Instead, we used potential selection bias in our analyses of homogeneity, by separately analyzing the homogeneity of studies with and without these potential biases. Generalizability of study results is also affected by the possible spectrum bias arising from study designs where patients with known CTS are compared to healthy volunteers, and the absence of a "gold standard" test for diagnosis of CTS.

Incomplete reporting of important study design and patient characteristics prevents one from ruling out selection biases and other confounding factors as the cause of clinical trial results. The quality of this evidence base is not sufficient to permit us to draw reliable conclusions from a single study. Meta-analysis and heterogeneity analysis can be used to try and identify the effects of these study variables on study results.

Table 12. Summary of Study Characteristics Affecting Internal Validity

Study characteristic	Number of studies reporting (percentage)	Specifics (percentage)
Whether trial was funded by a for-profit institution	24 (13%)	For-profit funding: 3 (2%) No for-profit funding: 21 (11%)
Was selection of patients prospective or retrospective?	75 (40%)	Prospective: 58 (28%) Retrospective: 17 (9%)
Patient inclusion criteria	185 (98%)	See **Table 46**
Patient exclusion criteria	87 (46%)	See **Table 46**
Was sex distribution of patients reported?	131 (69%)	[a]Percentage female: 61.5%
Was the percentage of females in the patient group within 20 percentage points of the control group?	89 (47%)	Yes: 65 (34%) No, patients were = 20% more female: 21 (11%) No, controls were =20% more female: 3 (2%)
Were patient ages reported?	123 (65%)	[a]Mean age 48.1 years
Was the mean patient age within 5 years of the mean control age?	89 (47%)	Yes: 52 (28%) No, patients were = 5 years older: 36 (19%) No, controls were =5 years older: 1 (1%)
Was duration of patients' condition reported?	18 (10%)	[a, b]Mean duration 28.1 months
Were patient comorbidities reported?	46 (24%)	NA
Was the test operator blinded?	13 (7%)	Yes: 13 (7%)
Was the test reader blinded?	23 (12%)	Yes: 23 (12%)
Were there multiple test readers?	7 (4%)	2 readers: 4 (2%) 3 readers: 2 (1%) 4 readers: 1 (1%)
What was the method for multiple test readers?	4 (57% of studies reporting multiple readers)	Independent: 2 (1%) Mean: 1 (1%) Consensus: 1 (1%)
Was the test compared to an independent reference standard?	38 (20%)	Yes: 38 (20%)
Were all patients given the test and the reference standard?	28 (15%)	Yes: 28 (15%)

Key:
NA—not applicable
[a]Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)
[b]Studies reporting median duration [109,136,137] were excluded from calculation.

Table 13. Study Characteristics Affecting Internal Validity of Results

Article	Funded by for-profit institution?	Inclusion criteria reported?	Exclusion criteria reported	Method of diagnosis reported	Patient selection	Comorbidity reported	[a]Percent female	Possible sex bias	[a]Mean age	Possible age bias	[a]Mean duration of condition	Test operator blinded	Test reader blinded	Multiple readers	Method for multiple readers	Independent reference standard	Were patients given both test and reference
Distal Motor Latency: Unspecified Diagnosi s Patient Group																	
Rosén, 1993 [138]	NR	Yes	Yes	Yes	NR	NR	75%	P	41	No	NR	NR	NR	NR	NR	No	No
Marin, 1983 [139]	NR	Yes	NR	NR	NR	NR	86%	P	49	P	13	NR	NR	NR	NR	No	No
Kimura, 1979 [140]	NR	Yes	Yes	Yes	NR	NR	75%	No	48	No	NR	NR	NR	NR	NR	No	No
Loong, 1972 [141]	NR	Yes	NR	NR	NR	NR	100%	No	43.7	MNR	12.7	NR	NR	NR	NR	No	No
Plaja, 1971 [142]	NR	NR	Yes	NR	Retrospective	NR	NR	GNR	NR	MNR	NR	NR	NR	NR	NR	No	No
Distal Motor Latency: Symptoms/Presented Patient Groups																	
Murthy, 1999 [143]	NR	Yes	NR	Yes	NR	NR	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	No	No
Atroshi, 1996 [136]	No	Yes	NR	NR	Prospective	Yes	69%	No	52	P	24	NR	NR	NR	NR	No	No
Kuntzer, 1994 [144]	NR	Yes	Yes	NR	Prospective	NR	80%	P	51	P	NR	NR	NR	NR	NR	No	No
Chang, 1991 [145]	NR	Yes	Yes	NR	NR	Yes	79%	GNR	42.3	No	NR	NR	NR	NR	NR	No	No
Cioni, 1989 [146]	NR	Yes	Yes	NR	NR	NR	16%	C	46.4	P	NR	NR	NR	NR	NR	No	No
Messina, 1980 [120]	NR	Yes	NR	NR	NR	NR	NR	GNR	45.1	No	NR	NR	NR	NR	NR	No	No
Melvin, 1972 [147]	NR	Yes	NR	NR	NR	NR	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	No	No
Loong, 1971 [148]	NR	Yes	Yes	NR	NR	Yes	100%	No	NR	ANR	7.6	NR	NR	NR	NR	No	No
Palmar Sensory Latency: Symptoms/Presented Patient Groups																	
Murthy, 1999 [143]	NR	Yes	NR	Yes	NR	NR	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	No	No
Girlanda, 1998 [149]	NR	Yes	Yes	NR	NR	Yes	93%	GNR	39	ANR	48	NR	NR	NR	NR	No	No
Chang, 1991 [145]	NR	Yes	Yes	NR	NR	Yes	79%	GNR	42.3	No	NR	NR	NR	NR	NR	No	No
Jackson, 1989 [150]	No	Yes	Yes	NR	NR	Yes	82%	No	52.6	P	NR	NR	NR	NR	NR	No	No
Escobar, 1985 [151]	NR	Yes	Yes	NR	NR	Yes	70%	No	NR	ANR	NR	NR	NR	NR	NR	No	No

Article	Funded by for-profit institution?	Inclusion criteria reported?	Exclusion criteria reported	Method of diagnosis reported	Patient selection	Comorbidity reported	[a]Percent female	Possible sex bias	[a]Mean age	Possible age bias	[a]Mean duration of condition	Test operator blinded	Test reader blinded	Multiple readers	Method for multiple readers	Independent reference standard	Were patients given both test and reference
Phalen's Maneuver: All Patient Groups																	
Szabo, 1999 [152]	No	Yes	NR	Yes	Prospective	NR	76%	No	NR	ANR	NR	NR	Yes	NR	NR	No	No
Fertl, 1998 [153]	NR	Yes	Yes	Yes	Prospective	NR	83%	P	55.5	P	NR	Yes	Yes	NR	NR	No	No
Gerr, 1998 [31]	NR	Yes	Yes	Yes	NR	NR	72%	No	46.6	P	NR	NR	NR	NR	NR	Yes	No
Ghavanini, 1998 [154]	NR	Yes	Yes	Yes	Prospective	NR	81%	No	40	No	15	NR	NR	NR	NR	No	No
Tetro, 1998 [102]	No	Yes	Yes	Yes	Prospective	NR	64%	No	49.3	No	NR	NR	NR	NR	NR	No	No
González del Pino, 1997 [104]	NR	Yes	NR	Yes	Prospective	NR	81%	No	50	No	37.9	NR	NR	3	NR	Yes	Yes
De Smet, 1995 [101]	NR	Yes	NR	Yes	NR	NR	88%	C	49.2	C	NR	NR	NR	NR	NR	No	No
Werner, 1994 [111]	NR	Yes	NR	Yes	NR	NR	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	No	No
Durkan, 1991 [155]	No	Yes	NR	Yes	NR	NR	NR	GNR	45	ANR	NR	NR	NR	NR	NR	Yes	Yes
Gellman, 1986 [106]	No	Yes	NR	Yes	NR	Yes	74%	GNR	NR	ANR	NR	NR	NR	NR	NR	Yes	Yes
Tinel's Sign: All Patient Groups																	
Szabo, 1999 [152]	No	Yes	NR	Yes	Prospective	NR	76%	No	NR	ANR	NR	NR	Yes	NR	NR	No	No
Gerr, 1998 [31]	NR	Yes	Yes	Yes	NR	NR	72%	No	46.6	P	NR	NR	NR	NR	NR	Yes	No
Ghavanini, 1998 [154]	NR	Yes	Yes	Yes	Prospective	NR	81%	No	40	No	15	NR	NR	NR	NR	No	No
Tetro, 1998 [102]	No	Yes	Yes	Yes	Prospective	NR	64%	No	49.3	No	NR	NR	NR	NR	NR	No	No
González del Pino, 1997 [104]	NR	Yes	NR	Yes	Prospective	NR	81%	No	50	No	37.9	NR	NR	3	NR	Yes	Yes
De Smet, 1995 [101]	NR	Yes	NR	Yes	NR	NR	88%	C	49.2	C	NR	NR	NR	NR	NR	No	No
Durkan, 1991 [155]	No	Yes	NR	Yes	NR	NR	74%	GNR	45	ANR	NR	NR	NR	NR	NR	Yes	Yes
Seror, 1987 [156]	NR	Yes	Yes	Yes	NR	NR	79%	No	56.8	No	NR	NR	NR	NR	NR	No	No
Gellman, 1986 [106]	No	Yes	NR	Yes	NR	Yes	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	Yes	Yes
Gelmers, 1979 [29]	NR	Yes	Yes	Yes	NR	NR	81%	No	57	No	NR	NR	NR	NR	NR	Yes	No
Stewart, 1978 [157]	NR	Yes	Yes	Yes	NR	Yes	81%	No	55	No	NR	NR	NR	NR	NR	Yes	No

Key:

[a]Percent female, mean age, and mean duration of condition for CTS patients

Possible sex bias: No—proportion women in epicondylitis group within 20% of proportion of women in control group; P—Patients were more likely to be female; C—Controls were more likely to be female; GNR—Genders not reported for both groups; NC—Study did not contain a separate control group

Possible age bias: No—mean age of epicondylitis group within 5 years of mean age of control group; P—Patients were older than controls; C—Controls were older than patients; ANR—Ages not reported for both groups; NC—Study did not contain a separate control group

Method for multiple test readers: Indep—Independent

Figure 7. Mean Ages of Patient and Control Groups in CTS Diagnostic Studies

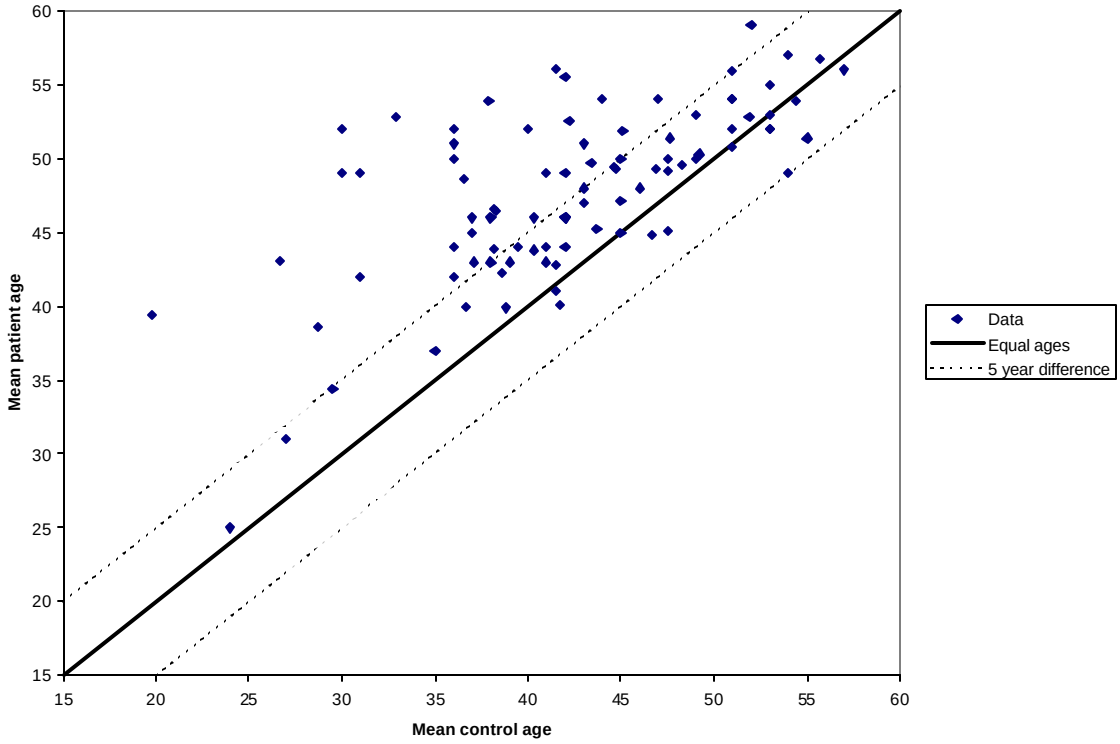


Figure 8. Sex Ratios of Patient and Control Groups in CTS Diagnostic Studies

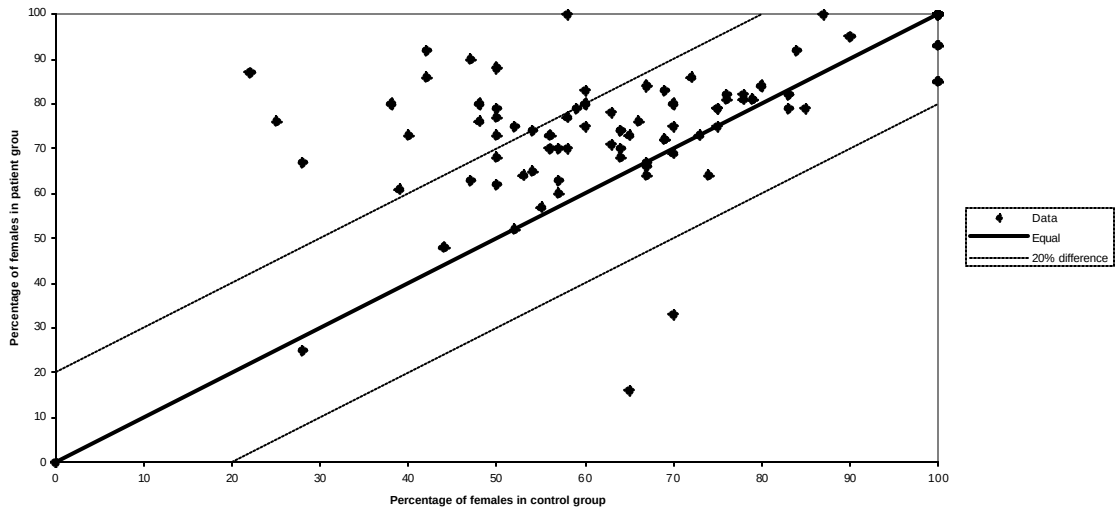


Table 14. Summary of Study Characteristics Affecting Generalizability

Study characteristic	Number of studies reporting (percentage)	Specifics (percentage)
Years in which study was conducted	39 (21%)	NA
Number of centers	189 (100%)	Single: 184 (97%) Multiple (<5): 4 (2%) Multiple (>5): 1 (1%)
Country in which study was conducted	189 (100%)	USA: 79 (42%) Other: 110 (58%)
Patient inclusion criteria	185 (98%)	See **Table 46**
Patient exclusion criteria	87 (46%)	See **Table 46**
Were patient comorbidities reported?	46 (24%)	NA
Was sex distribution of patients reported?	131 (69%)	[a]Percentage female: 61.5%
Were patient ages reported?	123 (65%)	[a]Mean age 48.1 years
Was duration of patients' condition reported?	18 (10%)	[a, b]Mean duration 28.1 months
Did all patients have previous conservative treatment?	1 (1%)	Yes: 1 (1%)
Did any patients have previous surgical treatment?	6 (3%)	Yes: 6 (3%)
Adequate reporting of study's source of patients	29 (15%)	NA
Was there a potential selection bias for easy cases?	58 (31%)	Yes: 58 (31%)
Was there a potential selection bias for hard cases?	40 (21%)	Yes: 40 (21%)

Key:
NA—not applicable
[a]Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)
[b]Studies reporting median duration [109,136,137] excluded from calculation

Table 15. Study Characteristics Affecting Generalizability of Results

Article	Years in which trial was conducted	Number of centers	Country where trial was conducted	Are patient comorbidity reported?	Percent female	Mean age	Mean duration of condition	Did all patients have previous conservative	Did any patients have previous surgical	Source of patients adequately described and generalizable to broader clinical practice?	Potential selection bias for easy cases?	Potential selection bias for difficult cases?
Distal Motor Latency: Unspecified Diagnosis Patient Group												
Rosén, 1993 [138]	1986-1987	Single	Sweden	No	75%	41	NR	No	No	Yes	No	No
Marin, 1983 [139]	NR	Single	USA	No	86%	49	13	No	No	No	Yes	No
Kimura, 1979 [140]	1978	Single	USA	No	75%	48	NR	No	No	No	No	Yes
Loong, 1972 [141]	NR	Single	Singapore	No	100%	43.7	12.7	No	No	No	No	No
Plaja, 1971 [142]	NR	Single	Spain	No	NR	NR	NR	No	No	No	Yes	No
Distal Motor Latency: Symptoms/Presented Patient Groups												
Murthy, 1999 [143]	NR	Single	India	No	NR	NR	NR	No	No	No	Yes	No
Atroshi, 1996 [136]	NR	Single	Sweden	Yes	69%	52	24	Yes	No	No	Yes	No
Kuntzer, 1994 [144]	NR	Single	Switzerland	No	80%	51	NR	No	No	Yes	No	No
Chang, 1991 [145]	NR	Single	Taiwan	Yes	79%	42.3	NR	No	No	No	No	No
Cioni, 1989 [146]	NR	Single	Italy	No	16%	46.4	NR	No	No	No	No	No
Messina, 1980 [120]	NR	Single	Italy	No	NR	45.1	NR	No	No	No	No	No
Melvin, 1972 [147]	NR	Single	USA	No	NR	NR	NR	No	No	No	No	No
Loong, 1971 [148]	NR	Single	Singapore	Yes	100%	NR	7.6	No	No	No	No	No
Palmar Sensory Latency: Symptoms/Presented Patient Groups												
Murthy, 1999 [143]	NR	Single	India	No	NR	NR	NR	No	No	No	Yes	No
Girlanda, 1998 [149]	NR	Single	Italy	Yes	93%	39	48	No	No	No	No	Yes
Chang, 1991 [145]	NR	Single	Taiwan	Yes	79%	42.3	NR	No	No	No	No	No
Jackson, 1989 [150]	NR	Single	Canada	Yes	82%	52.6	NR	No	No	No	No	No
Escobar, 1985 [151]	NR	Single	USA	Yes	70%	NR	NR	No	No	No	No	No

Article	Years in which trial was conducted	Number of centers	Country where trial was conducted	Are patient comorbidity reported?	Percent female	Mean age	Mean duration of condition	Did all patients have previous conservative	Did any patients have previous surgical	Source of patients adequately described and generalizable to broader clinical	Potential selection bias for easy cases?	Potential selection bias for difficult cases?
Phalen's Maneuver: All Patient Groups												
Szabo, 1999 [152]	1993-1996	Single	USA	No	76%	NR	NR	No	No	No	No	No
Fertl, 1998 [153]	1997	Single	Austria	No	83%	55.5	NR	No	No	Yes	No	No
Gerr, 1998 [31]	NR	Single	USA	No	72%	46.6	NR	No	No	No	No	No
Ghavanini, 1998 [154]	NR	Single	Iran	No	81%	40	15	No	No	No	No	No
Tetro, 1998 [102]	1995-1997	Single	USA	No	64%	49.3	NR	No	No	Yes	No	No
González del Pino, 1997 [104]	1992-1995	Single	Spain	No	81%	50	37.9	No	No	No	Yes	No
De Smet, 1995 [101]	NR	Single	Belgium	No	88%	49.2	NR	No	No	No	No	No
Werner, 1994 [111]	NR	Single	USA	No	NR	NR	NR	No	No	No	No	No
Durkan, 1991 [155]	1987-1990	Single	USA	No	NR	45	NR	No	No	No	No	No
Gellman, 1986 [106]	1982-1984	Single	USA	Yes	74%	NR	NR	No	No	No	Yes	No
Tinel's Sign: All Patient Groups												
Szabo, 1999 [152]	1993-1996	Single	USA	No	76%	NR	NR	No	No	No	No	No
Gerr, 1998 [31]	NR	Single	USA	No	72%	46.6	NR	No	No	No	No	No
Ghavanini, 1998 [154]	NR	Single	Iran	No	81%	40	15	No	No	No	No	No
Tetro, 1998 [102]	1995-1997	Single	USA	No	64%	49.3	NR	No	No	Yes	No	No
González del Pino, 1997 [104]	1992-1995	Single	Spain	No	81%	50	37.9	No	No	No	Yes	No
De Smet, 1995 [101]	NR	Single	Belgium	No	88%	49.2	NR	No	No	No	No	No
Durkan, 1991 [155]	1987-1990	Single	USA	No	74%	45	NR	No	No	No	No	No
Seror, 1987 [156]	NR	Single	France	No	79%	56.8	NR	No	No	No	No	No
Gellman, 1986 [106]	1982-1984	Single	USA	Yes	NR	NR	NR	No	No	No	Yes	No
Gelmers, 1979 [29]	NR	Single	Netherlands	No	81%	57	NR	No	No	No	Yes	No
Stewart, 1978 [157]	NR	Single	Canada	Yes	81%	55	NR	No	No	No	Yes	No

Key:
NR—not reported

Studies of "Early Diagnosis"

Because there is no broad agreement among clinicians of what constitutes and "early" diagnosis of CTS, we accepted any studies so described by their authors as studies of early identification of the condition.

Eighteen studies proposed tests specifically for the early detection of CTS. Table 16 shows the patient selection criteria used in these studies and the authors' proposed methods for early detection. Eleven of the 18 studies (61%) selected patients who had mild CTS as defined by positive symptoms and normal results on commonly-performed nerve conduction tests. None of these eleven studies, however, agreed on the specific kinds of nerve conduction tests and appropriate thresholds.

Thirteen of the 18 studies (72%) proposed sensory nerve conduction test(s) for the early diagnosis of carpal tunnel syndrome. As with the selection criteria, however, there was little agreement regarding test specifics. Two studies by Seror[158,159] each proposed the orthodromic sensory inching test for the early detection of CTS. Two studies by Uncini[160,161] each proposed the difference between median and ulnar orthodromic sensory latencies from the ring finger for the early detection of CTS. None of the other nine studies of sensory nerve conduction proposed the same specific tests or combination of tests. Therefore, studies of the early detection of CTS utilize the same general categories of nerve conduction tests, but there is wide variability in the specific tests employed. Furthermore, there are insufficient studies of any specific test to permit meta-analysis for drawing conclusions on whether it is effective for early identification of CTS. For this reason, we proceed to examine diagnostic tests for carpal tunnel syndrome, in general.

Table 16. Articles Self-Described as "Early Diagnosis" of CTS

Article	Patient selection criteria relevant to early detection	Symptoms and normal NCS?	Authors' proposed method for early detection	Sensory NCS?
Seror, 2000 [158]	Symptoms, but normal needle examination, normal DML (<4 ms) and normal palm-to-wrist orthodromic SCV (>45 m/s).	☑	Orthodromic sensory inching test from the middle finger.	☑
Girlanda, 1998 [149]	Symptoms, but no weakness, no muscle atrophy, and normal DML (<4 ms).	☑	Combination of nerve conduction tests:a) Difference between median and ulnar orthodromic SCV from ring finger to wrist, and b) Ratio of orthodromic SCV from middle finger to palm and orthodromic SCV from palm to wrist	☑
Seror, 1998 [159]	Symptoms, but normal DML (<4 ms) and normal palm-to-wrist orthodromic SCV (>45 m/s).	☑	Orthodromic sensory inching test from the middle finger.	☑
Terzis, 1998 [162]	Symptoms, but normal DML (<4.2 ms)	☑	Combination of orthodromic sensory nerve conduction tests from the ring finger.	☑
Bronson, 1997 [163]	Symptoms, but normal DML (<4 ms) and normal needle examination.	☑	Comparison of DMLs using five different wrist positions.	?
Murata, 1996 [164]	Workers at risk	?	Ratio of:a) Antidromic SCV from wrist to index finger, and b) Antidromic SCV from palm to index finger	☑
Padua, 1996 [165]	Symptoms, but no signs of severe CTS (e.g., absent SNAP at the wrist).	☑	Ratio of:a) Orthodromic SCV from middle finger to palm, and b) Orthodromic SCV from palm to wrist	☑
Young, 1995 [166]	Workers at risk	?	Total score on a grading scale that included seven clinical signs, four symptoms, and DML≥4.45 ms.	?
Johnson, 1993 [167]	Workers at risk	?	Track changes in DML over time	?
Uncini, 1993 [160]	Symptoms, but normal DML (<4.2 ms) and normal SCV from index finger to wrist (>45 m/s)	☑	Difference between: a) Median orthodromic latency between ring finger and wrist, and b) Ulnar orthodromic latency between ring finger and wrist	☑
Jetzer, 1991 [168]	Workers at risk	?	Vibrometry	?
Luchetti, 1991 [169]	Symptoms, but normal motor function, sensory function, quantitative sensory examination, cutaneous trophism, DSL (NR), and DML (NR).	☑	Antidromic inching test to the middle finger	☑

Article	Patient selection criteria relevant to early detection	Symptoms and normal NCS?	Authors' proposed method for early detection	Sensory NCS?
Charles, 1990 [170]	Clinical diagnosis of CTS by referring physician, and at least one of the following: a) DML ≥4.5 ms; b) Orthodromic SCV from index finger <45 m/s; c) Difference ≥0.5 ms between median and ulnar sensory antidromic latencies to the ring finger	?	Difference between: a) Median antidromic latency between ring finger and wrist, and b) Ulnar antidromic latency between ring finger and wrist	☑
Palliyath, 1990 [171]	Symptoms, but "very little electrophysiological changes on routine tests for CTS" (p 307).	☑	Duration of relative refractory period and absolute refractory period.	?
Cioni, 1989 [146]	Symptoms	?	Orthodromic SCV from ring finger to wrist	☑
Jackson, 1989 [150]	Symptoms. Patients were stratified into three groups, and one group represented mild CTS as defined by normal NCS (based on four tests) and normal needle examination.	☑	Combination of two nerve conduction tests: a) Difference between median and radial antidromic sensory latencies from wrist to thumb, and b) Difference between median and ulnar antidromic sensory latencies from wrist to ring finger	☑
Uncini, 1989 [161]	Symptoms, but normal DML (≤4.2 ms) and SNAPs were present with normal amplitude.	☑	Difference between:a) Median orthodromic latency between ring finger and wrist, and b) Ulnar orthodromic latency between ring finger and wrist	☑
Wongsam, 1983 [172]	Symptoms suggesting early CTS.	?	Ratio of:a) Antidromic latency from wrist to middle fingerb) Antidromic latency from palm to middle finger	☑

Key:
DML—Distal motor latency
DSL—Distal sensory latency
ms—Milliseconds
m/s—Meters per second
SCV—Sensory conduction velocity
SNAP—Sensory nerve action potential
NR—Not reported

"Diagnosis Studies"

Our evaluation of methods for diagnosing CTS is primarily meta-analytic. To identify diagnostic tests of CTS for which meta-analyses were appropriate, we performed several tabulations. These tabulations were restricted to studies that met each of the following three criteria: 1) Study included a carpal tunnel syndrome group; 2) Study included a normal group; 3) Study was not a screening study. There were 138 studies that met all of these criteria.

For each test, we determined the number of studies in each of four patient selection categories that reported the test. Within each of these four categories, we also determined the number of studies for which sensitivity and specificity could be derived (based on information provided in the article). These study counts appear in Table 17 through

Table 21. The first number in each cell is the count of all studies in a category, and the second number in each cell is the subset of studies from which we could derive sensitivity and specificity. We coded a study as having derivable sensitivity/specificity if *any* of the tests in that study had derivable sensitivity and specificity. Because this was not necessarily true for all tests in a study, the table's counts for some tests may slightly overestimate the numbers of studies with derivable sensitivity and specificity.

As an initial criterion for conducting meta-analyses, we required that a minimum of 10 studies that reported a specific test in a specific population had derivable sensitivity and specificity. In other words, the second number in the table cell was required to be 10 or more. We adopted this criterion to ensure that our analysis would focus on the diagnostic tests that are the subject of greatest research interest. When there was a minimum of 10 articles, we proceeded with a meta-analysis even if one or more articles were subsequently excluded because it did not report sensitivity and specificity for the particular test being analyzed (or for other reasons discussed below).

Three combinations of test and patient population (see shaded cells in Table 19) met the a priori analysis criterion of at least 10 articles reporting the test and reporting results in sufficient detail that sensitivity and specificity could be calculated. The table entries on level of reporting are based on the highest level for any test reported in the article, and all tests reported were not necessarily reported at the highest level. This was especially true for studies reporting distal motor latency. It may be the case that some investigators reported only summary data for distal motor latency because it was considered a more of a routine test than other reported tests.

Table 17. Numbers of Studies Reporting Signs/Symptoms Tests Across Patient Selection Categories

Legend:
First entry in cell—Total number of articles

Second entry in cell—Number of articles with derivable sensitivity and specificity

Sign/symptom	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
Closed fist test	0, 0	1, 1	1, 1	0, 0
Combined Phalen's/Durkan test	1, 1	0, 0	0, 0	0, 0
Decreased muscle strength	0, 0	0, 0	1, 1	0, 0
Durkan compression	5, 5	1, 1	3, 3	1, 1
Flick sign	0, 0	0, 0	0, 0	1, 1
Gilliat tourniquet	1, 1	1, 1	1, 1	1, 1
Grip strength	0, 0	0, 0	0, 0	1, 0
Hypesthesia	0, 0	0, 0	1, 1	0, 0
Pain on VAS	0, 0	0, 0	1, 1	1, 1
Paresthesia in APB	0, 0	0, 0	0, 0	1, 1
Phalen's/reverse Phalen's	7, 7	2, 1	6, 6	3, 3
Pinch strength	0, 0	0, 0	0, 0	1, 0
Symptoms measured systematically	3, 3	0, 0	2, 2	1, 0
Symptoms during ultrasound	0, 0	0, 0	1, 1	0, 0
Thenar atrophy	0, 0	0, 0	2, 2	0, 0
Thenar weakness	0, 0	0, 0	1, 1	0, 0
Tinel's	9, 9	2, 1	3, 3	2, 2

Table 18. Numbers of Studies Reporting Sensory Tests Across Patient Selection Categories

Legend:

First entry in cell—Total number of articles

Second entry in cell—Number of articles with derivable sensitivity and specificity

Sensory test	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
Object identification	0, 0	0, 0	0, 0	1, 0
Pinprick sensation	0, 0	0, 0	0, 0	1, 1
Pressure measurement	0, 0	0, 0	1, 1	1, 0
Ridge threshold	0, 0	0, 0	0, 0	1, 0
Semmes-Weinstein filament	1, 1	0, 0	0, 0	4, 1
Temperature measurement	0, 0	0, 0	1, 1	2, 1
Texture discrimination	0, 0	0, 0	0, 0	1, 0
Tuning fork	1, 1	0, 0	1, 1	0, 0
Two-point discrimination (moving or static)	2, 2	0, 0	2, 2	1, 0
Vibrometer	2, 2	0, 0	5, 5	1, 0

Table 19. Numbers of Studies Reporting Nerve Conduction Tests Across Patient Selection Categories

Legend:

Nerve tested: MED–median, RAD–radial, ULN–ulnar
MOT–motor, SEN–Sensory
Configuration (not applicable to motor nerve tests): OR–orthodromic, AN–antidromic
Stimulation electrode placement: ELB–elbow, FOR–forearm, WR–wrist, PAL–palm, TH–thumb, IN–index finger, MI–middle finger, RI–ring finger, LI–little finger, APB–abductor policis brevis, ADM–abductor digiti minimi, OTH–other
Recording electrode placement (see D for abbreviations)
Measured parameter: LAT–latency, PRE–presence/absence of signal, AMP–amplitude, VEL–velocity, INCH–inching, OTH–other
Blank cells—Not reported or not applicable

First entry in cell—Total number of articles

Second entry in cell—Number of articles with derivable sensitivity and specificity

Shaded cells—Ten or more articles reporting sensitivity and specificity.

Nerve Conduction Test						Patient selection type			
Nerve Tested	Nerve Tested	Configuration	Stimulation	Recording	Parameter	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
	MOT				LAT	1, 1	0, 0	0, 0	1, 1
	MOT		WR	OTH	LAT	0, 0	0, 0	0, 0	1, 1
	SEN				LAT	1, 1	0, 0	0, 0	1, 1
	SEN	OR	TH	WR	PRE	0, 0	0, 0	1, 1	0, 0
MED					OTH	0, 0	0, 0	2, 2	0, 0
MED	MOT					0, 0	0, 0	0, 0	1, 0
MED	MOT				AMP	0, 0	1, 0	0, 0	0, 0
MED	MOT				LAT	2, 1	1, 0	2, 2	2, 1
MED	MOT				OTH	1, 1	1, 0	2, 1	0, 0
MED	MOT				VEL	0, 0	1, 0	1, 1	1, 0
MED	MOT			APB	AMP	1, 1	0, 0	0, 0	0, 0
MED	MOT			APB	LAT	1, 1	0, 0	0, 0	0, 0
MED	MOT		ELB	APB	AMP	1, 0	0, 0	1, 1	1, 1
MED	MOT		ELB	APB	LAT	1, 1	0, 0	0, 0	1, 1
MED	MOT		ELB	APB	OTH	1, 1	0, 0	1, 1	0, 0
MED	MOT		ELB	APB	VEL	1, 0	0, 0	1, 1	2, 2
MED	MOT		ELB	IN	AMP	0, 0	0, 0	0, 0	1, 1
MED	MOT		ELB	IN	LAT	0, 0	0, 0	0, 0	1, 1
MED	MOT		ELB	IN	VEL	0, 0	0, 0	0, 0	1, 1
MED	MOT		ELB	WR	AMP	1, 0	0, 0	0, 0	0, 0
MED	MOT		ELB	WR	LAT	0, 0	0, 0	0, 0	0, 0
MED	MOT		ELB	WR	VEL	2, 1	0, 0	3, 3	1, 1
MED	MOT		FOR		VEL	1, 1	0, 0	0, 0	1, 1
MED	MOT		FOR	APB	AMP	1, 1	0, 0	0, 0	0, 0

Nerve Conduction Test						Patient selection type			
Nerve Tested	Nerve Tested	Configuration	Stimulation	Recording	Parameter	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
MED	MOT		FOR	APB	LAT	1, 1	0, 0	0, 0	0, 0
MED	MOT		FOR	APB	VEL	0, 0	0, 0	1, 1	0, 0
MED	MOT		FOR	PAL	AMP	1, 1	0, 0	0, 0	0, 0
MED	MOT		FOR	PAL	LAT	1, 1	0, 0	0, 0	0, 0
MED	MOT		FOR	WR	VEL	0, 0	0, 0	0, 0	1, 1
MED	MOT		PAL	APB	AMP	1, 1	0, 0	1, 0	2, 1
MED	MOT		PAL	APB	LAT	0, 0	0, 0	0, 0	2, 1
MED	MOT		PAL	IN	AMP	0, 0	0, 0	0, 0	1, 1
MED	MOT		PAL	IN	LAT	0, 0	0, 0	0, 0	1, 1
MED	MOT		PAL	IN	VEL	0, 0	0, 0	0, 0	1, 1
MED	MOT		WR		AMP	0, 0	0, 0	1, 1	0, 0
MED	MOT		WR		LAT	2, 2	1, 0	1, 1	0, 0
MED	MOT		WR		PRE	1, 1	0, 0	0, 0	0, 0
MED	MOT		WR		VEL	1, 1	0, 0	0, 0	0, 0
MED	MOT		WR	APB	AMP	2, 1	0, 0	9, 7	9, 6
MED	MOT		WR	APB	LAT	4, 4	3, 2	21, 17	24, 21
MED	MOT		WR	APB	OTH	2, 1	1, 0	1, 1	2, 2
MED	MOT		WR	APB	PRE	0, 0	0, 0	3, 3	1, 1
MED	MOT		WR	APB	VEL	0, 0	0, 0	2, 1	5, 5
MED	MOT		WR	IN	AMP	0, 0	0, 0	0, 0	1, 1
MED	MOT		WR	IN	LAT	0, 0	0, 0	0, 0	1, 1
MED	MOT		WR	IN	VEL	0, 0	0, 0	0, 0	1, 1
MED	MOT		WR	OTH	AMP	1, 0	0, 0	1, 1	1, 1
MED	MOT		WR	OTH	LAT	1, 1	1, 1	8, 8	3, 3
MED	MOT		WR	OTH	OTH	0, 0	0, 0	0, 0	1, 1
MED	MOT		WR	OTH	VEL	1, 0	0, 0	1, 1	0, 0
MED	MOT		WR	PAL	AMP	0, 0	0, 0	1, 1	0, 0
MED	MOT		WR	PAL	LAT	0, 0	0, 0	1, 1	0, 0
MED	MOT		WR	PAL	OTH	0, 0	0, 0	0, 0	1, 1
MED	MOT		WR	PAL	VEL	0, 0	0, 0	1, 0	0, 0
MED	MOT		WR	TH	LAT	0, 0	0, 0	2, 0	0, 0
MED	MOT		WR	TH	VEL	0, 0	0, 0	1, 1	0, 0
MED	SEN					0, 0	0, 0	0, 0	1, 0
MED	SEN				LAT	3, 2	0, 0	0, 0	1, 0
MED	SEN				OTH	0, 0	0, 0	1, 0	1, 0
MED	SEN				VEL	0, 0	1, 0	0, 0	0, 0
MED	SEN		WR		AMP	1, 1	0, 0	0, 0	0, 0
MED	SEN		WR		LAT	1, 1	0, 0	0, 0	0, 0
MED	SEN	AN			AMP	0, 0	0, 0	0, 0	1, 1
MED	SEN	AN			LAT	1, 1	0, 0	1, 1	1, 1
MED	SEN	AN			VEL	1, 1	0, 0	1, 1	0, 0
MED	SEN	AN	ELB	IN	AMP	0, 0	0, 0	1, 1	0, 0
MED	SEN	AN	ELB	IN	OTH	0, 0	0, 0	1, 1	0, 0

Nerve Conduction Test						Patient selection type			
Nerve Tested	Nerve Tested	Configuration	Stimulation	Recording	Parameter	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
MED	SEN	AN	ELB	MI	VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	AN	ELB	PAL	INCH	0, 0	0, 0	0, 0	1, 1
MED	SEN	AN	ELB	WR	VEL	0, 0	0, 0	2, 2	1, 1
MED	SEN	AN	FOR	IN	LAT	0, 0	0, 0	1, 0	0, 0
MED	SEN	AN	FOR	RI	LAT	0, 0	0, 0	1, 0	0, 0
MED	SEN	AN	FOR	TH	LAT	0, 0	0, 0	1, 0	0, 0
MED	SEN	AN	PAL	IN	AMP	1, 1	0, 0	2, 1	0, 0
MED	SEN	AN	PAL	IN	LAT	0, 0	0, 0	1, 1	0, 0
MED	SEN	AN	PAL	IN	PRE	1, 1	0, 0	0, 0	0, 0
MED	SEN	AN	PAL	IN	VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	AN	PAL	MI		0, 0	0, 0	1, 0	0, 0
MED	SEN	AN	PAL	MI	AMP	0, 0	0, 0	2, 1	0, 0
MED	SEN	AN	PAL	MI	LAT	0, 0	0, 0	2, 1	0, 0
MED	SEN	AN	PAL	MI	OTH	0, 0	0, 0	1, 1	0, 0
MED	SEN	AN	PAL	MI	VEL	0, 0	0, 0	1, 1	2, 2
MED	SEN	AN	WR		LAT	0, 0	0, 0	1, 1	0, 0
MED	SEN	AN	WR	IN	AMP	3, 2	0, 0	6, 5	5, 4
MED	SEN	AN	WR	IN	LAT	1, 1	0, 0	11, 9	5, 3
MED	SEN	AN	WR	IN	OTH	2, 1	0, 0	2, 2	0, 0
MED	SEN	AN	WR	IN	PRE	1, 1	0, 0	2, 2	2, 2
MED	SEN	AN	WR	IN	VEL	0, 0	0, 0	3, 2	0, 0
MED	SEN	AN	WR	MI	AMP	0, 0	0, 0	4, 3	0, 0
MED	SEN	AN	WR	MI	INCH	1, 1	0, 0	1, 1	0, 0
MED	SEN	AN	WR	MI	LAT	0, 0	0, 0	2, 1	0, 0
MED	SEN	AN	WR	MI	PRE	0, 0	0, 0	1, 1	0, 0
MED	SEN	AN	WR	MI	VEL	0, 0	0, 0	3, 3	1, 1
MED	SEN	AN	WR	OTH	VEL	0, 0	0, 0	1, 1	0, 0
MED	SEN	AN	WR	PAL	AMP	0, 0	0, 0	1, 0	0, 0
MED	SEN	AN	WR	PAL	LAT	0, 0	1, 0	1, 1	0, 0
MED	SEN	AN	WR	PAL	VEL	0, 0	0, 0	3, 2	2, 2
MED	SEN	AN	WR	RI	AMP	0, 0	0, 0	1, 0	0, 0
MED	SEN	AN	WR	RI	LAT	0, 0	0, 0	3, 2	3, 2
MED	SEN	AN	WR	RI	VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	AN	WR	TH	AMP	1, 1	0, 0	2, 1	0, 0
MED	SEN	AN	WR	TH	LAT	1, 1	0, 0	3, 2	0, 0
MED	SEN	AN	WR	TH	VEL	0, 0	0, 0	1, 1	1, 1
MED	SEN	OR			AMP	0, 0	1, 0	0, 0	0, 0
MED	SEN	OR			LAT	0, 0	1, 0	0, 0	0, 0
MED	SEN	OR		WR	AMP	0, 0	0, 0	2, 2	0, 0
MED	SEN	OR		WR	LAT	0, 0	0, 0	1, 1	2, 2
MED	SEN	OR		WR	VEL	0, 0	0, 0	2, 2	0, 0
MED	SEN	OR	IN		AMP	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	IN		LAT	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	IN		OTH	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	IN		VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	IN	PAL	VEL	0, 0	0, 0	0, 0	1, 1

Nerve Conduction Test						Patient selection type			
Nerve Tested	Nerve Tested	Configuration	Stimulation	Recording	Parameter	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
MED	SEN	OR	IN	WR	AMP	4, 3	0, 0	7, 5	2, 2
MED	SEN	OR	IN	WR	LAT	1, 1	0, 0	8, 7	3, 3
MED	SEN	OR	IN	WR	OTH	2, 2	0, 0	2, 1	1, 1
MED	SEN	OR	IN	WR	PRE	1, 1	0, 0	4, 4	0, 0
MED	SEN	OR	IN	WR	VEL	4, 3	1, 1	8, 7	3, 3
MED	SEN	OR	MI		AMP	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	MI		LAT	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	MI		OTH	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	MI		VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	MI	MI	AMP	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	MI	MI	VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	MI	PAL	AMP	1, 0	0, 0	0, 0	0, 0
MED	SEN	OR	MI	PAL	VEL	1, 0	0, 0	2, 2	0, 0
MED	SEN	OR	MI	WR	AMP	2, 1	0, 0	3, 3	4, 4
MED	SEN	OR	MI	WR	INCH	1, 1	0, 0	0, 0	2, 2
MED	SEN	OR	MI	WR	LAT	0, 0	0, 0	4, 3	0, 0
MED	SEN	OR	MI	WR	OTH	1, 1	0, 0	1, 1	0, 0
MED	SEN	OR	MI	WR	PRE	1, 1	0, 0	2, 2	1, 1
MED	SEN	OR	MI	WR	VEL	3, 2	0, 0	5, 5	5, 5
MED	SEN	OR	OTH		VEL	1, 1	0, 0	0, 0	0, 0
MED	SEN	OR	OTH	WR	AMP	0, 0	0, 0	1, 1	0, 0
MED	SEN	OR	OTH	WR	LAT	0, 0	0, 0	2, 2	0, 0
MED	SEN	OR	OTH	WR	VEL	0, 0	0, 0	2, 2	1, 1
MED	SEN	OR	PAL	WR	AMP	0, 0	0, 0	2, 2	1, 1
MED	SEN	OR	PAL	WR	LAT	1, 1	1, 1	11, 11	1, 1
MED	SEN	OR	PAL	WR	OTH	0, 0	0, 0	1, 1	0, 0
MED	SEN	OR	PAL	WR	PRE	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	PAL	WR	VEL	0, 0	0, 0	7, 7	7, 6
MED	SEN	OR	RI		AMP	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	RI		LAT	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	RI		OTH	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	RI		VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	RI	WR	AMP	3, 2	0, 0	3, 2	1, 1
MED	SEN	OR	RI	WR	LAT	1, 1	1, 1	4, 3	1, 1
MED	SEN	OR	RI	WR	OTH	1, 1	0, 0	1, 1	0, 0
MED	SEN	OR	RI	WR	PRE	1, 1	0, 0	1, 1	2, 2
MED	SEN	OR	RI	WR	VEL	2, 1	0, 0	3, 3	2, 2
MED	SEN	OR	TH		AMP	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	TH		LAT	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	TH		OTH	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	TH		VEL	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	TH	ELB	PRE	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	TH	MI	VEL	0, 0	0, 0	0, 0	0, 0
MED	SEN	OR	TH	PAL	VEL	0, 0	0, 0	0, 0	0, 0
MED	SEN	OR	TH	WR	AMP	1, 1	0, 0	3, 3	2, 2
MED	SEN	OR	TH	WR	LAT	0, 0	0, 0	3, 3	0, 0
MED	SEN	OR	TH	WR	OTH	1, 1	0, 0	1, 1	0, 0

Nerve Conduction Test						Patient selection type			
Nerve Tested	Nerve Tested	Configuration	Stimulation	Recording	Parameter	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
MED	SEN	OR	TH	WR	PRE	1, 1	0, 0	1, 1	1, 1
MED	SEN	OR	TH	WR	VEL	1, 1	0, 0	5, 5	2, 2
MED	SEN	OR	WR	ELB	AMP	2, 1	0, 0	0, 0	1, 1
MED	SEN	OR	WR	ELB	OTH	1, 1	0, 0	0, 0	0, 0
MED	SEN	OR	WR	ELB	PRE	0, 0	0, 0	0, 0	1, 1
MED	SEN	OR	WR	ELB	VEL	2, 1	0, 0	0, 0	1, 1
MED	Transcarpal				AMP	0, 0	0, 0	0, 0	1, 1
MED	Transcarpal				LAT	0, 0	0, 0	0, 0	1, 1
RAD	SEN	AN	FOR	TH	LAT	0, 0	0, 0	1, 0	0, 0
RAD	SEN	AN	WR	TH	AMP	1, 1	0, 0	0, 0	0, 0
RAD	SEN	AN	WR	TH	LAT	1, 1	0, 0	2, 2	2, 0
RAD	SEN	AN	WR	TH	VEL	0, 0	0, 0	0, 0	1, 1
RAD	SEN	OR	TH	WR	AMP	1, 0	0, 0	1, 1	0, 0
RAD	SEN	OR	TH	WR	LAT	0, 0	0, 0	1, 1	0, 0
RAD	SEN	OR	TH	WR	PRE	0, 0	0, 0	1, 1	0, 0
RAD	SEN	OR	TH	WR	VEL	1, 0	0, 0	2, 2	1, 1
ULN	MOT				LAT	0, 0	0, 0	0, 0	1, 1
ULN	MOT				OTH	1, 1	0, 0	1, 0	0, 0
ULN	MOT		ELB	ADM	LAT	1, 1	0, 0	0, 0	0, 0
ULN	MOT		ELB	ADM	OTH	1, 1	0, 0	0, 0	0, 0
ULN	MOT		ELB	OTH	AMP	0, 0	0, 0	0, 0	1, 1
ULN	MOT		ELB	OTH	PRE	0, 0	0, 0	0, 0	1, 1
ULN	MOT		ELB	OTH	VEL	0, 0	0, 0	0, 0	1, 1
ULN	MOT		ELB	WR	VEL	1, 1	0, 0	1, 1	1, 1
ULN	MOT		WR		LAT	1, 1	0, 0	1, 1	0, 0
ULN	MOT		WR		VEL	1, 1	0, 0	0, 0	0, 0
ULN	MOT		WR	ADM	AMP	0, 0	0, 0	1, 0	2, 1
ULN	MOT		WR	ADM	LAT	2, 2	1, 1	4, 2	5, 4
ULN	MOT		WR	ADM	OTH	1, 1	0, 0	0, 0	0, 0
ULN	MOT		WR	ADM	VEL	0, 0	0, 0	1, 0	0, 0
ULN	MOT		WR	APB	LAT	1, 1	0, 0	0, 0	0, 0
ULN	MOT		WR	OTH	AMP	0, 0	0, 0	1, 1	0, 0
ULN	MOT		WR	OTH	LAT	0, 0	1, 1	3, 3	4, 3
ULN	MOT		WR	OTH	PRE	0, 0	0, 0	1, 1	0, 0
ULN	MOT		WR	PAL	AMP	0, 0	0, 0	1, 1	0, 0
ULN	MOT		WR	PAL	LAT	0, 0	0, 0	1, 1	0, 0
ULN	SEN				OTH	0, 0	0, 0	1, 0	0, 0
ULN	SEN		WR		AMP	1, 1	0, 0	0, 0	0, 0
ULN	SEN		WR		LAT	1, 1	0, 0	0, 0	0, 0
ULN	SEN	AN	FOR	LI	LAT	0, 0	0, 0	1, 0	0, 0
ULN	SEN	AN	FOR	RI	LAT	0, 0	0, 0	1, 0	0, 0
ULN	SEN	AN	PAL	LI	LAT	0, 0	0, 0	1, 1	0, 0
ULN	SEN	AN	WR	LI	AMP	0, 0	0, 0	2, 2	1, 1
ULN	SEN	AN	WR	LI	LAT	0, 0	0, 0	2, 2	1, 1
ULN	SEN	AN	WR	LI	VEL	0, 0	0, 0	3, 3	0, 0
ULN	SEN	AN	WR	PAL	LAT	0, 0	0, 0	1, 1	0, 0
ULN	SEN	AN	WR	RI	LAT	0, 0	0, 0	2, 2	4, 2

Nerve Conduction Test						Patient selection type			
Nerve Tested	Nerve Tested	Configuration	Stimulation	Recording	Parameter	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis
ULN	SEN	AN	WR	RI	VEL	0, 0	0, 0	0, 0	1, 1
ULN	SEN	OR	LI	WR	AMP	2, 1	0, 0	4, 3	3, 3
ULN	SEN	OR	LI	WR	LAT	1, 1	0, 0	3, 2	1, 1
ULN	SEN	OR	LI	WR	OTH	1, 1	0, 0	1, 0	0, 0
ULN	SEN	OR	LI	WR	PRE	0, 0	0, 0	1, 1	0, 0
ULN	SEN	OR	LI	WR	VEL	2, 1	0, 0	3, 2	3, 3
ULN	SEN	OR	OTH		VEL	1, 1	0, 0	0, 0	0, 0
ULN	SEN	OR	OTH	WR	VEL	0, 0	0, 0	0, 0	1, 1
ULN	SEN	OR	PAL	WR	AMP	0, 0	0, 0	1, 1	0, 0
ULN	SEN	OR	PAL	WR	LAT	0, 0	1, 1	6, 6	0, 0
ULN	SEN	OR	PAL	WR	VEL	0, 0	0, 0	2, 2	1, 1
ULN	SEN	OR	RI	WR	AMP	2, 1	0, 0	2, 1	2, 2
ULN	SEN	OR	RI	WR	LAT	1, 1	1, 1	3, 2	1, 1
ULN	SEN	OR	RI	WR	PRE	0, 0	0, 0	1, 1	1, 1
ULN	SEN	OR	RI	WR	VEL	2, 1	0, 0	2, 2	3, 3
ULN	SEN	OR	WR	ELB	AMP	1, 1	0, 0	0, 0	0, 0
ULN	SEN	OR	WR	ELB	OTH	1, 1	0, 0	0, 0	0, 0
ULN	SEN	OR	WR	ELB	VEL	1, 1	0, 0	0, 0	0, 0

Table 20. Numbers of Studies Reporting Composite Nerve Conduction Tests Across Patient Selection Categories

Legend:

Blank cells—Not reported or not applicable

First entry in cell—Total number of articles

Second entry in cell—Number of articles with derivable sensitivity and specificity

Composite test type					Patient selection group			
Nerve for test 1	**Nerve for test 2**	**Motor or sensory**	**Unit of nerve test**	**Type composite**	**Complex objective standard**	**Simple nerve conduction**	**Symptoms/ presented**	**Unspecified diagnosis**
Median	Median	Motor	Amplitude	Difference	0, 0	0, 0	0, 0	1, 0
Median	Median	Motor	Amplitude	Ratio	1, 1	0, 0	1, 0	0, 0
Median	Median	Motor	Latency	Difference	0, 0	0, 0	2, 2	2, 2
Median	Median	Motor	Latency	Ratio	0, 0	0, 0	0, 0	1, 1
Median	Median	Motor	Velocity	Difference	1, 0	0, 0	0, 0	0, 0
Median	Median	Sensory	Amplitude	Difference	1, 1	0, 0	2, 2	0, 0
Median	Median	Sensory	Amplitude	Ratio	1, 1	0, 0	1, 0	1, 1
Median	Median	Sensory	Latency	Difference	1, 1	0, 0	6, 5	1, 1
Median	Median	Sensory	Latency	Ratio	0, 0	0, 0	0, 0	1, 1
Median	Median	Sensory	Velocity	Difference	0, 0	0, 0	2, 2	1, 1
Median	Median	Sensory	Velocity	Ratio	0, 0	0, 0	4, 4	2, 2
Median	Radial	Sensory	Latency	Difference	1, 1	0, 0	3, 3	2, 0
Median	Radial	Sensory	Velocity	Difference	0, 0	0, 0	0, 0	1, 1
Median	Radial	Sensory	Velocity	Ratio	0, 0	0, 0	1, 1	0, 0
Median	Ulnar	Motor	Latency	Difference	1, 1	2, 2	3, 3	5, 4
Median	Ulnar	Motor	Other	Difference	1, 1	0, 0	0, 0	0, 0
Median	Ulnar	Sensory	Amplitude	Ratio	0, 0	0, 0	2, 2	1, 1
Median	Ulnar	Sensory	Latency	Difference	1, 1	1, 1	10, 9	5, 3
Median	Ulnar	Sensory	Velocity	Difference	0, 0	0, 0	1, 1	1, 1
Median	Ulnar	Sensory	Velocity	Ratio	0, 0	0, 0	1, 1	0, 0
Radial	Median	Sensory	Velocity	Ratio	0, 0	0, 0	1, 1	0, 0
Radial	Radial	Sensory	Latency	Difference	0, 0	0, 0	1, 0	0, 0
Ulnar	Median	Sensory	Velocity	Difference	1, 0	0, 0	0, 0	0, 0
Ulnar	Median	Sensory	Velocity	Ratio	0, 0	0, 0	1, 1	0, 0
				Other Difference	3, 1	0, 0	3, 3	1, 1
				Other Ratio	0, 0	0, 0	3, 2	1, 1
				Other Composite	5, 4	0, 0	9, 8	4, 2

Table 21. Numbers of Articles Reporting Imaging Tests in Patient Selection Categories

Legend:

First entry in cell—Total number of articles

Second entry in cell—Number of articles with derivable sensitivity and specificity

Imaging test	Complex objective standard	Simple nerve conduction	Symptoms/presented	Unspecified diagnosis
CT	0, 0	0, 0	0, 0	2, 0
MRI	2, 0	2, 0	1, 1	5, 2
Ultrasound	1, 0	1, 0	1, 0	3, 3

Summary ROC Meta-Analysis of Diagnostic Test Results

Ideally, a meta-analysis of a test includes only studies that use the same definition of what is to be diagnosed. However, the absence of a gold standard for defining carpal tunnel syndrome resulted in there being as many different definitions of the condition (and therefore of positive cases) as there were studies. Therefore, we could only combine study results by permitting different authors to use different definitions of CTS. Testing for heterogeneity of results helps reduce, but does not eliminate the possibility that different definitions affected study results.

Distal Motor Latency: Patients with Unspecified Diagnosis of CTS v. Normal Controls

While there were 21 studies of distal motor latency (DML) in patient groups coded as "Unspecified diagnosis" that reported some 2 x 2 tables, only five of those studies ultimately could be included in a meta-analysis. Reasons for the exclusion of the others are shown in Table 22. Seven studies did not report any sensitivity or specificity results for the DML measurements, even though they reported them for other tests. Four studies reported sensitivity but not specificity, while one reported specificity but not sensitivity. These studies were excluded because data from both groups are necessary to ensure the validity of the results and because the summary ROC method requires both sensitivity and specificity for each study. The study by Bronson et al.[163] was excluded because DML results were reported for only some of the patients. So et al.[173] combined direct measurement of DML with abnormalities in the difference between median and ulnar latency when reporting their results, and we could not isolate results for DML. Charles et al.[170] was excluded because authors reported use of a mean + 2 SD threshold for defining abnormal latency, but the actual threshold reported (4.5 msec) did not agree with their reported results for their control subjects (mean + 2 SD = 4.0 msec). Since the number of controls with latency = 4.5 msec was not reported, we could not derive an internally-consistent 2 x 2 table from the article, and had to exclude it from analysis. Resende et al.[174] reported patient-level data, but did not report a threshold fordistinguishing normal

from abnormal latency. Because there is no agreement on a standard threshold for DML (and there was no way to objectively choose a threshold), we excluded this study.

Two of the five studies included in the meta-analysis[140,175] did not report counts of normal and abnormal results in the control subjects, but because their thresholds were based on two standard deviations from the mean, we estimated the number of false-positive results by multiplying the number of patients in the control group by the probability that a result would be two or more standard deviations above the mean (0.02275 based on the normal distribution). We also recalculated the results from the study by Rosén[176], which reported a histogram of latency results and did not report a 2 x 2 table for their specified threshold. In the other included articles, there were no discrepancies between the sensitivity and specificity figures reported by the authors and the figures calculated by ECRI and used in the meta-analysis.

Results of each included trial and of the meta-analysis are shown in Table 23 and Figure 9. No statistically significant heterogeneity was found in the results ($Q = 0.33$, $p = 0.99$). The results clustered in a small portion of the graph, suggesting there was good agreement among clinicians in how this test is used and how effective it is. The sensitivity and specificity at mean threshold, our best estimate of the effectiveness of the test, was 57.1% sensitivity, 97.9% specificity.

The section of the summary ROC curve above sensitivity = 70% is an extrapolation from the actual data. It represents thresholds that are much lower than the thresholds used in the published trials and as such, may not represent an accurate description of clinical events.

Table 22. Distal Motor Latency Studies Excluded from Meta-Analysis

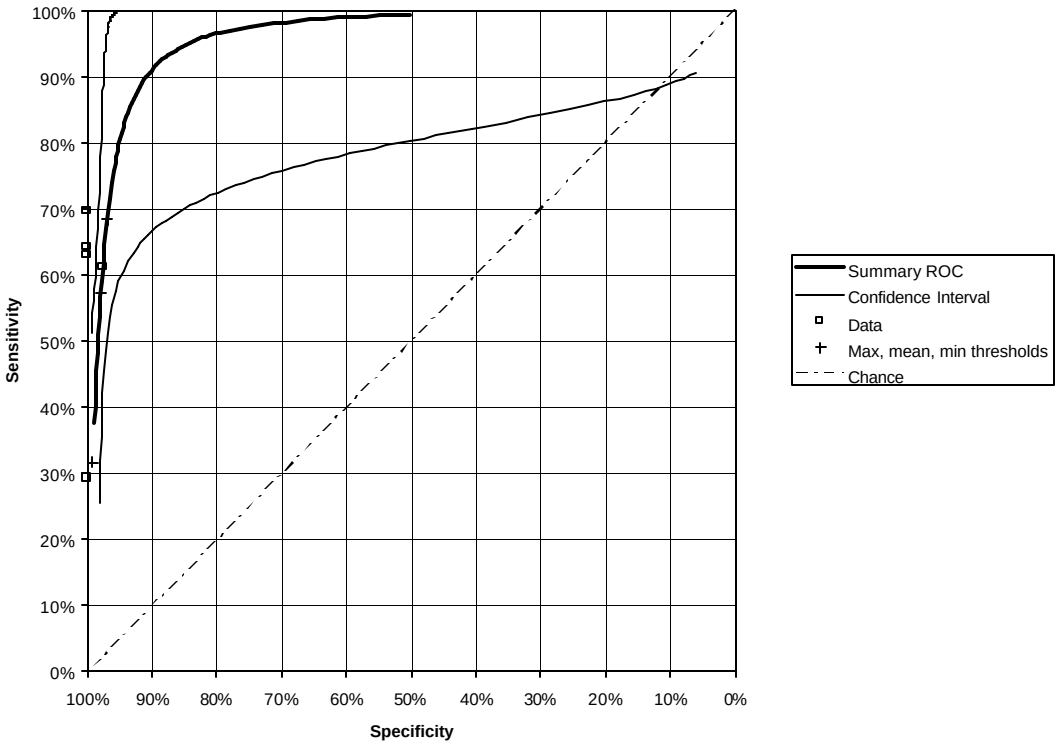
Study	Reason for Exclusion
Pease, 1990 [177]	Did not report sensitivity and specificity for distal motor latency test
Seror, 1998 [159]	Did not report sensitivity and specificity for distal motor latency test
Rossi, 1994 [178]	Did not report sensitivity and specificity for distal motor latency test
Seror, 1995 [179]	Did not report sensitivity and specificity for distal motor latency test
Lang, 1995 [109]	Did not report sensitivity and specificity for distal motor latency test
Tzeng, 1990 [180]	Did not report sensitivity and specificity for distal motor latency test
Mondelli, 2001 [181]	Did not report sensitivity and specificity for distal motor latency test
Simovic, 1997 [182]	Did not report distal motor latency results for control subjects
Simovic, 1999 [183]	Did not report distal motor latency results for control subjects
Resende, 2000 [184]	Did not report distal motor latency results for control subjects
Lauritzen, 1991 [185]	Did not report distal motor latency results for control subjects
Loscher, 2000 [175]	Did not report distal motor latency results for CTS patients
Bronson, 1997 [163]	Selective reporting of distal motor latency results
So, 1989 [173]	Reported combination test of distal motor latency and other nerve conduction measurements
Charles, 1990 [170]	Discrepancy in reported threshold
Resende, 2000 [174]	No diagnostic threshold reported

Table 23. Meta-analysis of Distal Motor Latency Results in Trials With Non-specific Diagnosis of Carpal Tunnel Syndrome Groups

Study	TP	FN	FP	TN	Sen. 95% CI	Spec. 95% CI	PPV 95% CI	NPV 95% CI	Prev.
[a]Kimura[140]	105	67	3	119	61.0% 53.4% 68.2%	97.5% 92.9% 99.2%	97.2% 92.0% 99.1%	64.0% 56.7% 70.7%	58.5%
Marin[139]	9	5	0	12	64.3% 38.3% 83.9%	100% 75.0% 100%	100% 69.2% 100%	70.6% 46.4% 86.9%	53.8%
Loong[141]	17	10	0	30	63.0% 43.9% 78.7%	100% 88.2% 100%	100% 81.0% 100%	75.0% 59.5% 86.0%	47.4%
Plaja[142]	16	7	0	20	69.6% 48.7% 84.6%	100% 83.3% 100%	100% 80.0% 100%	74.1% 54.9% 87.0%	53.5%
[b]Rosén[138]	12	29	0	50	29.3% 17.4% 44.8%	100% 92.6% 100%	100% 75.0% 100%	63.3% 52.0% 73.3%	45.1%
Meta-analysis results (mean threshold)					**57.1%** 49.1% 64.8%	**97.9%** 97.1% 98.5%			

Key:
TP–true positive, FN–false negative, FP–false positive, TN–true negative
Sen.–sensitivity, Spec–specificity, PPV–positive predictive value, NPV–negative predictive value, Prev.–prevalence of CTS
Confidence intervals on sensitivity, specificity, PPV, NPV calculated by Wilson method[96]
[a]Counts for control group (false positive, true negative) estimated by ECRI from threshold reported by authors (mean + 2 SD)
[b]Results calculated by ECRI from published histogram

Figure 9. Meta-analysis of Distal Motor Latency Results in Trials With Non-specific Diagnosis of Carpal Tunnel Syndrome Groups



Distal Motor Latency: Patients with Symptoms of CTS v. Normal Controls

Seventeen studies met the initial criteria for inclusion in a meta-analysis of DML for distinguishing patients with symptoms of CTS from healthy volunteer controls. As with the meta-analysis on patients with unspecified diagnosis of CTS, there were several articles that did not include sufficient data to permit inclusion in the meta-analysis (Table 24). Four articles were excluded because they did not report the number of CTS patients with normal and abnormal DML, and two articles were excluded because they did not report the corresponding data for control subjects. Two articles were excluded due to selection bias: DML was one of their patient selection criteria. Another article was excluded because of discrepancies in the reported results; ECRI could not verify or recalculate the 2 x 2 table.

Eight articles remained after those exclusions (see Table 25). Significant heterogeneity in their results was found by the Q statistic ($Q = 16.7$, $p = 0.019$), with one obvious outlier (Atroshi et al.[136], standardized residual = –3.68). Excluding that study left the remaining results homogeneous ($Q = 3.15$, $p = 0.79$). The meta-analysis was completed both with and without the outlier included, and there was no substantial effect on the results. With the outlier excluded (Figure 10), the sensitivity/specificity at mean threshold was 66.0%/98.3%. Including the outlier changed the results by less than a percentage point: the sensitivity/specificity at mean threshold was 65.0%/97.7%.

The results of this meta-analysis are very similar to the results for the meta-analysis of DML with patient groups with unspecified diagnosis of CTS. The results of both meta-analyses suggest that this test has very high specificity, but only moderate sensitivity.

Table 24. Distal Motor Latency Articles Excluded From Meta-Analysis

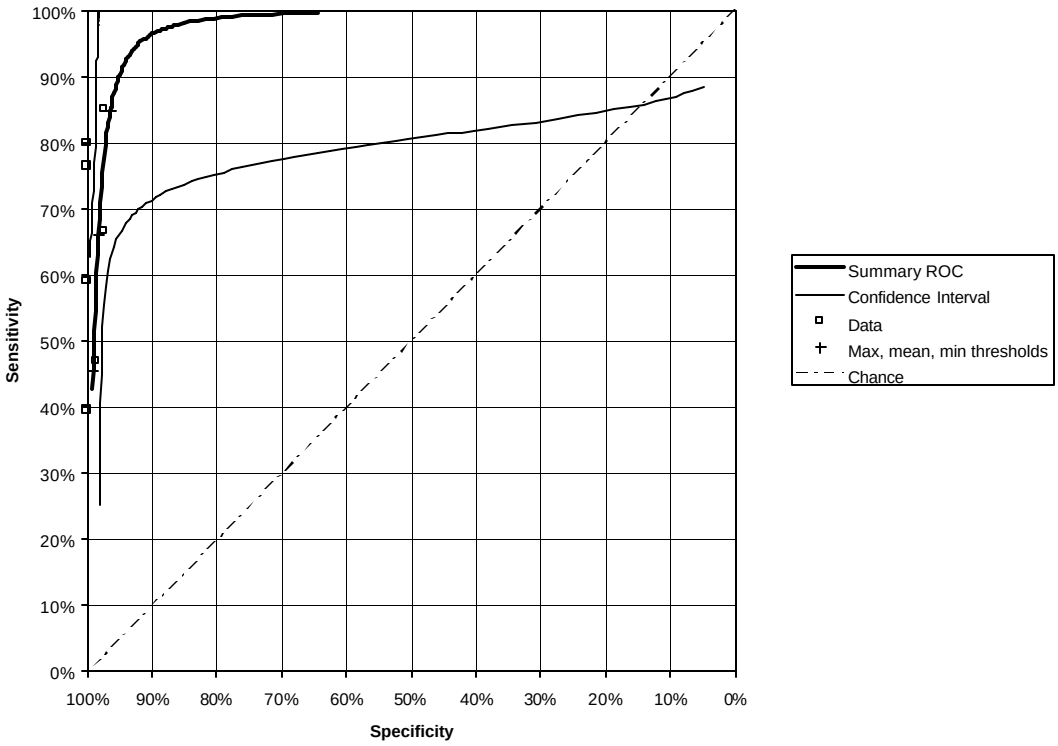
Study	Reason for Exclusion
Jackson, 1989 [150]	Did not report sensitivity and specificity for distal motor latency test
Sener, 2000 [186]	Did not report sensitivity and specificity for distal motor latency test
Schwartz, 1979 [187]	Did not report sensitivity and specificity for distal motor latency test
Escobar, 1985 [151]	Did not report sensitivity and specificity for distal motor latency test
Preston, 1992 [188]	Did not report distal motor latency results for control subjects
Kimura, 1985 [189]	Did not report distal motor latency results for control subjects
Cherniak, 1996 [190]	Used distal motor latency for patient selection
Sheean, 1995 [191]	Used distal motor latency for patient selection
Foresti, 1996 [192]	Discrepancies in reported results

Table 25. Meta-analysis of Distal Motor Latency Results in Trials With Patients Presenting with CTS Symptoms

Study	TP	FN	FP	TN	Sen. 95% CI	Spec. 95% CI	PPV 95% CI	NPV 95% CI	Prev.
[a, b]Chang[145]	17	26	0	40	39.5% 26.1% 54.7%	100% 90.9% 100%	100% 81.0% 100%	60.6% 48.3% 71.7%	51.8%
Kuntzer[144]	47	53	1	69	47.0% 37.3% 56.9%	98.6% 92.1% 99.8%	97.9% 88.8% 99.6%	56.6% 47.5% 65.2%	58.8%
[a]Murthy[143]	38	19	2	72	66.7% 53.5% 77.7%	97.3% 90.5% 99.3%	95.0% 83.2% 98.6%	79.1% 69.5% 86.3%	43.5%
Cioni[146]	300	75	0	56	80.0% 75.6% 83.8%	100% 93.3% 100%	100% 98.7% 100%	42.7% 34.4% 51.5%	87.0%
[b]Messina[120]	34	6	1	39	85.0% 70.6% 93.0%	97.5% 86.8% 99.6%	97.1% 85.1% 99.5%	86.7% 73.5% 93.8%	50.0%
Melvin[147]	13	4	0	24	76.5% 52.2% 90.6%	100% 85.7% 100%	100% 76.5% 100%	85.7% 68.1% 94.4%	41.5%
Loong[148]	13	9	0	60	59.1% 38.4% 77.0%	100% 93.8% 100%	100% 76.5% 100%	87.0% 76.8% 93.1%	26.8%
[c]Atroshi[136]	25	18	8	52	58.1% 43.0% 71.9%	86.7% 75.6% 93.2%	75.8% 58.6% 87.3%	74.3% 62.7% 83.2%	41.7%
Meta-analysis results (mean threshold)					**66.0%** 55.7% 75.0%	**98.3%** 97.4% 98.9%			

Key:
TP–true positive, FN–false negative, FP–false positive, TN–true negative
Sen.–sensitivity, Spec–specificity, PPV–positive predictive value, NPV–negative predictive value, Prev.–prevalence of CTS
Confidence intervals on sensitivity, specificity, PPV, NPV calculated by Wilson method
[a]Counts for control group (false positive, true negative) estimated by ECRI from threshold reported by authors (mean + 2 or 2.5 SD)
[b]Results calculated by ECRI from published graph
[c]Outlier (excluded from meta-analysis results): see text

Figure 10. Meta-analysis of Distal Motor Latency Results in Trials With Patients Presenting with CTS Symptoms



Note:
One outlier[136] was excluded (see text).

Palmar Sensory Latency: Patients with Symptoms of CTS v. Normal Controls

The cross-tabulation found 11 articles that included palmar sensory latency studies and reported some data in the form of a 2 x 2 table. The articles compared patients who presented with suspected CTS or symptoms of CTS to healthy normal controls. As with the other meta-analyses, several studies could not be included in the meta-analysis (Table 26). Five articles did not report sufficient data to allow us to calculate sensitivity and specificity for this particular test. One used palmar sensory latency as a patient selection criterion and was excluded due to selection bias.

After these exclusions, five studies remained in the meta-analysis. There was no statistically significant heterogeneity in their results ($Q = 4.87$, $p = 0.30$). The studies and their results are listed in Table 27 and the summary ROC plot is shown in Figure 11.

Like DML, palmar sensory latency has very high specificity. The normal volunteers studied in these trials rarely had abnormal results. This finding, however, does not reveal the test performance on persons with suspected CTS. To address that issue, a computation of sensitivity is required. The sensitivity/specificity at mean threshold was 75.8%/97.7%, and it is clear that the test has some ability to identify persons with

symptoms of CTS. Although the summary ROC can be extrapolated to a point where sensitivity and specificity are both quite high (i.e., 96%, 96% respectively), in actual practice it is likely that only specificity is so high. Sensitivity was lower than specificity in all five studies.

Table 26. Palmar Sensory Latency Articles Excluded from Meta-analysis

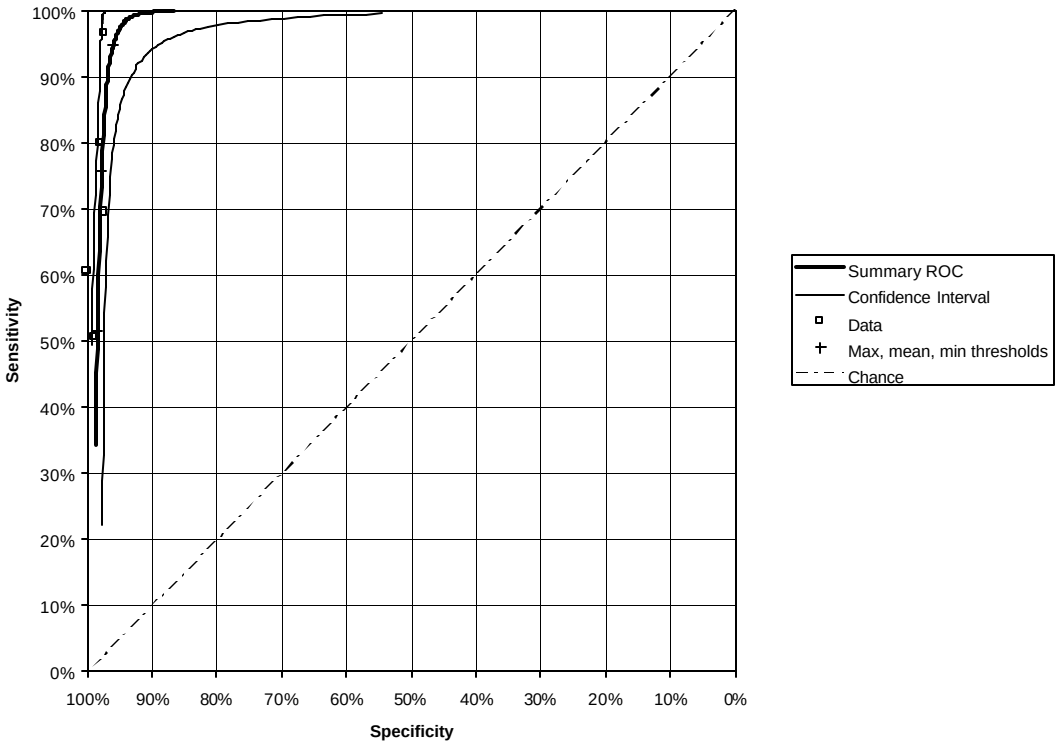
Study	Reason for Exclusion
Gerr, 1998 [31]	Did not report sensitivity and specificity for palmar sensory latency test
Foresti, 1996 [192]	Did not report sensitivity and specificity for palmar sensory latency test
Eisen, 1993 [193]	Did not report sensitivity and specificity for palmar sensory latency test
Mills, 1985 [194]	Did not report sensitivity and specificity for palmar sensory latency test
Kim, 1983 [195]	Did not report sensitivity and specificity for palmar sensory latency test
Andary, 1996 [196]	Palmar sensory latency results used as patient selection criterion

Table 27. Meta-analysis of Palmar Sensory Latency Results

Study	TP	FN	FP	TN	Sen. 95% CI	Spec. 95% CI	PPV 95% CI	NPV 95% CI	Prev.
[a, b]Chang[145]	26	17	0	40	60.5% 45.3% 73.9%	100% 90.9% 100%	100% 86.7% 100%	70.2% 57.1% 80.6%	51.8%
[c]Jackson[150]	91	40	1	37	69.5% 60.9% 76.8%	97.4% 86.2% 99.5%	98.9% 93.9% 99.8%	48.1% 37.0% 59.3%	77.5%
[a]Murthy[143]	55	2	2	72	96.5% 87.8% 99.1%	97.3% 90.5% 99.3%	96.5% 87.8% 99.1%	97.3% 90.5% 99.3%	43.5%
[a]Escobar[151]	32	8	2	102	80.0% 64.9% 89.6%	98.1% 93.1% 99.5%	94.1% 80.5% 98.4%	92.7% 86.1% 96.3%	27.8%
[c]Girlanda[149]	38	37	1	89	50.7% 39.4% 61.9%	98.9% 93.8% 99.8%	97.4% 86.5% 99.6%	70.6% 62.0% 78.0%	45.5%
Meta-analysis results (mean threshold)					75.8% 68.8% 81.6%	97.7% 96.8% 98.4%			

Key:
TP–true positive, FN–false negative, FP–false positive, TN–true negative
Sen.–sensitivity, Spec–specificity, PPV–positive predictive value, NPV–negative predictive value, Prev.–prevalence of CTS
Confidence intervals on sensitivity, specificity, PPV, NPV calculated by Wilson method
[a]Counts for control group (false positive, true negative) estimated by ECRI from threshold reported by authors (mean + 2 or 2.5 SD)
[b]Results calculated by ECRI from published graph
[c]Results calculated by ECRI from published percentages

Figure 11. Meta-analysis of Palmar Sensory Latency Results



Phalen's Maneuver: Combined CTS Groups v. Normal Controls

There were no clinical signs or symptoms for which at least 10 articles reported sensitivity and specificity in a specific patient population. Therefore, we loosened the inclusion criteria by first combining the four patient selection categories, and then requiring a total of 20 or more sensitivity/specificity articles. Because none of the signs and symptoms data met that loosened criterion, we again lowered the threshold to a total of 15 studies or more. Two tests met that criterion: Phalen's maneuver and Tinel's sign. We proceeded to attempt meta-analysis of these data, recognizing that combining patient selection groups could cause heterogeneity of study results that could prevent meta-analysis.

The evidence base on Phalen's maneuver comprised 15 studies. Two of these reported two CTS groups, for a total of 17 entries in the cross-tabulation. For analyzing the two studies with two CTS groups,[101,154] we combined results of all CTS patients. Three articles were excluded because they did not report sufficient data to allow specificity to be calculated. Phalen's maneuver data from the article by Glass and King[28] was excluded because results were reported for only 22 of the 159 hands with CTS, and the authors did not report the reason for this. Finally, we determined while abstracting data that two publications by Gerr[31,197] reported the same controls and likely the same patients. Only the later publication[31] was included in the analysis. Excluded articles are listed in Table 28.

This left a total of 10 articles for meta-analysis (Table 29). We found significant heterogeneity among the studies' results ($Q = 71.4$, $p < 0.000001$). Six studies selected CTS patients using procedures we categorized as "complex objective standard." Analyzing this subgroup separately did not eliminate the heterogeneity ($Q = 59.4$, $p < 0.000001$), nor did excluding the one study[111] that used the reverse Phalen maneuver. ($Q = 70.8$, $p < 0.000001$). There were no obvious outliers to explain the heterogeneity, and grouping studies according to criteria that might affect the validity or generalizability of the results (Table 30) did not reduce heterogeneity to statistically non-significant levels. Thus we could not confidently report a single point as the most likely sensitivity and specificity of the test.

The variability of results is shown in Figure 12; sensitivity/specificity covered a large range. We can only conclude that Phalen's maneuver has some ability to distinguish CTS patients from normal controls; the data are too heterogeneous to estimate sensitivity or specificity.

Table 28. Phalen's Maneuver Articles Excluded from Meta-Analysis

Study	Reason for Exclusion
Koris, 1988 [198]	Did not report specificity of Phalen's maneuver
Brahme, 1997 [199]	Did not report specificity of Phalen's maneuver
Lang, 1995 [109]	Did not report specificity of Phalen's maneuver
Glass, 1995 [28]	Reported results for only 22 of 159 affected hands
Gerr, 1994 [197]	Duplicate publication

Table 29. Diagnostic Trial Results for Phalen's Maneuver

Study	TP	FN	FP	TN	Sen. 95% CI	Spec. 95% CI	PPV 95% CI	NPV 95% CI	Prev.
De Smet[101]	57	9	4	77	86.4% 75.8% 92.7%	95.1% 87.8% 98.1%	93.4% 84.1% 97.5%	89.5% 81.1% 94.5%	44.9%
Durkan[155]	32	14	8	42	69.6% 54.9% 81.1%	84.0% 71.2% 91.8%	80.0% 64.9% 89.6%	75.0% 62.0% 84.6%	47.9%
Gellman[106]	45	18	10	40	71.4% 59.0% 81.3%	80.0% 66.7% 88.9%	81.8% 69.4% 89.9%	69.0% 55.9% 79.6%	55.8%
[a, b]Gerr[31]	48	67	4	119	41.7% 33.0% 51.1%	96.7% 91.8% 98.8%	92.3% 81.5% 97.0%	64.0% 56.7% 70.7%	48.3%
[b]Ghavanini[154]	34	40	17	41	45.9% 34.9% 57.4%	70.7% 57.7% 81.0%	66.7% 52.7% 78.2%	50.6% 39.7% 61.4%	56.1%
González del Pino[104]	174	26	20	180	87.0% 81.5% 91.0%	90.0% 84.9% 93.5%	89.7% 84.5% 93.3%	87.4% 82.0% 91.3%	50.0%
[a]Szabo[152]	65	22	5	95	74.7% 64.4% 82.8%	95.0% 88.7% 97.9%	92.9% 84.1% 97.0%	81.2% 73.0% 87.3%	46.5%
Tetro[102]1	58	37	16	80	61.1% 50.8% 70.4%	83.3% 74.4% 89.6%	78.4% 67.5% 86.4%	68.4% 59.3% 76.2%	49.7%
Fertl[153]	50	23	3	36	68.5% 56.9% 78.2%	92.3% 79.3% 97.4%	94.3% 84.4% 98.1%	61.0% 48.0% 72.6%	65.2%
[c]Werner[111]	17	14	0	20	54.8% 37.5% 71.1%	100% 83.3% 100%	100% 81.0% 100%	58.8% 41.9% 73.9%	60.8%
Meta-analysis results (mean threshold)					**NA**	**NA**			

Key:
TP–true positive, FN–false negative, FP–false positive, TN–true negative
Sen.–sensitivity, Spec–specificity, PPV–positive predictive value, NPV–negative predictive value, Prev.–prevalence of CTS
Confidence intervals on sensitivity, specificity, PPV, NPV calculated by Wilson method
NA—Results not valid because of excessive heterogenity in study results
[a]Results calculated by ECRI from published percentages
[b]Errors in published results corrected by ECRI
[c]Tested reverse Phalen's maneuver

Figure 12. Diagnostic Trial Results for Phalen's Maneuver

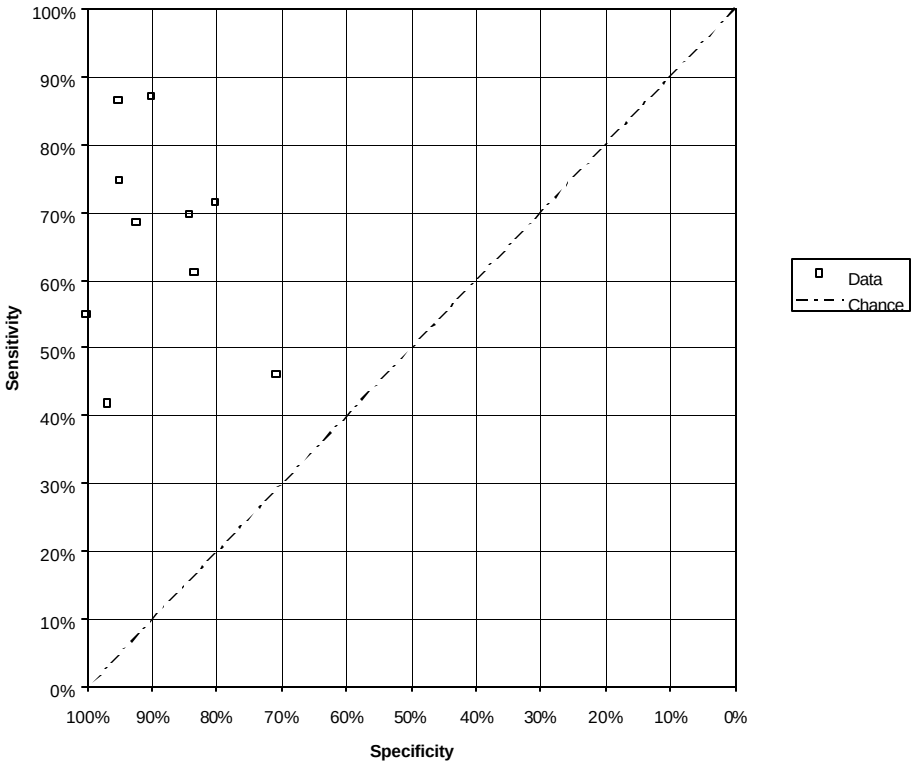


Table 30. Heterogeneity of Diagnostic Trial Results for Phalen's Maneuver

Group	Q (p-value) for larger group
All articles (N = 10)	71.4 (p <0.000001)
Patients selected with complex objective standard (N = 6) v. other selection	59.4 (p <0.000001)
Reverse Phalen's maneuver (N = 1) v. conventional	70.8 (p <0.000001)
Not funded by for-profit device or drug manufacturer (N = 4) v. not reported	58.5 (p <0.000001)
Reported both inclusion and exclusion criteria (N = 4) v. reported only inclusion criteria	20.5 (p = 0.001)
Prospective patient selection (N = 5) v. not reported	58.7 (p <0.000001)
Comorbidity reported (N = 1) v. not reported	69.9 (p <0.000001)
Sex ratios of patients, controls within 20% of each other (N = 5) v. possible sex bias	58.5 (p <0.000001)
Mean ages of patients, controls within 5 years (N = 3) v. possible age bias	15.4 (p = 0.017)
Duration of condition reported (N = 2) v. not reported	48.4 (p <0.000001)
Independent reference standard (N = 4) v. no independent reference standard reported	48.2 (p <0.000001)
Patients given both study test and reference test (N = 3) v. did not do so	49.3 (p <0.000001)
Studies done in USA (N = 6) v. other countries	58.1 (p <0.000001)
Potential selection bias for easy cases (N = 4) v. no bias or not reported	49.3 (p <0.000001)

Q—Q-statistic, with probability that variability in study results [D, logit (sensitivity) + logit (specificity)] is the result of random variability within a homogeneous sample of studies.

Tinel's Sign: Combined CTS Groups v. Normal Controls

The evidence base on Tinel's sign comprised 13 studies; three of these reported two CTS groups, for a total of 16 entries in the cross-tabulation. As mentioned in the meta-analysis of Phalen's maneuver, only the later of the duplicate Gerr publications[31,197] was included in the analysis, and we pooled patient groups in studies with two CTS groups. Two articles were excluded because they did not report specificity. Exclusions are summarized in Table 31

Eleven studies remained for meta-analysis (Table 32). The meta-analysis found significant heterogeneity among the studies' results ($Q = 59.1$, $p < 0.000001$). All but two studies (De Smet et al.[101] and Seror et al.[156]) selected CTS patients using procedures we categorized as "complex objective standard." Excluding those studies from the analysis did not substantially reduce the heterogeneity ($Q = 46.7$, $p < 0.000001$).

The heterogeneity is evident in Figure 13. Sensitivity/specificity results are widely dispersed in the graph, and there is no pattern of results that is obvious on inspection. The data suggest that Tinel's sign has some ability to diagnose CTS, but the sensitivity and specificity of the test are uncertain. However, the sensitivity of the test appears to be low.

To see whether other factors, particularly those relating to the validity or generalizability of results, could explain the observed heterogeneity, we repeated the heterogeneity tests for groups defined by reporting criteria in Table 13 and Table 15. The results of those analyses are shown in Table 33. Significant heterogeneity remained regardless of the criteria used to group trials. Therefore none of these criteria are sufficient to explain the heterogeneity that prevents us from meta-analyzing the results.

Table 31. Tinel's Sign Articles Excluded from Meta-analysis

Study	Reason for Exclusion
Brahme, 1997 [199]	Did not report specificity of Tinel's sign
Lang, 1995 [109]	Did not report specificity of Tinel's sign
Gerr, 1994 [197]	Duplicate publication

Table 32. Diagnostic Trial Results for Tinel's Sign

Study	TP	FN	FP	TN	Sen. 95% CI	Spec. 95% CI	PPV 95% CI	NPV 95% CI	Prev.
De Smet[101]	14	17	0	81	45.2% 28.9% 62.5%	100% 95.3% 100%	100% 77.8% 100%	82.7% 73.8% 89.0%	27.7%
Durkan[155]	26	20	10	40	56.5% 42.0% 70.0%	80.0% 66.7% 88.9%	72.2% 55.7% 84.3%	66.7% 53.8% 77.5%	47.9%
Gellman[106]	29	37	3	47	43.9% 32.4% 56.2%	94.0% 83.5% 98.0%	90.6% 75.4% 96.8%	56.0% 45.1% 66.3%	56.9%
Gelmers[29]	20	27	11	32	42.6% 29.3% 57.0%	74.4% 59.4% 85.2%	64.5% 46.6% 79.1%	54.2% 41.4% 66.5%	52.2%
[a, b]Gerr[31]	8	50	2	121	13.8% 7.1% 25.2%	98.4% 94.1% 99.6%	80.0% 48.4% 94.5%	70.8% 63.4% 77.2%	32.0%
Ghavanini[154]	24	52	9	49	31.6% 22.1% 42.9%	84.5% 72.8% 91.7%	72.7% 55.4% 85.1%	48.5% 38.8% 58.3%	56.7%
González del Pino[104]	42	87	6	194	32.6% 24.9% 41.2%	97.0% 93.5% 98.6%	87.5% 75.0% 94.2%	69.0% 63.3% 74.3%	39.2%
[a]Seror[156]	63	37	18	22	63.0% 53.0% 72.0%	55.0% 39.5% 69.6%	77.8% 67.4% 85.6%	37.3% 25.9% 50.3%	71.4%
Stewart[157]	23	28	15	37	45.1% 32.0% 58.9%	71.2% 57.4% 81.8%	60.5% 44.4% 74.6%	56.9% 44.6% 68.5%	49.5%
[a]Szabo[152]	56	31	1	99	64.4% 53.7% 73.8%	99.0% 94.4% 99.8%	98.2% 90.5% 99.7%	76.2% 68.0% 82.8%	46.5%
[a]Tetro[102]	70	25	9	87	73.7% 63.8% 81.6%	90.6% 82.9% 95.1%	88.6% 79.5% 94.0%	77.7% 68.9% 84.5%	49.7%
Meta-analysis results (mean threshold)					**NA**	**NA**			

TP–true positive, FN–false negative, FP–false positive, TN–true negative

Sen.–sensitivity, Spec–specificity, PPV–positive predictive value, NPV–negative predictive value, Prev.–prevalence of CTS

Confidence intervals on sensitivity, specificity, PPV, NPV calculated by Wilson method

NA—Results not valid because of excessive heterogenity in study results

[a]Results calculated by ECRI from published percentages

[b]Errors in published results corrected by ECRI

Figure 13. Diagnostic Trial Results for Tinel's Sign

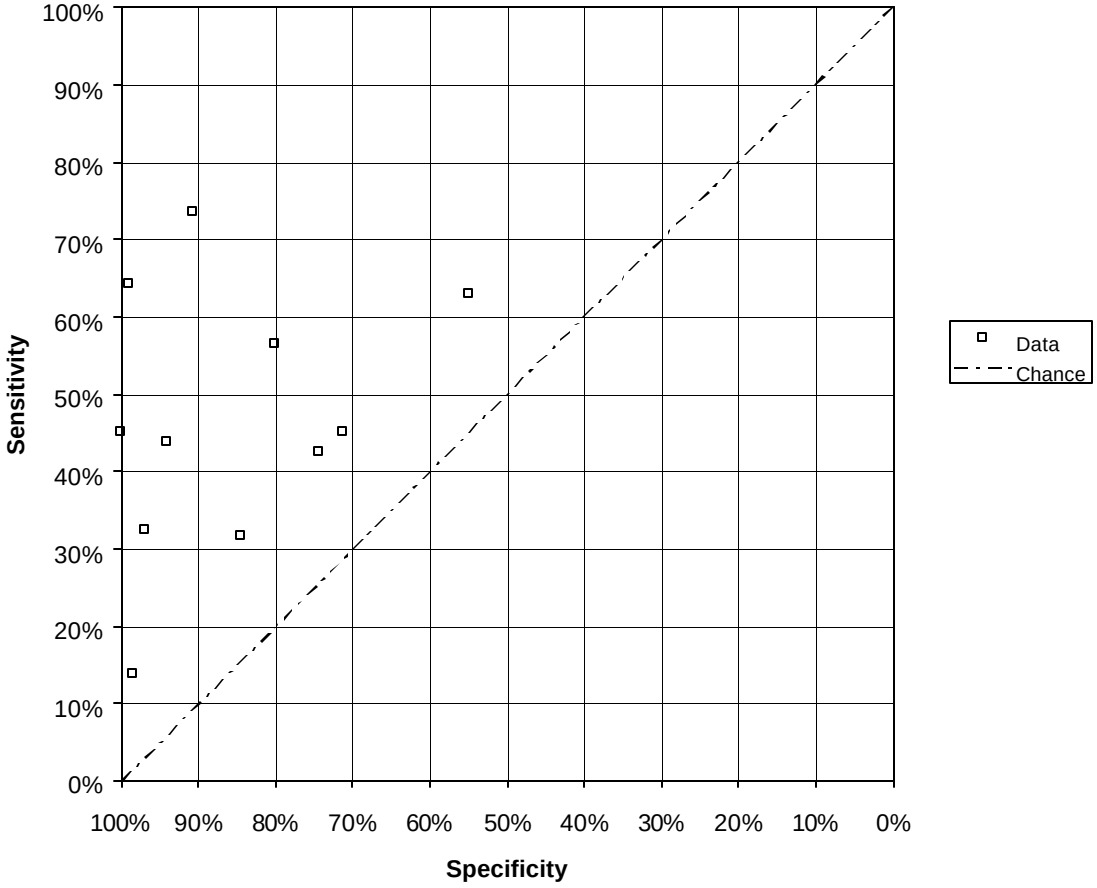


Table 33. Heterogeneity of Diagnostic Trial Results for Tinel's Sign

Group	Q (p-value) for larger group
All articles (N = 11)	59.1 (p <0.000001)
Patients selected with complex objective standard (N = 9) v. other selection	46.1 (p <0.000001)
Not funded by for-profit device or drug manufacturer (N = 5) v. not reported	10.7 (p = 0.057)
Reported both inclusion and exclusion criteria (N = 6) v. reported only inclusion criteria	30.2 (p = 0.000013)
Prospective patient selection (N = 4) v. not reported	16.6 (p = 0.011)
Comorbidity reported (N = 2) v. not reported	51.4 (p <0.000001)
Mean ages of patients, controls within 5 years (N = 6) v. possible age bias	37.8 (p <0.000001)
Possible sex bias (N = 3) vs. sex ratios of patients, controls within 20% of each other (N = 8)	52.8 (p <0.000001)
Duration of condition reported (N = 2) v. not reported	50.6 (p <0.000001)
Independent reference standard (N = 6) v. no independent reference standard reported	16.5 (p = 0.005545)
Patients given both study test and reference test (N = 3) v. did not do so	51.6 (p <0.000001)
Studies done in USA (N = 5) v. other countries	22.3 (p = 0.000454)
Potential selection bias for easy cases (N = 4) v. no bias or not reported	41.9 (p <0.000001)

Q—Q-statistic, with probability that variability in study results [D, logit (sensitivity) + logit (specificity)] is the result of random variability within a homogeneous sample of studies.

Articles on Carpal Tunnel Syndrome Screening

Screening tests are intended to identify persons at risk of developing a condition in the future, not those who already have the condition. Because there is no agreement on what constitutes screening for CTS, we accepted any studies so described by their authors as screening studies. There were 28 articles described by their authors as screening studies. Two (Bland[200] and Rosen[201]) were excluded from this analysis because they required all participants to be symptomatic. Two[202,203] were sequential reports on the same study. Therefore, 25 studies (Table 34) were included in the analysis of screening of carpal tunnel syndrome. Twenty-two of the studies screened workers at risk, and the remaining three studies screened the general population; the table is stratified according to these two categories.

The reported methods of diagnosis in the 28 screening studies appear in Table 35. The most common diagnostic criteria were symptoms (12 studies, 43%) and the difference between median and ulnar sensory tests (9 studies, 32%). Thirteen studies (46%) used both clinical criteria and nerve conduction criteria, three studies (11%) used nerve conduction criteria only, and no studies used clinical criteria only. The table demonstrates the variability in authors' methods for screening for CTS. As with the diagnostic articles on CTS, we tabulated the number of screening articles reporting use of each particular test (Table 36, Table 37, Table 38, Table 39, Table 40). In no case were there sufficient articles reporting a particular test to meet our a priori criteria for meta-analyzing their data.

The presence of symptoms and the presence of a positive nerve conduction test appeared to be independent of each other in the screening studies. Figure 14 plots the prevalence of symptoms on the horizontal axis and the prevalence of positive nerve conduction tests on the vertical axis. We could only plot the 15 studies that reported both variables. The

correlation between symptoms and nerve conduction was 0.21 ($r^2 = 0.04$) and was not statistically different from zero. Because two of the 15 studies screened a general population, we recomputed the correlation after removing these two studies. The correlation was 0.16 ($r^2 = 0.02$) and was not statistically different from zero. The weak association between symptoms and abnormal nerve conduction suggests that a high incidence of CTS symptoms in workers at risk does not necessarily imply that those same workers will have a high incidence of abnormal nerve conduction.

Lack of agreement on what constitutes carpal tunnel syndrome is another obstacle to analyzing these studies. Table 41 lists all the different criteria used to define true cases of CTS in the screening articles. In 13 of the 28 articles (46%), the criteria were not reported at all. The majority of articles that did report criteria (80%) considered both nerve conduction and symptoms; the others used nerve conduction only. In some cases, it was not clearly reported how the elements of the diagnosis were to be combined: whether any sign of CTS would be considered diagnostic for the condition or whether all the criteria must be met.

The ideal study design for evaluating screening tests for WRUEDs would first test a group of at-risk persons, and then perform followup for a period of time to determine whether symptoms develop. Only six articles in our evidence base reported this kind of trial, and two reported on the same trial. The bulk of the "screening" literature was made up of articles intended to diagnose CTS in screening populations (asymptomatic workers presumed to be at risk for CTS). The five longitudinal studies of screening populations are listed in Table 42. The evidence base is small enough that each study will be discussed individually in this report.

Kearns[204] measured nerve conduction in new workers at a pork processing plant. Tests were done before the workers started employment and after two months' employment, though the actual time of the followup test ranged from 42 days to 83 days. Only the nerve conduction tests were done; no symptoms were reported and the authors cautioned that the study was not intended to identify workers who developed CTS. Therefore, this study cannot be used to base conclusions of nerve conduction measurement as a screening test for CTS.

Nathan et al. performed the longest longitudinal study on nerve conduction measurements: 11 years. Two articles[202,203] reported on the same group of subjects: 471 workers from a variety of manufacturing and clerical jobs. Their initial testing was in 1984, with subsequent testing in 1989 (316 subjects followed)[203] and 1994-95 (283 subjects)[202]. Both inching tests and sensory latency measurements were reported in the latest article, though several other nerve conduction tests were also done.

The first followup article reports that there was a statistically significant association between slowing of nerve conduction in 1984 and CTS symptoms in 1989, but did not report sufficient data to allow us to verify these findings or determine the sensitivity and specificity of the test. There were sufficient data of this type reported from the 1994-95 followup to calculate sensitivity and specificity of one nerve conduction test: the

"maximum latency difference" test, which is a variation of the inching test. We reanalyzed this data: the resulting sensitivities and specificities at different threshold values are shown in Table 43 and an ROC curve fitted to the data using the logit regression method is shown in Figure 15. While it is clear that this test had a significant ability to predict future CTS in this screening population, this is just one of several nerve conduction tests done in this study, and the possibility of a chance result cannot be discounted. Independent confirmation of this finding would be necessary for us to conclude that this is an effective predictive test. Reanalysis of the unpublished results from this study could verify whether or not other nerve conduction tests also predict future CTS, and could help clinicians decide which test is most effective.

Table 34. Articles Described as Screening Studies

Article	N	Population	Symptoms	Positive NCS	Symptoms & Positive NCS
Workers-at-risk screening studies for carpal tunnel syndrome					
Kearns, 2000 [204]	45	Pork processors	NR	NR	NR
Missere, 1999 [205]	45	Meat manufacturers	NR	[a] 28.9%	NR
Nathan, 1998 [202]	283	Steel mill workers, food processors, electronics workers, and plastics workers	12.9%	43.0%	8.2%
Tan, 1998 [206]	64	Carpet weavers	NR	NR	NR
Werner, 1998 [207]	119	Automobile parts manufacturers	NR	27%	[b] 20.2%
	98	Furniture manufacturers	NR	26%	[b] 10.2%
	77	Paper containers manufacturers	NR	34%	[b] 14.3%
	64	Automobile parts manufacturers	NR	30%	[b] 17.2%
	164	Clerical insurance workers	NR	15%	[b] 11.0%
	202	Spark plugs manufacturers	NR	28%	[b] 9.4%
Franzblau, 1997 [208]	148	Automobile parts manufacturers	41%	NR	NR
Jeng, 1997 [209]	27	Food processors	48.8%	34.1%	22.0%
Werner, 1997 [210]	59	Manufacturing workers and clerical workers	11.1%	45.4%	5.6%
Bingham, 1996 [211]	1021	Applicants for jobs in meat packers, plastics assemblers, food processors, furniture manufacturers, or grocery warehousing workers	[c] 6.0%	[a] 17.4%	[c] 1.8%
Murata, 1996 [164]	27	Data entry operators	NR	37%	NR
Pierre-Jerome, 1996 [212]	24	Floor cleaners	NR	NR	NR
Werner, 1995 [213]	167	Automobile parts manufacturers	19.8%	24.6%	9.0%
Young, 1995 [166]	157	Poultry processors	70%b	31%	NR
Franzblau, 1994 [113]	84	Automobile parts manufacturers	21.4%	19.3%	8.40%
Kirschberg, 1994 [214]	112	Poultry processors	22.3%	29.5%	17.0%

Article	N	Population	Symptoms	Positive NCS	Symptoms & Positive NCS
Workers-at-risk screening studies for carpal tunnel syndrome					
Nathan, 1994 [215]	101	Japanese furniture factory workers	[a, b] 4.5%	[b] 17.8%	[b] 2.0%
	316	Steel mill workers, food processors, electronics workers, and plastics workers	[a, b] 23.4%	[b] 22.0%	[b] 8.3%
Nilsson, 1994 [216]	61	Office workers	NR	33%	NR
	58	Truck assemblers	NR	40%	NR
	56	Platers	NR	55%	NR
Werner, 1994 [217]	130	Automobile parts manufacturers	27.7%	[d] 20.2%	NR
Johnson, 1993 [167]	184	Poultry processors	[a, b] 37.3%	[a, b] 19.2%	[a, b] 6.0%
Nathan, 1993 [218]	737	Steel mill workers, meat/food processors, electronics workers, plastics workers, aluminum reduction workers, and cable plant workers.	[a, b] 51.0%	[a, b] 33.6%	[a, b] 19.8%
Grant, 1992 [219]	63	Manufacturing plant workers	[a] 25.4%	NR	NR
Jetzer, 1991 [168]	39	Computer assemblers	NR	NR	NR
	100	Meat processors	NR	NR	NR
	284	Keyboard operators	NR	NR	NR
General population screening studies for carpal tunnel syndrome					
Atroshi, 1999 [220]	2466	General population	14.4%	[c] 22.3%	[c] 6.6%
Ferry, 1998 [221]	648	General population	18.5%	17.4%	7.7%
DeKrom, 1990 [222]	500	General population	13.8%	NR	[c] 7.8%

Key
NR-Not reported
NCS-Nerve conduction studies
[a]Based on hands instead of participants
[b]Calculated by ECRI based on information reported in the article
[c]Estimated by ECRI based on information reported in the article
[d]Prevalence of positive NCS in the study by Werner[217] was based on 129 participants .

Table 35. Definitions of CTS Reported in Screening Articles

Author, Year	Clinical findings			Nerve conduction studies						Comments
	SYM	CLN	OTH CLN	DML	DSL	PAL	SEN DIF	MOT DIF	OTH NCS	
Bland, 2000 [200]	?	?	?	☑	?	?	?	?	☑	If tests equivocal, authors measured sensory potential or inching test
Kearns, 2000 [204]	?	?	?	?	?	?	?	?	?	NR
Atroshi, 1999 [220]	☑	☑	?	?	?	?	☑	?	?	
Missere, 1999 [205]	?	?	?	?	?	?	?	?	☑	
Ferry, 1998 [221]	?	?	?	?	?	?	?	?	?	NR
Nathan, 1998 [202]	☑	?	?	?	☑	☑	?	?	☑	
Rosen, 1998 [201]	?	?	?	?	?	?	?	?	?	NR
Tan, 1998 [206]	?	?	?	?	?	?	?	?	?	NR
Werner, 1998 [207]	☑	?	?	?	?	?	☑	?	?	
Franzblau, 1997 [208]	?	?	?	?	?	?	?	?	?	NR
Jeng, 1997 [209]	☑	?	?	☑	☑	?	☑	?	?	
Werner, 1997 [210]	☑	?	?	?	?	?	☑	?	?	
Bingham, 1996 [211]	?	?	?	?	?	?	?	?	?	NR
Murata, 1996 [164]	?	?	?	?	?	?	?	?	?	NR
Pierre-Jerome, 1996 [212]	?	?	?	?	?	?	?	?	?	NR
Werner, 1995 [213]	☑	?	?	?	?	?	☑	?	?	
Young, 1995 [166]	?	?	?	?	?	?	?	?	?	NR
Franzblau, 1994 [113]	☑	?	?	?	?	?	☑	?	?	
Kirschberg, 1994 [214]	☑	☑	☑	☑	?	☑	☑	?	☑	
Nathan, 1994 [215]	☑	?	?	?	☑	☑	?	?	☑	
Nilsson, 1994 [216]	?	?	?	?	?	?	?	?	?	NR
Werner, 1994 [217]	?	?	?	?	?	?	?	?	?	NR
Johnson, 1993 [167]	?	?	?	?	?	?	?	?	?	NR
Nathan, 1993 [218]	☑	?	?	?	☑	☑	?	?	☑	
Grant, 1992 [219]	?	?	?	☑	☑	?	☑	☑	?	

Author, Year	Clinical findings			Nerve conduction studies						Comments
	SYM	CLN	OTH CLN	DML	DSL	PAL	SEN DIF	MOT DIF	OTH NCS	
Jetzer, 1991 [168]	☑	?	?	?	?	?	?	?	?	Or positive NCS (tests not reported)
DeKrom, 1990 [222]	☑	?	?	☑	?	?	☑	?	?	
Welch, 1973 [223]	?	?	?	?	?	?	?	?	?	NR
Totals	12	2	1	5	5	4	9	1	6	

Key
SYM—Were positive symptoms included in the author's method of diagnosis?
CLN—Was a positive clinical exam included in the author's method of diagnosis?
OTH CLN—Were other clinical findings included in the author's method of diagnosis?
DML—Was distal motor latency included in the author's method of diagnosis?
DSL—Was distal sensory latency included in the author's method of diagnosis?
PAL—Was palmar sensory latency included in the author's method of diagnosis?
SEN DIF—Was the difference between median and ulnar sensory studies included in the author's method of diagnosis?
MOT DIF—Was the difference between median and ulnar motor studies included in the author's method of diagnosis?
OTH NCS—Were other nerve conduction studies included in the author's method of diagnosis?
NR—Method of diagnosis was not reported

Figure 14. Association of Symptoms with Positive NCS Findings in Screening Studies

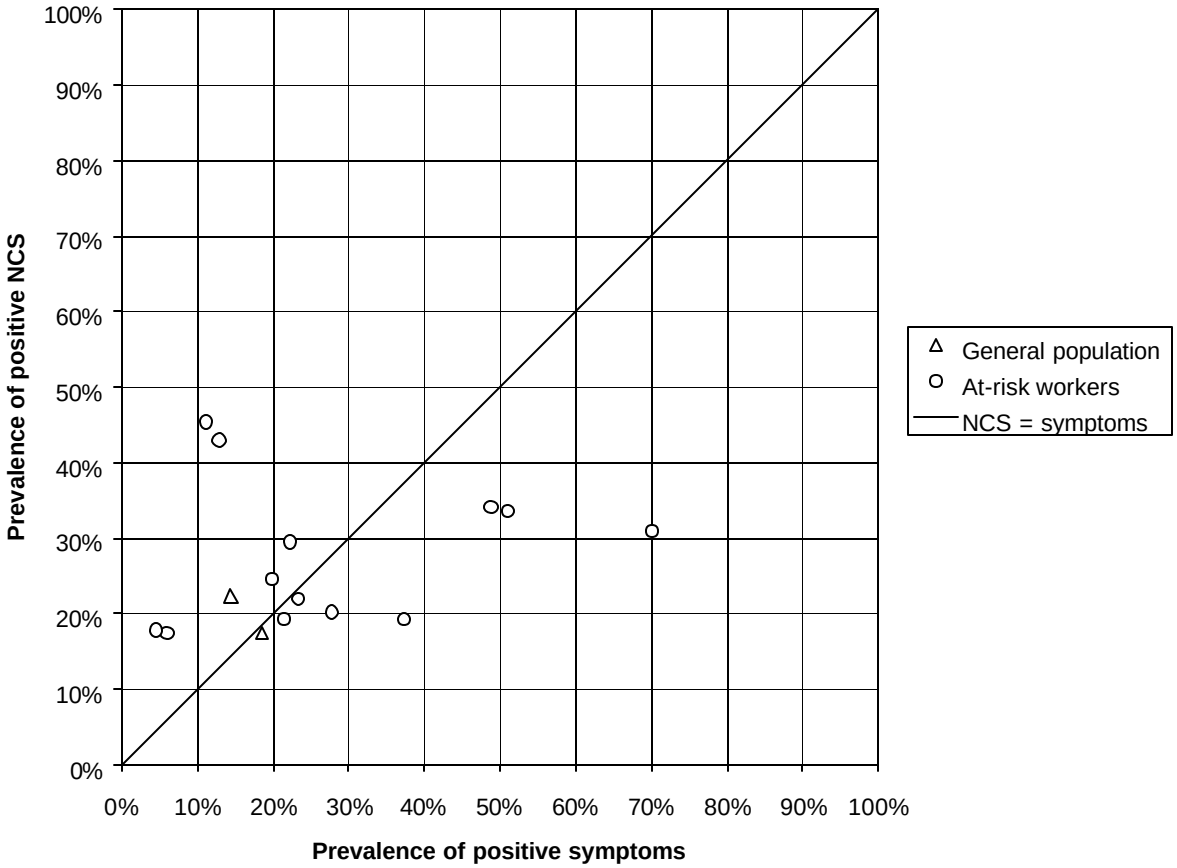


Table 36. Signs and Symptoms Reported in Screening Articles

Legend:
First entry in cell—Total number of articles
Second entry in cell—Number of articles with derivable sensitivity and specificity

Sign/symptom	Number of articles reporting
Clinical exam and history	1, 0
Durkan compression	1, 1
Flick sign	1, 1
Flick: Does shaking alleviate night symptoms?	1, 1
Gilliat tourniquet	1, 1
Grip strength	2, 0
Hypalgesia	1, 0
Hyperpathia	1, 0
Lateral pinch strength	1, 0
Luthy's test	1, 1
Night symptoms	1, 1
Opponens pollicus weakness	1, 1
Phalen's/reverse Phalen's	3, 2
Right or left hand worse? Or bilateral?	1, 1
Signs	1, 0
Symptoms measured systematically	15, 7
Symptoms	2, 0
Symptoms and signs	1, 0
Thenar atrophy	1, 1
Thenar weakness	1, 1
Three-point pinch strength	1, 0
Tinel's	3, 2
When are symptoms worse?	1, 1
Which fingers are worst affected?	1, 1

Table 37. Sensory Tests Reported in Screening Articles

Legend:
First entry in cell—Total number of articles
Second entry in cell—Number of articles with derivable sensitivity and specificity

Sensory test	Number of articles reporting
Current perception	1, 1
Gap detection test	1, 1
Semmes-Weinstein monofilament	1, 0
Tactile discrimination	1, 1
Vibrometer	6, 3

Table 38. Nerve Conduction Tests Reported in Screening Articles

Legend:

Nerve tested: MED–median, RAD–radial, ULN–ulnar
Nerve tested: MOT–motor, SEN–Sensory
Configuration (not applicable to motor nerve tests: OR–orthodromic, AN–antidromic
Stimulation/measurement sites: ELB–elbow, FOR–forearm, WR–wrist, PAL–palm, IN–index finger, MI–middle finger, RI–ring finger, LI–little finger, APB–abductor policis brevis, ADM–abductor digiti minimi, OTH–other
Measured parameter: LAT–latency, AMP–amplitude, VEL–velocity, INCH–inching, OTH–other
Blank cells—characteristic not reported
First entry in cell—Total number of articles
Second entry in cell—Number of articles with derivable sensitivity and specificity
Numeric entries—Total number of articles, articles from which sensitivity and specificity can be calculated

Nerve tested		Configuration	Stimulation site	Measurement site	Parameter measured	Number of articles reporting
MED	MOT				LAT	2, 0
MED	MOT		FOR	APB	LAT	1, 1
MED	MOT		WR	APB	LAT	4, 2
MED	MOT		WR	APB	VEL	1, 1
MED	MOT		WR	OTH	AMP	1, 0
MED	MOT		WR	OTH	LAT	3, 2
MED	MOT		WR	OTH	VEL	1, 0
MED	SEN				AMP	1, 0
MED	SEN				LAT	4, 0
MED	SEN				OTH	1, 1
MED	SEN	AN			LAT	1, 1
MED	SEN	AN	PAL	IN	VEL	1, 1
MED	SEN	AN	PAL	MI	AMP	1, 1
MED	SEN	AN	PAL	MI	VEL	1, 1
MED	SEN	AN	WR	IN	AMP	2, 2
MED	SEN	AN	WR	IN	LAT	5, 3
MED	SEN	AN	WR	IN	VEL	1, 1
MED	SEN	AN	WR	MI	AMP	1, 1
MED	SEN	AN	WR	MI	INCH	3, 1
MED	SEN	AN	WR	MI	VEL	1, 1
MED	SEN	AN	WR	OTH	LAT	3, 1
MED	SEN	AN	WR	PAL	VEL	2, 2
MED	SEN	AN	WR	RI	LAT	1, 1
MED	SEN	OR	IN	WR	LAT	1, 1
MED	SEN	OR	IN	WR	VEL	1, 0
MED	SEN	OR	PAL	WR	LAT	5, 2
MED	SEN	OR	WR	ELB	VEL	1, 1
ULN	MOT				LAT	1, 0
ULN	MOT		WR	ADM	LAT	1, 0
ULN	SEN				LAT	2, 0
ULN	SEN	AN			LAT	1, 1
ULN	SEN	AN	WR	LI	AMP	2, 2
ULN	SEN	AN	WR	LI	LAT	4, 2
ULN	SEN	AN	WR	RI	LAT	1, 1
ULN	SEN	OR	LI	WR	LAT	1, 0
ULN	SEN	OR	LI	WR	VEL	1, 0
ULN	SEN	OR	PAL	WR	LAT	3, 2

Table 39. Composite Nerve Conduction Tests Reported in Screening Articles

Legend:
Nerves: MED—median, ULN—Ulnar
Measured parameter: LAT–latency, VEL–velocity
First entry in cell—Total number of articles
Second entry in cell—Number of articles with derivable sensitivity and specificity

First nerve	Second nerve	Motor or Sensory	Parameter Measured	Combination	Number of articles reporting
MED	MED	SEN	VEL	Ratio	1, 1
MED	ULN	MOT	LAT	Difference	2, 0
MED	ULN	SEN	LAT	Difference	11, 6
ULN	MED	SEN	LAT	Difference	1, 0
				Other composite	7, 3

Table 40. Imaging Tests Reported in Screening Articles

Legend:
First entry in cell—Total number of articles
Second entry in cell—Number of articles with derivable sensitivity and specificity

Imaging modality	Number of articles reporting
CT	1, 0
MRI	1, 0
Ultrasound	1, 1

Table 41. Definitions of CTS Reported in Screening Articles

Article	Method of diagnosis used to determine patient condition
Bland, 2000 [200]	Median and ulnar sensory conduction (velocity?), DML to APB. Sensory potential or segmental study of conduction used if previous tests equivocal. Threshold 2.5 SD from the mean.
Kearns, 2000 [204]	Not reported
Atroshi, 1999 [220]	Two definitions: 1) Symptoms and positive clinical exam. Symptoms were pain, numbness and/or tingling in 2 or more of the first 4 fingers at least twice weekly during the preceding 4 weeks, as stated on a questionnaire. Clinical exam required the presence of nocturnal and/or activity-related numbness and/or tingling involving the palmar aspects of at least 2 of the first 4 fingers. The presence of median nerve sensory and/or motor deficit was supportive of the diagnosis but not necessary. 2) Symptoms and positive clinical exam and positive nerve conduction. Included the same definitions as above, and in addition required a difference of 0.8 ms or more between the median sensory latency (middle finger to wrist) and the ulnar sensory latency (little finger to wrist).
Missere, 1999 [205]	SCV <42.5 m/s as measured by the nerve conduction inching test.
Ferry, 1998 [221]	Not reported
Nathan, 1998 [202]	Symptoms and abnormal nerve conduction. Symptoms defined as positive when the patient has either one of two sets of symptoms: 1) Two or more specific CTS symptoms such as numbness, tingling, nocturnal awakening occurring at least twice per month in the median nerve distribution. 2) One specific CTS symptoms and two or more nonspecific symptoms such as pain, tightness, clumsiness occurring at least twice per month in the median nerve distribution. NCS was defined as abnormal when a patient had any of the following three abnormalities: 1) Maximum latency difference = 0.4 ms in the orthodromic inching test. 2) Antidromic wrist-to-digit sensory latency >3.6 ms. 3) Orthodromic palm to wrist sensory latency >2.2 ms
Rosen, 1998 [201]	Not reported
Tan, 1998 [206]	Not reported
Werner, 1998 [207]	Nerve conduction abnormality defined as a difference >0.5 ms between median and ulnar antidromic sensory latencies to index and little fingers, respectively. Symptom abnormality defined as numbness, tingling, burning, or pain in the wrist, fingers, or hand.
Franzblau, 1997 [208]	Not reported
Jeng, 1997 [209]	Two definitions: One required both symptoms and abnormal conduction, and the other required either symptoms or abnormal nerve conduction :Symptoms: tingling, numbness, pain, perceived weakness, and clumsiness.Nerve conduction was abnormal on any of the following three tests: 1) DML >4.5 ms. 2) Antidromic sensory latency from index finger >3.7 ms. 3) Difference between median palm-to-wrist latency and ulnar palm-to-wrist latency >0.5 ms.
Werner, 1997 [210]	Difference between median and ulnar sensory latency >0.5 ms, and symptoms.
Bingham, 1996 [211]	Not reported
Murata, 1996 [164]	Not reported
Pierre-Jerome, 1996 [212]	Not reported
Werner, 1995 [213]	Symptoms and abnormal NCS. Positive symptoms were defined as any of the following: numbness, tingling, buning, pain, or nocturnal paresthesia in the hand. Abnormal CTS was defined as a difference greater than 0.5 ms between the median and ulnar sensory antidromic latencies.
Young, 1995 [166]	Not reported

Article	Method of diagnosis used to determine patient condition
Franzblau, 1994 [113]	Symptoms and abnormal nerve conduction. Positive symptoms was defined as having both 1) numbness, tingling, burning, or pain in the fingers, hand, wrist, or forearm and 2) nocturnal occurrence of above symptoms. Abnormal nerve conduction was defined as a difference >0.5 between median sensory antidromic wrist-to-index latency and ipsilateral ulnar sensory antidromic wrist-to-little-finger latency.
Kirschberg, 1994 [214]	Clinical CTS: One or more of the following 7 findings: 1) nocturnal paresthesia of the hand, relieved by shaking; 2) sensory symptoms in the specific distribution of the median nerve; 3) specific median nerve sensory loss; 4) positive Phalen's sign; 5) Positive Tinel's sign; 6) Thenar atrophy; 7) Thenar weakness. Electrodiagnostic CTS (using Mayo Clinic criteria) involved any of the following 4 findings: 1) Median DML >4.6 ms; 2) Median palmar sensory latency >2.2 ms; 3) Difference >0.2 ms between median and ulnar palmar latencies; 4) Difference >1.8 ms between median and ulnar latencies.
Nathan, 1994 [215]	Symptoms and abnormal nerve conduction. Symptoms defined as positive when the patient has either one of two sets of symptoms: 1) Two or more specific CTS symptoms such as numbness, tingling, nocturnal awakening occurring at least twice per month in the median nerve distribution 2) One specific CTS symptom and two or more nonspecific symptoms such as pain, tightness, clumsiness occurring at least twice per month in the median nerve distribution. NCS was defined as abnormal when a patient had any of the following three abnormalities: 1) Maximum latency difference = 0.4 ms in the orthodromic inching test. 2) Antidromic wrist-to-digit sensory latency >3.6 ms 3) Orthodromic palm to wrist sensory latency >2.2 ms
Nilsson, 1994 [216]	Not reported
Werner, 1994 [217]	Not reported
Johnson, 1993 [167]	Not reported
Nathan, 1993 [218]	Symptoms and abnormal nerve conduction. Symptoms defined as positive when the patient has either one of two sets of symptoms: 1) Two or more specific CTS symptoms such as numbness, tingling, nocturnal awakening occurring at least twice per month in the median nerve distribution 2) One specific CTS symptoms and two or more nonspecific symptoms such as pain, tightness, clumsiness occurring at least twice per month in the median nerve distributionNCS was defined as abnormal when a patient had any of the following three abnormalities: 1) Maximum latency difference = 0.4 ms in the orthodromic inching test. 2) Antidromic wrist-to-digit sensory latency >3.6 ms 3) Orthodromic palm to wrist sensory latency >2.2 ms
Grant, 1992 [219]	Median DML >4.5 ms or median DSL >3.5 ms or median-ulnar DML difference >1.2 ms or median-ulnar DSL difference >0.5 ms
Jetzer, 1991 [168]	Symptoms and either positive EMG or recent prior carpal tunnel surgery.
DeKrom, 1990 [222]	Nocturnal paresthesia at least twice a week and either DML >4.5 ms or a difference >0.4 ms between median and ulnar antidromic latencies to the ring finger.
Welch, 1973 [223]	Not reported

Table 42. Screening Articles Reporting Longitudinal Results

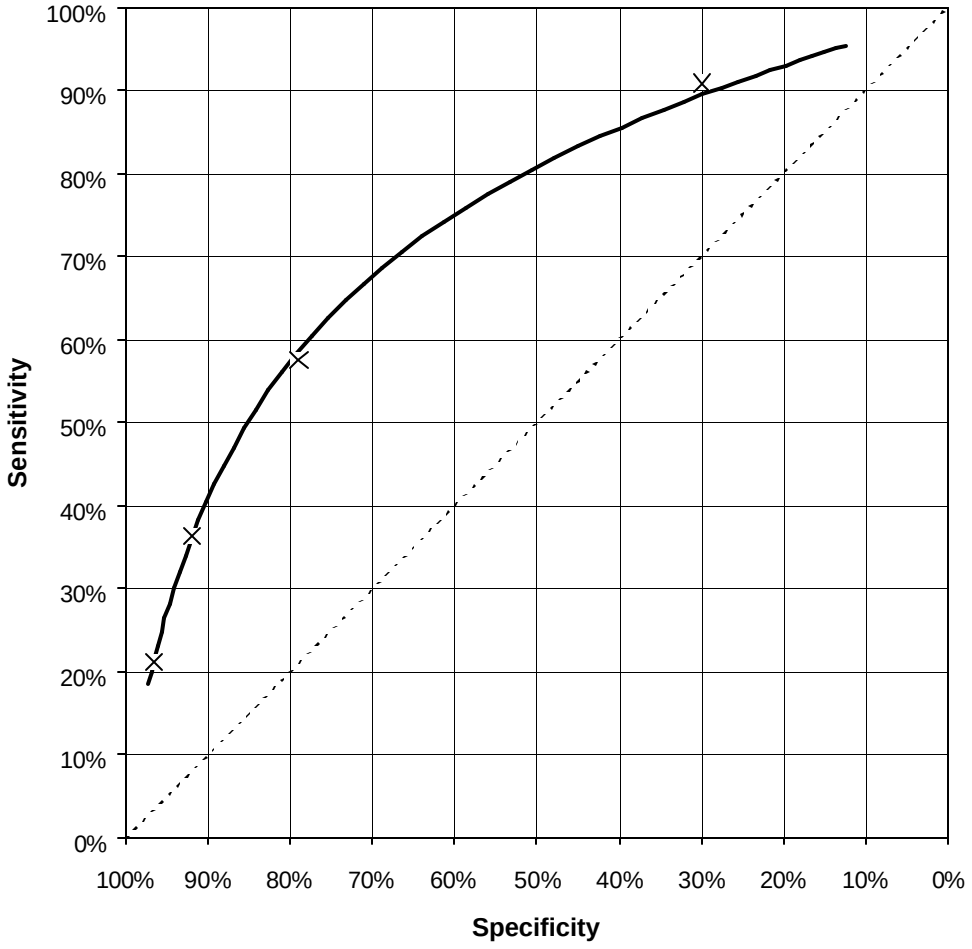
Article	N	Population	Selection	Followup
Kearns, 2000 [204]	45	Porkprocessors	Starting employment	42-83 days, mean 64
Nathan, 1998 [202] [203] [218]	283	Various manufacturing and clerical	Randomly-selected workers	11 years
Werner, 1997 [210]	NR, though over 700	Various manufacturing and clerical	NCS positive workers and matched controls	10 to 24 months
Johnson, 1993 [167]	184	Meat processors	Mostly new employees	Not reported, but few followed more than 3 months

Table 43. Prediction of Future CTS by Maximum Latency Difference

MLD result	Future CTS	No CTS	Threshold	Sensitivity	Specificity	PPV	NPV
<0.28 ms	3	129	0.28 ms	90.9% 76.1% 96.9%	29.9% 25.7% 34.5%	9.0% 6.4% 12.7%	97.7% 93.4% 99.2%
0.28–0.35 ms	11	211	0.36 ms	57.6% 40.5% 73.0%	78.9% 74.7% 82.5%	17.3% 11.2% 25.6%	96.0% 93.4% 97.7%
0.36–0.43 ms	7	56	0.44 ms	36.4% 22.0% 53.7%	91.9% 88.8% 94.1%	25.5% 15.1% 39.8%	95.0% 92.4% 96.7%
0.44–0.51 ms	5	20	0.52 ms	21.2% 10.5% 38.1%	96.5% 94.3% 97.9%	31.8% 16.1% 53.1%	94.1% 91.5% 96.0%
>0.51 ms	7	15					

Data from Nathan et al., 1998 [202]
Future CTS—Patients developed CTS during the 11-year followup periof
No CTS—Patients did not develop CTS during followup period.

Figure 15. Prediction of Future CTS by Maximum Latency Difference



Data from Nathan et al.[202]

Conclusions

The evidence base on most individual diagnostic tests for carpal tunnel syndrome is small, even though the total number of articles on CTS diagnosis is large (Table 19). This is because there are so many different tests that have been reported. Nerve conduction tests are most frequently reported in the literature, but there is great diversity in their methods, and one cannot conclude that one of these tests is effective based on clinical trial results for another test.

The most frequently reported nerve conduction tests were distal motor latency and palmar sensory latency. There were sufficient clinical trial articles available for us to meta-analyze their results and obtain estimates of their sensitivity sensitivities and specificites. For both tests, clinicians chose thresholds that yielded high specificity (a low incidence of false-positive results). ECRI's meta-analyses of distal motor latency studies found the sensitivity of the test to be 57% to 66% and the specificity to be 98%. The meta-analysis of palmar sensory latency studies found a sensitivity of 76% and a specificity of 98%.

Because all of the trials in these analyses used healthy asymptomatic persons as controls, the results of these analyses may overestimate the specificity of nerve conduction measurements in typical practice, where the test would be used on workers believed to be at risk for CTS or persons suspected of having CTS. There are not enough data to permit us to test the hypothesis that high specificity may be an effect of selection criteria for the control groups creating a control population unrepresentative of the population the test would be used on in routine practice: patients with suspected CTS.

Clinical signs and symptoms are also used in the diagnosis of CTS. The evidence base on these tests was smaller than the evidence base on nerve conduction measurement. Like nerve conduction tests, there were many different signs and symptoms reported in the literature, and one cannot infer a test's effectiveness based on the effectiveness of other tests. We attempted to use our meta-analysis techniques to obtain summary values for the sensitivity and specificity of Tinel's sign and Phalen's maneuver. In both cases, there was heterogeneity in the published results that could not be explained by differences in patient selection or by single outlier studies. Therefore, we did not calculate summary measurements for sensitivity or specificity. The sensitivity of Phalen's maneuver was lower than its specificity, and two trials reported sensitivity of 80% to 90%. All of the studies of Tinel's sign found that its sensitivity was lower than its specificity, and none found a sensitivity of 75 percent or greater. There was too much heterogeneity in the results for us to conclude that one test was superior to the other, or to compare these tests to nerve conduction testing.

Regarding sensory tests, composite nerve conduction tests, and imaging tests, there was insufficient evidence for us to perform meta-analyses of clinical trial results.

Analysis of tests for CTS screening and for early diagnosis of CTS is hampered by the lack of agreement by investigators on what those terms mean. We identified 28 articles described by their authors as "screening" studies, but only five of these studies provided longitudinal data. Most employed cross-sectional designs in which the authors evaluated the ability of other tests to identify subjects with abnormal nerve conduction.

One well-designed study by Nathan et al[202] suggests that nerve conduction measurement may be able to identify some workers at risk of developing CTS in the future. By itself, this evidence is not sufficient for us to conclude that nerve conduction screening for CTS is effective, but there could be sufficient unpublished results from this study to confirm the findings of the one reported test.

Table 44. Carpal Tunnel Syndrome–Study Design

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Finsen, 2001 [224]	☑	☐	☐	☑	☐	☐	Single	1	68	0	0	Prospective	Counts	No: thresholds not reported
Mondelli, 2001 [181]	☐	☐	☑	☐	☐	☑	Single	1	20	1	19	Not reported	Counts	Calculated by ECRI
Atroshi, 2000 [225]	☐	☐	☑	☐	☐	☐	Single	1	262	1	125	Prospective	Summary	No: only summary statistics reported
Bland, 2000 [200]	☑	☐	☐	☐	☐	☑	Single	1	8223	1	3533	Retrospective	Counts	Reported by authors
Cuturic, 2000 [226]	☐	☐	☑	☐	☐	☑	Single	1	19	1	16	Prospective	Patient level	Calculated by ECRI
Kearns, 2000 [204]	☐	☐	☑	☑	☐	☐	Single	1	45	0	0	Prospective	Summary	No: only summary statistics reported
Loscher, 2000 [175]	☐	☐	☑	☑	☐	☐	Single	2	NR	1	87	Prospective	Counts	Reported by authors
Montagna, 2000 [227]	☐	☐	☐	☐	☐	☑	Single	1	30	1	15	Not reported	Counts	Reported by authors
Nakamichi, 2000 [228]	☐	☐	☑	☐	☑	☐	Single	1	125	1	200	Not reported	Summary	No: only summary statistics reported
Raudino, 2000 [229]	☑	☐	☐	☐	☐	☐	Single	1	83	0	0	Not reported	Counts	Reported by authors
Resende, 2000 [184]	☐	☐	☑	☑	☐	☐	Single	1	32	1	20	Not reported	Patient level	Calculated by ECRI
Resende, 2000 [174]	☐	☐	☑	☐	☐	☐	Single	1	20	1	20	Not reported	Patient level	Calculated by ECRI
Sener, 2000 [186]	☑	☐	☑	☐	☐	☑	Single	1	31	1	21	Not reported	Counts	Calculated by ECRI
Seror, 2000 [158]	☐	☐	☑	☑	☐	☐	Single	1	20	1	20	Not reported	Counts	Reported by authors
Stalberg, 2000 [230]	☐	☐	☐	☑	☐	☐	Single	1	136	1	32	Not reported	Counts	Reported by authors
Weber, 2000 [108]	☑	☑	☐	☑	☐	☐	Single	1	53	1	26	Not reported	Counts	Reported by authors
Atroshi, 1999 [220]	☑	☐	☑	☑	☐	☐	Single	1	2466	0	0	Prospective	Counts	No: only one patient group
Burke, 1999 [231]	☑	☐	☑	☑	☐	☐	Multiple (<5)	1	186	0	0	Prospective	Counts	Calculated by ECRI
Duncan, 1999 [232]	☐	☐	☐	☐	☑	☐	Single	1	68	1	36	Prospective	Counts	Reported by authors
Kabiraj, 1999 [233]	☐	☐	☑	☑	☐	☐	Single	1	31	1	38	Not reported	Counts	Calculated by ECRI
Lee, 1999 [234]	☐	☐	☐	☐	☑	☐	Single	1	50	1	28	Prospective	Counts	Reported by authors
Missere, 1999 [205]	☐	☐	☑	☐	☑	☐	Single	1	45	0	0	Not reported	Counts	Reported by authors
Mongale, 1999 [235]	☐	☐	☐	☐	☑	☐	Single	1	8	2	16	Not reported	Summary	No: only summary statistics reported

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Murthy, 1999 [143]	☐	☐	☑	☑	☐	☑	Single	1	84	1	37	Not reported	Counts	Reported by authors
Rudolfer, 1999 [236]	☐	☐	☐	☑	☐	☐	Single	1	937	0	0	Retrospective	Counts	Calculated by ECRI
Sander, 1999 [237]	☐	☐	☑	☑	☐	☑	Single	1	59	1	34	Prospective	Counts	Reported by authors
Simovic, 1999 [183]	☐	☐	☑	☑	☐	☐	Single	2	66	1	19	Prospective	Counts	Reported by authors
Szabo, 1999 [152]	☑	☑	☑	☐	☐	☑	Single	1	50	2	100	Prospective	Counts	Reported by authors
Thonnard, 1999 [117]	☐	☑	☑	☑	☐	☑	Single	1	11	1	10	Prospective	Summary	No: only summary statistics reported
Wang, 1999 [238]	☐	☐	☑	☑	☐	☐	Single	1	12	1	12	Prospective	Summary	No: only summary statistics reported
Aurora, 1998 [239]	☐	☐	☑	☐	☐	☐	Single	1	19	1	20	Not reported	Summary	No: only summary statistics reported
Ferry, 1998 [221]	☑	☐	☑	☑	☐	☐	Single	1	648	0	0	Prospective	Counts	Reported by authors
Fertl, 1998 [153]	☑	☐	☑	☐	☐	☑	Single	1	47	1	20	Prospective	Counts	Reported by authors
Gerr, 1998 [31]	☑	☑	☑	☑	☐	☑	Single	1	60	1	59	Not reported	Counts	Reported by authors
Ghavanini, 1998 [154]	☑	☑	☑	☐	☐	☐	Single	1	74	1	58	Prospective	Counts	Reported by authors
Girlanda, 1998 [149]	☑	☐	☑	☑	☐	☐	Single	1	41	1	45	Not reported	Counts	Reported by authors
Kabiraj, 1998 [240]	☐	☐	☑	☑	☐	☐	Single	1	72	1	65	Retrospective	Summary	No: only summary statistics reported
Kleindienst, 1998 [241]	☐	☐	☐	☐	☑	☐	Single	1	77	1	18	Prospective	Summary	No: only summary statistics reported
Luchetti, 1998 [242]	☐	☐	☐	☐	☐	☑	Single	1	39	1	12	Not reported	Summary	No: only summary statistics reported
Nathan, 1998 [202]	☑	☐	☑	☑	☐	☐	Single	1	283	0	0	Prospective	Counts	No: only one patient group
Rosen, 1998 [201]	☐	☑	☐	☐	☐	☐	Single	2	34	1	60	Prospective	Counts	Reported by authors
Scelsa, 1998 [243]	☐	☐	☑	☐	☐	☐	Single	2	63	1	25	Prospective	Counts	Reported by authors
Seror, 1998 [159]	☐	☐	☑	☐	☐	☐	Single	1	85	1	80	Not reported	Counts	Reported by authors
Smith, 1998 [244]	☐	☐	☑	☐	☐	☐	Single	1	82	0	0	Prospective	Counts	Calculated by ECRI
Tan, 1998 [206]	☐	☐	☑	☐	☑	☐	Single	1	64	1	56	Not reported	Summary	No: only summary statistics reported
Terzis, 1998 [162]	☐	☐	☑	☐	☐	☐	Single	1	72	1	43	Not reported	Counts	Reported by authors
Tetro, 1998 [102]	☑	☑	☑	☐	☐	☑	Single	1	64	1	50	Prospective	Counts	Reported by authors
Werner, 1998 [207]	☑	☐	☑	☑	☐	☐	Multiple (>5)	1	727	0	0	Prospective	Counts	No: only one patient group
Wilson, 1998 [245]	☐	☐	☑	☑	☐	☐	Single	1	23	1	14	Not reported	Summary	No: only summary statistics reported
Bak, 1997 [246]	☐	☐	☐	☑	☑	☐	Single	1	20	0	0	Prospective	Counts	No: no control group
Brahme, 1997 [199]	☑	☐	☐	☐	☑	☐	Single	1	20	1	15	Prospective	Counts	Reported by authors

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Bronson, 1997 [163]	☐	☐	☑	☑	☐	☐	Single	1	22	1	16	Prospective	Patient level	Calculated by ECRI
Del Pino, 1997 [104]	☑	☐	☐	☐	☐	☐	Single	1	180	1	100	Prospective	Counts	Reported by authors
Dellon, 1997 [107]	☑	☑	☐	☐	☐	☐	Single	1	72	2	94	Not reported	Counts	No: inconsistent thresholds
Franzblau, 1997 [208]	☑	☐	☐	☐	☐	☐	Single	1	148	0	0	Prospective	Summary	No: only summary statistics reported
Guglielmo, 1997 [247]	☐	☐	☑	☑	☐	☐	Single	1	198	1	69	Prospective	Summary	No: only summary statistics reported
Gunnarsson, 1997 [248]	☑	☐	☑	☑	☐	☐	Single	1	100	0	0	Prospective	Counts	Reported by authors
Horch, 1997 [249]	☐	☐	☐	☐	☑	☐	Single	1	19	1	17	Not reported	Summary	No: only summary statistics reported
Jeng, 1997 [209]	☑	☑	☑	☑	☐	☑	Single	1	27	0	0	Prospective	Counts	Reported by authors
Kaneko, 1997 [250]	☐	☐	☑	☑	☐	☐	Single	1	15	3	66	Not reported	Summary	No: only summary statistics reported
King, 1997 [114]	☐	☑	☐	☐	☐	☐	Single	1	29	1	100	Not reported	Summary	No: only summary statistics reported
Pierre-Jerome, 1997 [251]	☐	☐	☑	☐	☑	☐	Single	1	27	1	28	Prospective	Summary	No: only summary statistics reported
Radack, 1997 [252]	☐	☐	☐	☐	☑	☐	Single	1	161	1	NR	Retrospective	Counts	Reported by authors
Rosecrance, 1997 [253]	☐	☐	☐	☑	☐	☑	Single	1	28	1	25	Not reported	Summary	No: only summary statistics reported
Simovic, 1997 [182]	☐	☐	☑	☑	☐	☐	Single	1	107	1	15	Retrospective	Counts	Reported by authors
Werner, 1997 [210]	☐	☐	☑	☑	☐	☐	Single	2	108	0	0	Retrospective	Counts	No: incomplete reporting
Andary, 1996 [196]	☐	☐	☑	☑	☐	☐	Single	1	81	1	17	Prospective	Counts	Reported by authors
Atroshi, 1996 [136]	☐	☐	☑	☐	☐	☐	Single	1	36	2	60	Prospective	Counts	Reported by authors
Bingham, 1996 [211]	☑	☐	☑	☑	☐	☐	Single	1	1021	0	0	Prospective	Counts	No: only one patient group
Checkosky, 1996 [254]	☐	☑	☐	☐	☐	☐	Single	1	24	1	20	Not reported	Patient level	Reported by authors
Cherniak, 1996 [190]	☐	☑	☑	☑	☐	☑	Single	1	49	1	10	Not reported	Counts	Reported by authors
Foresti, 1996 [192]	☐	☐	☑	☑	☐	☐	Single	1	100	1	25	Prospective	Counts	Reported by authors
Ghavanini, 1996 [255]	☐	☐	☑	☑	☐	☐	Single	1	50	1	50	Not reported	Summary	No: only summary statistics reported
Kleindienst, 1996 [256]	☐	☐	☐	☐	☑	☐	Single	1	55	1	18	Not reported	Counts	Reported by authors
Murata, 1996 [164]	☑	☐	☑	☑	☐	☐	Single	1	27	1	19	Not reported	Counts	Calculated by ECRI

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Padua, 1996 [165]	☐	☐	☑	☑	☐	☐	Single	1	43	1	36	Not reported	Counts	Reported by authors
Pierre-Jerome, 1996 [212]	☑	☐	☑	☐	☑	☐	Single	1	24	1	19	Prospective	Summary	No: only summary statistics reported
Britz, 1995 [257]	☑	☐	☑	☑	☑	☑	Single	1	32	1	5	Prospective	Patient level	No: results not reported for controls
De Smet, 1995 [101]	☑	☐	☐	☐	☐	☐	Single	2	50	2	55	Not reported	Counts	Reported by authors
Gerr, 1995 [118]	☐	☑	☐	☐	☐	☐	Single	2	60	1	59	Not reported	Counts	Reported by authors
Glass, 1995 [28]	☑	☐	☑	☐	☐	☐	Single	1	82	1	24	Not reported	Counts	Calculated by ECRI
Golovchinsky, 1995 [258]	☐	☐	☑	☑	☐	☑	Single	1	571	0	0	Retrospective	Counts	Reported by authors
Hamanaka, 1995 [259]	☐	☐	☑	☑	☐	☑	Single	2	647	1	31	Retrospective	Counts	Calculated by ECRI
Hansson, 1995 [137]	☐	☐	☑	☑	☐	☐	Single	2	30	1	10	Not reported	Counts	Reported by authors
Kothari, 1995 [260]	☐	☐	☑	☐	☐	☐	Single	1	59	1	30	Not reported	Summary	No: only summary statistics reported
Lang, 1995 [109]	☑	☑	☑	☐	☐	☑	Single	1	23	1	16	Prospective	Counts	Reported by authors
Lesser, 1995 [261]	☐	☐	☑	☑	☐	☑	Single	1	45	1	20	Not reported	Counts	Reported by authors
Nakamichi, 1995 [262]	☐	☐	☐	☐	☑	☐	Single	1	15	1	15	Not reported	Patient level	Calculated by ECRI
Seradge, 1995 [263]	☐	☐	☐	☐	☐	☑	Single	1	72	1	21	Not reported	Summary	No: only summary statistics reported
Seror, 1995 [179]	☐	☐	☑	☑	☐	☐	Single	3	75	1	40	Not reported	Counts	Reported by authors
Shafshak, 1995 [264]	☐	☐	☑	☐	☐	☑	Single	2	36	2	36	Not reported	Counts	No: no diagnostic results reported
Sheean, 1995 [191]	☐	☐	☑	☑	☐	☐	Single	1	49	1	NR	Not reported	Counts	Calculated by ECRI
Tassler, 1995 [115]	☐	☑	☐	☑	☐	☐	Single	1	14	1	13	Retrospective	Counts	Reported by authors
Valls-Sole, 1995 [265]	☐	☐	☑	☑	☐	☐	Single	1	18	1	15	Prospective	Summary	No: only summary statistics reported
Werner, 1995 [213]	☑	☑	☑	☑	☐	☐	Single	1	167	0	0	Not reported	Counts	Reported by authors
Young, 1995 [166]	☑	☑	☑	☐	☐	☐	Single	1	157	0	0	Prospective	Counts	No: only one patient group
Clifford, 1994 [266]	☐	☐	☑	☑	☐	☐	Single	1	20	1	10	Not reported	Summary	No: only summary statistics reported
Durkan, 1994 [267]	☑	☐	☐	☐	☐	☐	Single	1	30	1	25	Not reported	Counts	Calculated by ECRI
Franzblau, 1994 [113]	☑	☑	☑	☑	☐	☐	Single	1	83	0	0	Prospective	Counts	Reported by authors
Gerr, 1994 [197]	☑	☑	☐	☐	☐	☐	Single	2	NR	1	NR	Not reported	Counts	Reported by authors

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Kirschberg, 1994 [214]	☑	☐	☑	☑	☐	☐	Single	1	112	0	0	Retrospective	Counts	No: only one patient group
Kuntzer, 1994 [144]	☐	☐	☑	☑	☐	☑	Single	1	100	1	70	Prospective	Counts	Reported by authors
Nathan, 1994 [215]	☑	☐	☑	☑	☐	☐	Multiple (<5)	2	417	0	0	Retrospective	Counts	No: no control subjects
Nilsson, 1994 [216]	☐	☐	☑	☐	☐	☐	Single	3	175	0	0	Prospective	Counts	Reported by authors
Para, 1994 [103]	☑	☐	☑	☑	☐	☑	Single	2	51	1	12	Not reported	Counts	Reported by authors
Rossi, 1994 [178]	☐	☐	☑	☑	☐	☐	Single	1	62	1	27	Not reported	Counts	Reported by authors
Werner, 1994 [217]	☑	☑	☑	☑	☐	☐	Single	1	130	0	0	Prospective	Counts	Calculated by ECRI
Werner, 1994 [111]	☑	☐	☑	☑	☐	☐	Single	1	31	1	20	Not reported	Counts	Calculated by ECRI
Eisen, 1993 [193]	☐	☐	☑	☑	☐	☐	Single	1	NR	1	NR	Not reported	Counts	Reported by authors
Johnson, 1993 [167]	☑	☐	☑	☐	☐	☐	Single	1	184	0	0	Prospective	Summary	No: only summary statistics reported
Nakamichi, 1993 [268]	☐	☐	☐	☐	☑	☐	Single	1	128	0	0	Not reported	Counts	No: only one patient group
Nathan, 1993 [218]	☑	☐	☑	☑	☐	☐	Single	2	1125	1	45	Prospective	Counts	Reported by authors
Rodriquez, 1993 [269]	☐	☐	☑	☐	☐	☑	Single	1	10	1	8	Prospective	Patient level	Calculated by ECRI
Rosen, 1993 [270]	☐	☑	☑	☐	☐	☐	Single	2	62	2	71	Not reported	Counts	Calculated by ECRI
Rosén, 1993 [138]	☐	☐	☑	☑	☐	☐	Single	1	28	3	86	Not reported	Counts	Calculated by ECRI
Uncini, 1993 [160]	☐	☐	☑	☑	☐	☐	Single	1	70	1	47	Not reported	Counts	Reported by authors
Buchberger, 1992 [271]	☐	☐	☐	☐	☑	☐	Multiple (<5)	1	18	1	NR	Not reported	Counts	Reported by authors
Grant, 1992 [219]	☐	☑	☑	☐	☐	☐	Single	1	22	1	47	Not reported	Counts	Calculated by ECRI
Imaoka, 1992 [272]	☐	☐	☑	☐	☐	☐	Single	1	42	1	32	Not reported	Counts	Calculated by ECRI
Kindstrand, 1992 [273]	☐	☐	☐	☐	☐	☑	Single	1	94	1	127	Prospective	Patient level	Calculated by ECRI
Preston, 1992 [188]	☐	☐	☑	☑	☐	☐	Single	1	8	1	NR	Not reported	Counts	Calculated by ECRI
Tchou, 1992 [274]	☐	☐	☐	☐	☐	☑	Single	1	61	1	40	Not reported	Patient level	Reported by authors
Buchberger, 1991 [275]	☐	☐	☐	☐	☑	☐	Single	1	25	1	14	Not reported	Summary	No: only summary statistics reported

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Chang, 1991 [145]	☐	☐	☑	☑	☐	☐	Single	1	43	1	40	Not reported	Counts	Calculated by ECRI
Durkan, 1991 [155]	☑	☐	☐	☐	☐	☐	Single	1	31	1	50	Not reported	Counts	Reported by authors
Jetzer, 1991 [168]	☑	☑	☐	☐	☐	☑	Single	3	323	1	284	Prospective	Counts	No: no control subjects
Katz, 1991 [276]	☑	☑	☑	☑	☐	☑	Single	1	78	0	0	Not reported	Counts	Reported by authors
Lauritzen, 1991 [185]	☐	☐	☑	☑	☐	☑	Single	1	38	1	23	Not reported	Counts	Calculated by ECRI
Luchetti, 1991 [169]	☑	☐	☑	☑	☐	☐	Single	1	14	0	0	Retrospective	Patient level	No: only one patient group
Radwin, 1991 [116]	☐	☑	☐	☐	☐	☐	Single	1	12	1	15	Not reported	Patient level	No: no diagnostic threshols used
Charles, 1990 [170]	☐	☐	☑	☑	☐	☐	Single	1	158	2	90	Not reported	Counts	Reported by authors
De Krom, 1990 [222]	☑	☐	☑	☑	☐	☐	Single	1	50	0	0	Prospective	Counts	Calculated by ECRI
Fitz, 1990 [277]	☐	☐	☑	☑	☐	☐	Single	1	36	1	44	Not reported	Counts	Calculated by ECRI
Gilliatt, 1990 [278]	☐	☐	☑	☑	☐	☐	Single	1	10	1	15	Not reported	Counts	Calculated by ECRI
MacDonell, 1990 [90]	☐	☐	☑	☐	☐	☐	Single	1	34	1	12	Not reported	Counts	Reported by authors
Merchut, 1990 [279]	☐	☑	☑	☐	☐	☐	Single	1	23	1	54	Not reported	Counts	Reported by authors
Palliyath, 1990 [171]	☐	☐	☑	☐	☐	☐	Single	1	10	1	11	Not reported	Summary	No: only summary statistics reported
Pease, 1990 [177]	☐	☐	☑	☐	☐	☐	Single	1	21	1	16	Not reported	Counts	Calculated by ECRI
Rojviroj, 1990 [280]	☐	☑	☐	☐	☐	☐	Single	1	33	1	16	Prospective	Counts	Reported by authors
Tzeng, 1990 [180]	☐	☐	☑	☐	☐	☐	Single	1	84	1	50	Not reported	Counts	Calculated by ECRI
Uncini, 1990 [135]	☐	☐	☑	☑	☐	☐	Single	1	35	1	39	Not reported	Summary	No: only summary statistics reported
Winn, 1990 [281]	☐	☑	☐	☐	☐	☐	Single	2	61	0	0	Prospective	Summary	No: only summary statistics reported
Braun, 1989 [282]	☑	☑	☐	☐	☐	☐	Single	1	40	0	0	Not reported	Counts	No: no diagnostic thresholds reported
Cioni, 1989 [146]	☐	☐	☑	☑	☐	☐	Single	1	307	1	54	Not reported	Counts	Reported by authors
Jackson, 1989 [150]	☐	☐	☑	☑	☐	☑	Single	1	123	1	38	Not reported	Counts	Reported by authors
Meyers, 1989 [283]	☐	☐	☐	☐	☐	☑	Single	1	14	1	19	Not reported	Counts	Calculated by ECRI
So, 1989 [173]	☐	☐	☑	☐	☐	☑	Single	1	22	2	35	Not reported	Counts	Reported by authors
Szabo, 1989 [284]	☐	☑	☐	☐	☐	☐	Single	1	22	0	0	Not reported	Summary	No: only summary statistics reported
Uncini, 1989 [161]	☐	☐	☑	☑	☐	☐	Single	1	32	1	33	Not reported	Summary	No: only summary statistics reported
De Léan, 1988 [285]	☐	☐	☑	☐	☐	☐	Single	1	150	0	0	Not reported	Counts	Calculated by ECRI

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Koris, 1988 [198]	☑	☑	☐	☐	☐	☐	Single	1	21	1	15	Prospective	Counts	Reported by authors
Molitor, 1988 [110]	☑	☐	☐	☐	☐	☑	Single	1	19	1	NR	Not reported	Counts	Calculated by ECRI
Mortier, 1988 [286]	☐	☐	☑	☑	☐	☐	Single	1	116	1	102	Retrospective	Counts	Reported by authors
Pease, 1988 [287]	☐	☐	☑	☑	☐	☐	Single	1	25	1	23	Not reported	Summary	No: only summary statistics reported
Carroll, 1987 [288]	☐	☐	☑	☑	☐	☐	Single	1	101	1	50	Not reported	Counts	Reported by authors
Jessurun, 1987 [289]	☐	☐	☐	☐	☑	☐	Multiple (<5)	1	24	1	10	Not reported	Summary	No: only summary statistics reported
Johnson, 1987 [290]	☐	☐	☑	☑	☐	☐	Single	1	20	1	78	Not reported	Counts	Calculated by ECRI
Liang, 1987 [291]	☐	☐	☐	☐	☑	☐	Single	1	68	2	139	Not reported	Summary	No: only summary statistics reported
Macleod, 1987 [292]	☑	☐	☑	☐	☐	☐	Single	1	111	1	125	Not reported	Summary	No: only summary statistics reported
Seror, 1987 [156]	☑	☐	☐	☐	☐	☐	Single	1	62	1	20	Not reported	Counts	Reported by authors
Borg, 1986 [293]	☑	☑	☑	☐	☐	☐	Single	1	22	0	0	Not reported	Counts	Calculated by ECRI
Gellman, 1986 [106]	☑	☐	☑	☑	☐	☐	Single	1	NR	2	NR	Not reported	Counts	Reported by authors
Escobar, 1985 [151]	☐	☐	☑	☐	☐	☐	Single	1	23	1	55	Not reported	Counts	Calculated by ECRI
Kimura, 1985 [189]	☐	☐	☑	☑	☐	☑	Single	1	438	1	148	Not reported	Counts	Reported by authors
Mills, 1985 [194]	☐	☐	☑	☑	☐	☐	Single	1	47	2	49	Not reported	Counts	Calculated by ECRI
Borg, 1984 [294]	☐	☑	☐	☐	☐	☐	Single	3	45	0	0	Prospective	Patient level	Calculated by ECRI
Pryse-Phillips, 1984 [105]	☑	☐	☐	☐	☐	☐	Single	1	212	4	184	Retrospective	Counts	Reported by authors
Satoh, 1984 [295]	☑	☐	☑	☐	☐	☐	Single	1	14	0	0	Retrospective	Patient level	No: only one patient group
Szabo, 1984 [30]	☑	☑	☐	☐	☐	☐	Single	1	20	0	0	Prospective	Counts	No: only one patient group
Goddard, 1983 [296]	☐	☐	☑	☐	☐	☐	Single	1	24	1	49	Not reported	Counts	Calculated by ECRI
Kim, 1983 [195]	☐	☐	☑	☑	☐	☐	Single	1	39	1	33	Not reported	Counts	Reported by authors
Marin, 1983 [139]	☐	☐	☑	☑	☐	☐	Single	1	14	1	12	Not reported	Counts	Calculated by ECRI
Wongsam, 1983 [172]	☐	☐	☑	☐	☐	☐	Single	1	15	2	56	Not reported	Summary	No: only summary statistics reported
Johnson, 1981 [297]	☐	☐	☑	☑	☐	☐	Single	1	18	1	37	Not reported	Summary	No: only summary statistics reported

Article	SGN	SEN	NCS	CMP	IMG	OTH	Centers	CTS groups	CTS pts.	Neg. groups	Neg. subjects	Prospective or retrospective	Level of reporting	Could sensitivity & specificity be determined?
Dekel, 1980 [21]	☐	☐	☐	☐	☑	☐	Single	1	26	1	33	Prospective	Patient level	No: could not extract 2 x 2 counts from graph
Messina, 1980 [120]	☐	☐	☑	☑	☐	☐	Single	1	40	1	40	Not reported	Counts	Reported by authors
Gelmers, 1979 [29]	☑	☐	☑	☑	☐	☐	Single	1	47	1	43	Not reported	Counts	Reported by authors
Kimura, 1979 [140]	☐	☐	☑	☑	☐	☐	Single	1	105	1	61	Not reported	Counts	Calculated by ECRI
Schwartz, 1979 [187]	☐	☐	☑	☑	☐	☐	Single	1	20	1	10	Not reported	Counts	Calculated by ECRI
Stewart, 1978 [157]	☑	☐	☐	☐	☐	☐	Single	1	37	1	38	Not reported	Counts	Reported by authors
Eisen, 1977 [298]	☐	☐	☑	☑	☐	☐	Single	1	30	3	101	Not reported	Patient level	Calculated by ECRI
Sedal, 1973 [299]	☐	☐	☑	☐	☐	☐	Single	1	214	1	34	Retrospective	Counts	Reported by authors
Welch, 1973 [223]	☐	☑	☐	☐	☐	☐	Single	1	428	1	111	Not reported	Summary	No: only summary statistics reported
Casey, 1972 [300]	☐	☐	☑	☐	☐	☐	Single	1	16	2	112	Not reported	Patient level	Calculated by ECRI
Loong, 1972 [141]	☐	☐	☑	☑	☐	☐	Single	1	18	1	30	Not reported	Patient level	Calculated by ECRI
Melvin, 1972 [147]	☐	☐	☑	☐	☐	☐	Single	1	17	1	24	Not reported	Counts	Calculated by ECRI
Buchthal, 1971 [301]	☐	☐	☑	☐	☐	☑	Single	1	22	1	10	Not reported	Counts	Calculated by ECRI
Loong, 1971 [148]	☐	☐	☑	☑	☐	☐	Single	1	15	1	30	Not reported	Patient level	Calculated by ECRI
Plaja, 1971 [142]	☐	☐	☑	☐	☐	☑	Single	1	56	1	20	Retrospective	Counts	Reported by authors

Table 45. Carpal Tunnel Syndrome–Patient Groups

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Finsen, 2001 [224]	CTS	Unspecified diagnosis	68	74	48	21	86				Yes
Mondelli, 2001 [181]	Normal	Healthy volunteers	19	NR	51.9	31	72				No
Mondelli, 2001 [181]	CTS	Unspecified diagnosis	20	80	52.8	35	75				No
Atroshi, 2000 [225]	CTS	Symptoms/ presented	262	57	52						No
Atroshi, 2000 [225]	Normal	Healthy volunteers	125	55	51						No
Bland, 2000 [200]	CTS	Complex objective standard	4690	65	57						No
Bland, 2000 [200]	CTS	Symptoms/ presented	8223	66	53	10	98				No
Bland, 2000 [200]	Normal	Other	3533	67	49						No
Cuturic, 2000 [226]	CTS	Unspecified diagnosis	19	0	43	29	62				No
Cuturic, 2000 [226]	Normal	Healthy volunteers	16	0	41	26	58				No
Kearns, 2000 [204]	CTS	Workers at risk	45	4							Yes
Loscher, 2000 [175]	Normal	Healthy volunteers	87	NR	47	15	86				No
Loscher, 2000 [175]	CTS	Unspecified diagnosis		NR							No
Loscher, 2000 [175]	CTS	Other		NR							No
Montagna, 2000 [227]	Cubital tunnel syndrome	Unspecified diagnosis	10	NR							No
Montagna, 2000 [227]	Normal	Healthy volunteers	15	NR							No
Montagna, 2000 [227]	CTS	Unspecified diagnosis	30	NR							No
Nakamichi, 2000 [228]	CTS	Simple nerve conduction	125	100	56	40	70				No
Nakamichi, 2000 [228]	Normal	Healthy volunteers	200	NR	57	40	70				No
Raudino, 2000 [229]	CTS	Complex objective standard	83	82	48.9	19	82	26.9	1	180	Yes
Resende, 2000 [174]	CTS	Unspecified diagnosis	20	NR							No
Resende, 2000 [174]	Normal	Healthy volunteers	20	NR		21	55				No
Resende, 2000 [184]	Normal	Healthy volunteers	20	100	36	20	54				No
Resende, 2000 [184]	CTS	Unspecified diagnosis	32	100	44	25	59				No
Sener, 2000 [186]	CTS	Symptoms/ presented	31	NR	46	26	70				Yes

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Sener, 2000 [186]	Normal	Healthy volunteers	21	NR	38	18	60				Yes
Seror, 2000 [158]	Normal	Healthy volunteers	20	75	43	20	67				No
Seror, 2000 [158]	CTS	Complex objective standard	20	75	47	32	76				No
Stalberg, 2000 [230]	CTS	Symptoms/ presented	136	NR							No
Stalberg, 2000 [230]	Normal	Healthy volunteers	32	NR		21	62				No
Weber, 2000 [108]	CTS	Symptoms/ presented	53	79	45						No
Weber, 2000 [108]	Normal	Healthy volunteers	26	85	37						No
Burke, 1999 [231]	CTS	Symptoms/ presented	186	NR							No
Atroshi, 1999 [220]	Normal	Other	2466	NR							No
Duncan, 1999 [232]	CTS	Complex objective standard	68	74	54						Yes
Duncan, 1999 [232]	CTS	Complex objective standard		NR							Yes
Duncan, 1999 [232]	Normal	Healthy volunteers	36	64	44						Yes
Kabiraj, 1999 [233]	Normal	Healthy volunteers	38	50		20	79				No
Kabiraj, 1999 [233]	CTS	Complex objective standard	31	68		28	85				No
Lee, 1999 [234]	Normal	Healthy volunteers	28	54		22	47				No
Lee, 1999 [234]	CTS	Unspecified diagnosis	50	74		32	81				No
Missere, 1999 [205]	CTS	Workers at risk	45	0	37.7						No
Mongale, 1999 [235]	Normal	Healthy volunteers	9	100	39	26	50				No
Mongale, 1999 [235]	Normal	Healthy volunteers	7	0	39	27	58				No
Mongale, 1999 [235]	CTS	Unspecified diagnosis	8	100	43	24	54				No
Murthy, 1999 [143]	CTS	Symptoms/ presented	84	NR							No
Murthy, 1999 [143]	Normal	Healthy volunteers	37	NR							No
Rudolfer, 1999 [236]	CTS	Symptoms/ presented	937	NR							No
Sander, 1999 [237]	Normal	Healthy volunteers	34	NR	41	26	71				No
Sander, 1999 [237]	CTS	Complex objective standard	59	NR	49	29	73				No
Simovic, 1999 [183]	CTS	Other	12	NR							Yes
Simovic, 1999 [183]	Normal	Healthy volunteers	19	63	40	25	68				Yes
Simovic, 1999 [183]	CTS	Unspecified diagnosis	54	NR							Yes

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Szabo, 1999 [152]	Normal	Healthy volunteers	50	66		18	59				No
Szabo, 1999 [152]	CTS	Complex objective standard	50	76		20	73		2	240	No
Szabo, 1999 [152]	Unrelated disease	Other	50	80		28	72		0	180	No
Thonnard, 1999 [117]	CTS	Unspecified diagnosis	11	73	52						No
Thonnard, 1999 [117]	Normal	Healthy volunteers	11	73	53						No
Wang, 1999 [238]	CTS	Complex objective standard	12	92	46	30	65				No
Wang, 1999 [238]	Normal	Healthy volunteers	12	42	37	28	59				No
Aurora, 1998 [239]	CTS	Symptoms/ presented	19	NR	52.8						No
Aurora, 1998 [239]	Normal	Healthy volunteers	20	NR	32.9						No
Ferry, 1998 [221]	Normal	Other	648	56	46.9						No
Fertl, 1998 [153]	Normal	Healthy volunteers	20	60	42	25	77				No
Fertl, 1998 [153]	CTS	Symptoms/ presented	47	83	55.5	21	78				No
Gerr, 1998 [31]	Normal	Healthy volunteers	59	69	38.2						No
Gerr, 1998 [31]	CTS	Symptoms/ presented	60	72	46.6						No
Ghavanini, 1998 [154]	CTS	Complex objective standard	26	100	37	20	50	9	1	36	No
Ghavanini, 1998 [154]	CTS	Symptoms/ presented	74	81	40	20	50	15	1	60	No
Ghavanini, 1998 [154]	Normal	Healthy volunteers	58	76	36.7	20	50				No
Ghavanini, 1998 [154]	CTS	Complex objective standard	26	69	41	20	50	19.4	1	48	No
Ghavanini, 1998 [154]	CTS	Complex objective standard	22	73	42	30	50	19	4	60	No
Girlanda, 1998 [149]	CTS	Symptoms/ presented	41	93	39	24	65	48	1	180	Yes
Girlanda, 1998 [149]	Normal	Healthy volunteers	45	NR							Yes
Kabiraj, 1998 [240]	CTS	Symptoms/ presented	72	NR							No
Kabiraj, 1998 [240]	Normal	Healthy volunteers	65	45	39.8	20	75				No
Kleindienst, 1998 [241]	CTS	Complex objective standard		NR							No
Kleindienst, 1998 [241]	CTS	Other		NR							No
Kleindienst, 1998 [241]	CTS	Complex objective standard		NR							No
Kleindienst, 1998 [241]	CTS	Other		NR							No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Kleindienst, 1998 [241]	Normal	Healthy volunteers	18	83	51	43	59				No
Kleindienst, 1998 [241]	CTS	Complex objective standard		NR							No
Kleindienst, 1998 [241]	CTS	Unspecified diagnosis	77	82	54	22	79				No
Luchetti, 1998 [242]	CTS	Unspecified diagnosis	39	79	31	26	45				No
Luchetti, 1998 [242]	Normal	Healthy volunteers	12	83	27	24	36				No
Nathan, 1998 [202]	CTS	Workers at risk	283	45	35.2						No
Rosen, 1998 [201]	Normal	Healthy volunteers	60	NR							No
Rosen, 1998 [201]	CTS	Workers at risk	20	5	46	26	65				No
Rosen, 1998 [201]	CTS	Unspecified diagnosis	14	100	53	33	78				No
Scelsa, 1998 [243]	CTS	Other	21	48	46	10	69				No
Scelsa, 1998 [243]	CTS	Unspecified diagnosis	42	76	50	25	85				No
Scelsa, 1998 [243]	Normal	Healthy volunteers	25	44	42	23	63				No
Seror, 1998 [159]	CTS	Unspecified diagnosis	85	74	46	25	83				No
Seror, 1998 [159]	Normal	Healthy volunteers	80	64	42	22	68				No
Smith, 1998 [244]	CTS	Symptoms/ presented	82	61	44	17	88	14	1	120	No
Tan, 1998 [206]	CTS	Workers at risk	64	63		22	28				No
Tan, 1998 [206]	Normal	Healthy volunteers	56	57		21	29				No
Terzis, 1998 [162]	CTS	Unspecified diagnosis	72	92	49.6						No
Terzis, 1998 [162]	Normal	Healthy volunteers	43	84	48.3						No
Tetro, 1998 [102]	Normal	Healthy volunteers	50	74	46.9	22	79				No
Tetro, 1998 [102]	CTS	Complex objective standard	64	64	49.3	21	83				No
Werner, 1998 [207]	CTS	Workers at risk	727	54	42	25	69				Yes
Wilson, 1998 [245]	Normal	Healthy volunteers	14	NR	52	33	76				No
Wilson, 1998 [245]	CTS	Complex objective standard	23	NR	59	24	76				No
Bak, 1997 [246]	CTS	Symptoms/ presented	20	55							Yes
Brahme, 1997 [199]	CTS	Unspecified diagnosis	20	90	37	21	61				No
Brahme, 1997 [199]	Normal	Healthy volunteers	15	47	35	22	60				No
Bronson, 1997 [163]	Normal	Other	16	56	29.5	21	44				Yes

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Bronson, 1997 [163]	CTS	Unspecified diagnosis	22	73	34.4	21	59				Yes
Del Pino, 1997 [104]	Normal	Healthy volunteers	100	78	49	37	67				No
Del Pino, 1997 [104]	CTS	Complex objective standard	180	81	50	16	84	37.9	1	216	No
Dellon, 1997 [107]	CTS	Unspecified diagnosis	72	NR							Yes
Dellon, 1997 [107]	Cubital tunnel syndrome	Unspecified diagnosis	42	NR							Yes
Dellon, 1997 [107]	Normal	Other	52	62							Yes
Franzblau, 1997 [208]	CTS	Workers at risk	148	57	44.2						Yes
Guglielmo, 1997 [247]	CTS	Symptoms/ presented	198	60	46	13	84				No
Guglielmo, 1997 [247]	Normal	Healthy volunteers	69	57	40.3	20	86				No
Gunnarsson, 1997 [248]	CTS	Symptoms/ presented	100	NR							No
Horch, 1997 [249]	Normal	Healthy volunteers	17	71	43.4	24	58				No
Horch, 1997 [249]	CTS	Simple nerve conduction	19	63	49.7	25	67				No
Jeng, 1997 [209]	CTS	Workers at risk	27	52	40.2	23	57				No
Kaneko, 1997 [250]	CTS	Unspecified diagnosis	15	87		40	54				Yes
Kaneko, 1997 [250]	Normal	Healthy volunteers	46	22		25	45				Yes
Kaneko, 1997 [250]	Cubital tunnel syndrome	Unspecified diagnosis	10	20		45	56				Yes
Kaneko, 1997 [250]	Combined WRUEDs	Unspecified diagnosis	10	50		40	62				Yes
King, 1997 [114]	CTS	Unspecified diagnosis	29	62							No
King, 1997 [114]	Normal	Healthy volunteers	100	50							No
Pierre-Jerome, 1997 [251]	Normal	Healthy volunteers	28	100	45.1	26	67				No
Pierre-Jerome, 1997 [251]	CTS	Simple nerve conduction	27	100	51.9	16	78	36	12	72	No
Radack, 1997 [252]	CTS	Complex objective standard		NR							No
Radack, 1997 [252]	Normal	Unrelated disease		NR							No
Radack, 1997 [252]	CTS	Symptoms/ presented	161	53	37.4	13	86				No
Rosecrance, 1997 [253]	CTS	Complex objective standard	20	70	41.5			[a]32			No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Rosecrance, 1997 [253]	CTS	Complex objective standard	10	60	39.9			[a]14			No
Rosecrance, 1997 [253]	Normal	Healthy volunteers	25	28	38.8						No
Rosecrance, 1997 [253]	CTS	Complex objective standard	28	NR							No
Simovic, 1997 [182]	Normal	Healthy volunteers	15	NR		18	70				No
Simovic, 1997 [182]	CTS	Unspecified diagnosis	107	61	51	19	86				No
Werner, 1997 [210]	CTS	Workers at risk	59	64	40.1						No
Werner, 1997 [210]	Normal	Simple nerve conduction	49	67	41.7						No
Andary, 1996 [196]	Normal	Healthy volunteers	17	NR	36						No
Andary, 1996 [196]	CTS	Symptoms/ presented	81	NR	42						No
Atroshi, 1996 [136]	Normal	Healthy volunteers	30	57	36	25	62				Yes
Atroshi, 1996 [136]	CTS	Symptoms/ presented	36	69	52	20	87	[a]24	1	120	Yes
Atroshi, 1996 [136]	Normal	Healthy volunteers	30	70	40	19	65				Yes
Bingham, 1996 [211]	CTS	Workers at risk	1021	29	30.1	17	60				No
Checkosky, 1996 [254]	Normal	Healthy volunteers	10	70		25	44				No
Checkosky, 1996 [254]	Normal	Healthy volunteers	20	75		25	67				No
Checkosky, 1996 [254]	CTS	Symptoms/ presented	12	83		45	70				No
Checkosky, 1996 [254]	CTS	Symptoms/ presented	24	79	46.7	27	70				No
Checkosky, 1996 [254]	Normal	Healthy volunteers	10	80		46	67				No
Checkosky, 1996 [254]	CTS	Symptoms/ presented	12	75		27	45				No
Cherniak, 1996 [190]	Normal	Healthy volunteers	10	70	37.1	26	52				No
Cherniak, 1996 [190]	CTS	Symptoms/ presented	49	33	43	19	71				No
Foresti, 1996 [192]	Normal	Healthy volunteers	25	28	42	18	69				Yes
Foresti, 1996 [192]	CTS	Symptoms/ presented	100	25	49	27	78				Yes
Ghavanini, 1996 [255]	CTS	Unspecified diagnosis	50	82	38.6	27	59				Yes
Ghavanini, 1996 [255]	Normal	Healthy volunteers	50	78	28.7	20	42				Yes
Kleindienst, 1996 [256]	CTS	Other	55	82	54						No
Kleindienst, 1996 [256]	Normal	Healthy volunteers	18	83	51						No
Murata, 1996 [164]	Normal	Healthy volunteers	19	100	24	19	31				Yes

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Murata, 1996 [164]	CTS	Workers at risk	27	100	25	19	37				Yes
Padua, 1996 [165]	Normal	Healthy volunteers	36	69	43.7	19	79				No
Padua, 1996 [165]	CTS	Symptoms/ presented	43	72	45.2	23	80	27	2	48	No
Pierre-Jerome, 1996 [212]	CTS	Workers at risk	24	100	44	26	59				Yes
Pierre-Jerome, 1996 [212]	Normal	Other	19	100	39.5	25	44				Yes
Britz, 1995 [257]	CTS	Unspecified diagnosis	32	NR							No
Britz, 1995 [257]	Normal	Healthy volunteers	0	NR							No
De Smet, 1995 [101]	CTS	Simple nerve conduction	10	70	42.8	22	53				No
De Smet, 1995 [101]	Normal	Healthy volunteers	46	100	51	34	76				No
De Smet, 1995 [101]	Normal	Other	9	100							No
De Smet, 1995 [101]	CTS	Symptoms/ presented	40	93	50.8	23	77				No
Gerr, 1995 [118]	Symptomatic /normal NCS	Complex objective standard	30	60	43.9						No
Gerr, 1995 [118]	CTS	Complex objective standard	30	83	50.1						No
Gerr, 1995 [118]	Normal	Healthy volunteers	59	69	38.2						No
Glass, 1995 [28]	CTS	Symptoms/ presented	82	77		23	69				No
Glass, 1995 [28]	Normal	Contralateral arm	26	NR							No
Glass, 1995 [28]	Normal	Healthy volunteers	24	58		24	69				No
Golovchinsky, 1995 [258]	Combined WRUEDs	Unspecified diagnosis	571	49	45.2	22	86				No
Hamanaka, 1995 [259]	CTS	Unrelated disease	31	39	37.9	18	67				Yes
Hamanaka, 1995 [259]	CTS	Unspecified diagnosis	647	61	53.9	21	87				Yes
Hansson, 1995 [137]	CTS	Symptoms/ presented	20	95	45	31	60	[a]9	2	120	Yes
Hansson, 1995 [137]	Normal	Healthy volunteers	10	90	45	26	65	[a]9	2	120	Yes
Hansson, 1995 [137]	CTS	Complex objective standard	10	100	57	41	79	[a]9	2	120	Yes
Kothari, 1995 [260]	CTS	Symptoms/ presented	59	75	50	22	91				No
Kothari, 1995 [260]	Normal	Healthy volunteers	30	70	36	21	70				No
Lang, 1995 [109]	CTS	Unspecified diagnosis	23	78	51.4			[a]36	12	420	No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Lang, 1995 [109]	Normal	Healthy volunteers	16	63	55						No
Lesser, 1995 [261]	Normal	Healthy volunteers	20	40	36	22	50				No
Lesser, 1995 [261]	CTS	Complex objective standard	45	73	52	27	79				No
Nakamichi, 1995 [262]	CTS	Unspecified diagnosis	15	100	53.9	50	58				Yes
Nakamichi, 1995 [262]	Normal	Healthy volunteers	15	100	54.4	50	58				Yes
Seradge, 1995 [263]	CTS	Unspecified diagnosis	72	75	45.6	18	80				No
Seradge, 1995 [263]	Normal	Unrelated disease	21	52		20	74				No
Seror, 1995 [179]	Normal	Healthy volunteers	40	70	53						No
Seror, 1995 [179]	CTS	Unspecified diagnosis	25	80	56						No
Seror, 1995 [179]	CTS	Unspecified diagnosis	25	84	52						No
Seror, 1995 [179]	CTS	Unspecified diagnosis	25	84	55						No
Shafshak, 1995 [264]	CTS	Complex objective standard	25	52		22	40				Yes
Shafshak, 1995 [264]	Other	Other	11	27		23	51				Yes
Shafshak, 1995 [264]	Normal	Healthy volunteers	25	52	42	18	57				Yes
Shafshak, 1995 [264]	CTS	Unspecified diagnosis	11	100		27	53				Yes
Sheean, 1995 [191]	CTS	Symptoms/ presented	49	71	56.2	29	84				No
Sheean, 1995 [191]	Normal	Healthy volunteers		NR		22	59				No
Tassler, 1995 [115]	Cubital tunnel syndrome	Unspecified diagnosis	13	NR							Yes
Tassler, 1995 [115]	CTS	Unspecified diagnosis	14	NR							Yes
Valls-Sole, 1995 [265]	CTS	Complex objective standard	18	100		34	53		6	144	No
Valls-Sole, 1995 [265]	Normal	Healthy volunteers	15	87		25	51				No
Werner, 1995 [213]	CTS	Workers at risk	167	NR							No
Young, 1995 [166]	CTS	Workers at risk	157	82	39.9	20	64				No
Clifford, 1994 [266]	CTS	Symptoms/ presented	20	100	43.1						No
Clifford, 1994 [266]	Normal	Healthy volunteers	10	NR	26.7						No
Durkan, 1994 [267]	CTS	Unspecified diagnosis	30	43	52	21	88				No
Durkan, 1994 [267]	Normal	Healthy volunteers	25	NR							No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Franzblau, 1994 [113]	CTS	Workers at risk	83	53	33.8						No
Gerr, 1994 [197]	Normal	Healthy volunteers		NR	38						No
Gerr, 1994 [197]	CTS	Complex objective standard		NR	43						No
Gerr, 1994 [197]	CTS	Complex objective standard		NR	50						No
Kirschberg, 1994 [214]	CTS	Workers at risk	112	85	33.3						No
Kuntzer, 1994 [144]	Normal	Healthy volunteers	70	60	43	25	70				No
Kuntzer, 1994 [144]	CTS	Symptoms/ presented	100	80	51	26	85				No
Nathan, 1994 [215]	CTS	Workers at risk	316	47	40.4						No
Nathan, 1994 [215]	CTS	Workers at risk	101	26	38.6						No
Nilsson, 1994 [216]	CTS	Workers at risk	58	0	24.6						No
Nilsson, 1994 [216]	CTS	Workers at risk	61	0	37.4						No
Nilsson, 1994 [216]	CTS	Workers at risk	56	0	32.4						No
Para, 1994 [103]	CTS	Symptoms/ presented	24	71	51.6	26	62				No
Para, 1994 [103]	CTS	Symptoms/ presented	27	70	48.6	28	60				No
Para, 1994 [103]	Normal	Healthy volunteers	12	58	36.6	17	55				No
Rossi, 1994 [178]	CTS	Unspecified diagnosis	62	84	49.4	22	63				No
Rossi, 1994 [178]	Normal	Healthy volunteers	27	67	44.6	22	62				No
Werner, 1994 [217]	CTS	Workers at risk	130	56	34						No
Werner, 1994 [111]	CTS	Symptoms/ presented	31	NR							No
Werner, 1994 [111]	Normal	Healthy volunteers	20	NR							No
Eisen, 1993 [193]	CTS	Symptoms/ presented		NR							Yes
Eisen, 1993 [193]	Normal	Healthy volunteers		NR							Yes
Johnson, 1993 [167]	CTS	Workers at risk	184	NR							No
Nakamichi, 1993 [268]	CTS	Unspecified diagnosis	128	74	54	33	86				No
Nathan, 1993 [218]	Normal	Healthy volunteers	45	47	19.8						No
Nathan, 1993 [218]	CTS	Workers at risk	388	63	39.4						No
Nathan, 1993 [218]	CTS	Workers at risk	737	28	42.4						No
Rodriquez, 1993 [269]	Normal	Healthy volunteers	8	38	40.3	23	82				No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Rodriquez, 1993 [269]	CTS	Unspecified diagnosis	10	80	43.8	22	83				No
Rosen, 1993 [270]	Normal	Healthy volunteers	21	48	33.6	20	50				No
Rosen, 1993 [270]	Normal	Healthy volunteers	50	0	41.5	27	63				No
Rosen, 1993 [270]	CTS	Symptoms/ presented	47	0	42.8	23	63				No
Rosen, 1993 [270]	CTS	Symptoms/ presented	15	80	37.9	26	53				No
Rosén, 1993 [138]	Normal	Healthy volunteers	15	60	34	21	46				No
Rosén, 1993 [138]	Normal	Other	50	0	41.5	27	63				No
Rosén, 1993 [138]	CTS	Unspecified diagnosis	28	75	41	26	77				No
Rosén, 1993 [138]	Normal	Healthy volunteers	21	48	33.6	20	50				No
Uncini, 1993 [160]	Normal	Healthy volunteers	47	72	44.7	18	78				No
Uncini, 1993 [160]	CTS	Simple nerve conduction	70	86	49.3	26	78				No
Buchberger, 1992 [271]	Normal	Healthy volunteers		NR							No
Buchberger, 1992 [271]	CTS	Unspecified diagnosis	18	78	57	23	82				No
Grant, 1992 [219]	CTS	Complex objective standard	22	NR		22	71				Yes
Grant, 1992 [219]	Normal	Healthy volunteers	47	100		16	65				Yes
Grant, 1992 [219]	CTS	Workers at risk		NR							Yes
Grant, 1992 [219]	CTS	Symptoms/ presented		NR							Yes
Imaoka, 1992 [272]	CTS	Unspecified diagnosis	42	79	50.3	20	76				Yes
Imaoka, 1992 [272]	Normal	Healthy volunteers	32	59	49.2	24	76				Yes
Kindstrand, 1992 [273]	Normal	Other	127	65	47.5	15	84				Yes
Kindstrand, 1992 [273]	CTS	Complex objective standard	94	73	50	19	95		1	121	Yes
Preston, 1992 [188]	Normal	Healthy volunteers		NR	31	18	50				Yes
Preston, 1992 [188]	CTS	Other	8	NR							Yes
Preston, 1992 [188]	CTS	Symptoms/ presented		NR	49	21	98				Yes
Tchou, 1992 [274]	CTS	Unspecified diagnosis	61	NR							No
Tchou, 1992 [274]	Normal	Healthy volunteers	40	50		22	45				No
Buchberger, 1991 [275]	Normal	Healthy volunteers	14	64							No
Buchberger, 1991 [275]	CTS	Symptoms/ presented	25	68	61	38	85				No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Chang, 1991 [145]	Normal	Healthy volunteers	40	NR	38.6	22	60				Yes
Chang, 1991 [145]	CTS	Symptoms/ presented	43	79	42.3	25	64				Yes
Durkan, 1991 [155]	CTS	Complex objective standard	31	74	45	22	79				No
Durkan, 1991 [155]	Normal	Healthy volunteers	50	NR							No
Jetzer, 1991 [168]	CTS	Workers at risk	100	NR							No
Jetzer, 1991 [168]	CTS	Workers at risk	284	NR							No
Jetzer, 1991 [168]	CTS	Workers at risk	39	NR							No
Jetzer, 1991 [168]	Normal	Healthy volunteers	284	NR							No
Katz, 1991 [276]	CTS	Symptoms/ presented	78	63	43.4						Yes
Lauritzen, 1991 [185]	CTS	Unspecified diagnosis	38	68	53						Yes
Lauritzen, 1991 [185]	Normal	Healthy volunteers	23	NR							Yes
Luchetti, 1991 [169]	CTS	Unspecified diagnosis	14	93	41	21	64	31.3	2	120	Yes
Radwin, 1991 [116]	CTS	Unspecified diagnosis	12	58		29	60				No
Radwin, 1991 [116]	Normal	Healthy volunteers	15	NR	34.5	25	67				No
Charles, 1990 [170]	Other	Other	30	60	45.5	25	63				Yes
Charles, 1990 [170]	Normal	Healthy volunteers	60	80	45	23	76				Yes
Charles, 1990 [170]	CTS	Unspecified diagnosis	158	84	47.1	20	64				Yes
De Krom, 1990 [222]	Normal	Other	50	86							No
Fitz, 1990 [277]	Normal	Healthy volunteers	44	NR	30	22	66				No
Fitz, 1990 [277]	CTS	Complex objective standard	36	NR	52	25	88				No
Gilliatt, 1990 [278]	CTS	Unspecified diagnosis	10	NR	44						No
Gilliatt, 1990 [278]	Normal	Healthy volunteers	15	NR	42						No
MacDonell, 1990 [90]	CTS	Complex objective standard	34	NR	44	29	67				No
MacDonell, 1990 [90]	Normal	Healthy volunteers	12	NR	41	26	61				No
Merchut, 1990 [279]	Normal	Healthy volunteers	54	NR	53						No
Merchut, 1990 [279]	CTS	Symptoms/ presented	23	87	53	25	74				No
Palliyath, 1990 [171]	Normal	Healthy volunteers	11	NR	31						No
Palliyath, 1990 [171]	CTS	Unspecified diagnosis	10	NR	42	30	50				No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Pease, 1990 [177]	Normal	Healthy volunteers	16	NR		21	63				No
Pease, 1990 [177]	CTS	Unspecified diagnosis	21	NR							No
Rojviroj, 1990 [280]	CTS	Complex objective standard	33	76	46.5	19	67	19	1	120	No
Rojviroj, 1990 [280]	Normal	Healthy volunteers	16	25							No
Tzeng, 1990 [180]	CTS	Unspecified diagnosis	84	70	48	21	67				No
Tzeng, 1990 [180]	Normal	Healthy volunteers	50	56	46	20	65				No
Uncini, 1990 [135]	Normal	Healthy volunteers	39	NR	54	16	81				No
Uncini, 1990 [135]	CTS	Complex objective standard	35	80	49	28	68			8	No
Winn, 1990 [281]	CTS	Other	34	NR							No
Winn, 1990 [281]	CTS	Symptoms/ presented	27	NR							No
Braun, 1989 [282]	CTS	Symptoms/ presented	40	80	38						Yes
Cioni, 1989 [146]	Normal	Healthy volunteers	54	65	38.3	18	68				No
Cioni, 1989 [146]	CTS	Symptoms/ presented	307	16	46.4	20	72				No
Jackson, 1989 [150]	CTS	Symptoms/ presented	123	82	52.6	21	85				Yes
Jackson, 1989 [150]	Normal	Healthy volunteers	38	76	42.2	21	66				Yes
Meyers, 1989 [283]	Normal	Healthy volunteers	19	53	36	22	60				No
Meyers, 1989 [283]	CTS	Unspecified diagnosis	14	64	51	36	68				No
So, 1989 [173]	Normal	Healthy volunteers	20	NR							No
So, 1989 [173]	Cubital tunnel syndrome	Unspecified diagnosis	15	NR							No
So, 1989 [173]	CTS	Unspecified diagnosis	22	NR							No
Szabo, 1989 [284]	CTS	Unspecified diagnosis	22	73	51	24	79	29	7	120	Yes
Uncini, 1989 [161]	CTS	Symptoms/ presented	32	NR							No
Uncini, 1989 [161]	Normal	Healthy volunteers	33	55		16	81				No
De Léan, 1988 [285]	CTS	Simple signs/symptoms	150	73	47.6	18	84	31	1	144	Yes
Koris, 1988 [198]	CTS	Unspecified diagnosis	21	86	60	28	85		1	120	Yes
Koris, 1988 [198]	Normal	Healthy volunteers	15	NR		28	40				Yes
Molitor, 1988 [110]	CTS	Symptoms/ presented	19	NR							No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Molitor, 1988 [110]	Normal	Healthy volunteers		NR	49	23	79				No
Mortier, 1988 [286]	CTS	Simple nerve conduction	116	67	49.2	20	82				No
Mortier, 1988 [286]	Normal	Healthy volunteers	102	67	47.5	22	86				No
Pease, 1988 [287]	Normal	Healthy volunteers	23	NR		21	62				No
Pease, 1988 [287]	CTS	Unspecified diagnosis	25	NR							No
Carroll, 1987 [288]	CTS	Symptoms/ presented	101	76	44.8	22	82				No
Carroll, 1987 [288]	Normal	Healthy volunteers	50	48	46.7	16	82				No
Jessurun, 1987 [289]	Normal	Healthy volunteers	10	50							No
Jessurun, 1987 [289]	CTS	Unspecified diagnosis	24	88							No
Johnson, 1987 [290]	Normal	Healthy volunteers	78	NR		20	79				Yes
Johnson, 1987 [290]	CTS	Complex objective standard	20	NR							Yes
Liang, 1987 [291]	CTS	Other	10	100							No
Liang, 1987 [291]	CTS	Unspecified diagnosis	68	79	50	24	73				No
Liang, 1987 [291]	Normal	Contralateral arm	39	67							No
Liang, 1987 [291]	Normal	Healthy volunteers	100	50	45	20	69				No
Liang, 1987 [291]	CTS	Other	28	82							No
Liang, 1987 [291]	CTS	Other	20	90							No
Liang, 1987 [291]	CTS	Other	20	65							No
Liang, 1987 [291]	CTS	Other	58	76							No
Macleod, 1987 [292]	CTS	Simple nerve conduction	111	NR							No
Macleod, 1987 [292]	Normal	Healthy volunteers	26	58	39	17	63				No
Macleod, 1987 [292]	Normal	Healthy volunteers	125	52	41	17	82				No
Seror, 1987 [156]	CTS	Symptoms/ presented	62	79	56.8	29	85				No
Seror, 1987 [156]	Normal	Healthy volunteers	20	75	55.7	34	79				No
Borg, 1986 [293]	CTS	Symptoms/ presented	22	82	45.5			33			No
Gellman, 1986 [106]	CTS	Complex objective standard		NR							Yes
Gellman, 1986 [106]	Normal	Healthy volunteers		NR							Yes
Gellman, 1986 [106]	Other	Other		NR							Yes

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Escobar, 1985 [151]	CTS	Symptoms/ presented	23	70		22	55				Yes
Escobar, 1985 [151]	Normal	Healthy volunteers	55	64		20	70				Yes
Kimura, 1985 [189]	Normal	Healthy volunteers	148	54	47.6	20	81				No
Kimura, 1985 [189]	CTS	Symptoms/ presented	438	65	51.4	18	85				No
Mills, 1985 [194]	CTS	Symptoms/ presented	47	77		29	74		0	60	No
Mills, 1985 [194]	Normal	Healthy volunteers	29	45		19	63				No
Mills, 1985 [194]	Normal	Other	20	50		19	75				No
Borg, 1984 [294]	CTS	Unspecified diagnosis	21	NR							No
Borg, 1984 [294]	CTS	Other	12	NR							No
Borg, 1984 [294]	CTS	Unspecified diagnosis	12	NR							No
Pryse-Phillips, 1984 [105]	Other	Complex objective standard	44	NR							No
Pryse-Phillips, 1984 [105]	Cubital tunnel syndrome	Complex objective standard	67	NR							No
Pryse-Phillips, 1984 [105]	CTS	Complex objective standard	212	NR							No
Pryse-Phillips, 1984 [105]	Other	Complex objective standard	41	NR							No
Pryse-Phillips, 1984 [105]	Other	Complex objective standard	32	NR							No
Satoh, 1984 [295]	CTS	Complex objective standard	14	100							No
Szabo, 1984 [30]	CTS	Unspecified diagnosis	20	50		32	81		2	180	No
Goddard, 1983 [296]	CTS	Unspecified diagnosis	24	NR							No
Goddard, 1983 [296]	Normal	Healthy volunteers	49	NR							No
Kim, 1983 [195]	Normal	Healthy volunteers	33	NR	41.3	20	68				No
Kim, 1983 [195]	CTS	Symptoms/ presented	39	NR							No
Marin, 1983 [139]	CTS	Unspecified diagnosis	14	86	49	23	79	13	1	24	No
Marin, 1983 [139]	Normal	Healthy volunteers	12	42	30	22	48				No
Wongsam, 1983 [172]	DM with peripheral neuropathy	Unrelated disease	6	NR							No
Wongsam, 1983 [172]	CTS	Symptoms/ presented	15	NR							No

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Wongsam, 1983 [172]	Normal	Healthy volunteers	50	56		20	68				No
Johnson, 1981 [297]	CTS	Unspecified diagnosis	18	NR							No
Johnson, 1981 [297]	Normal	Healthy volunteers	37	49							No
Dekel, 1980 [21]	Normal	Healthy volunteers	33	58	40.3						No
Dekel, 1980 [21]	CTS	Unspecified diagnosis	26	100							No
Messina, 1980 [120]	CTS	Symptoms/ presented	40	NR	45.1	19	67				No
Messina, 1980 [120]	Normal	Healthy volunteers	40	NR	47.5						No
Gelmers, 1979 [29]	Normal	Healthy volunteers	43	79	54	26	74				No
Gelmers, 1979 [29]	CTS	Complex objective standard	47	81	57	29	78				No
Kimura, 1979 [140]	CTS	Unspecified diagnosis	105	70	48	20	78				No
Kimura, 1979 [140]	Normal	Unrelated disease	61	57	43	15	50				No
Schwartz, 1979 [187]	CTS	Symptoms/ presented	20	85	52	27	77				No
Schwartz, 1979 [187]	Normal	Healthy volunteers	10	100		20	28				No
Stewart, 1978 [157]	CTS	Complex objective standard	37	81	55	36	84				Yes
Stewart, 1978 [157]	Normal	Healthy volunteers	38	79	53	30	84				Yes
Eisen, 1977 [298]	Cubital tunnel syndrome	Complex objective standard	18	NR	51.7	26	65				No
Eisen, 1977 [298]	Normal	Healthy volunteers	60	NR	41.5	11	74				No
Eisen, 1977 [298]	Combined WRUEDs	Other	23	NR	50	7	68				No
Eisen, 1977 [298]	CTS	Complex objective standard	30	NR	56.1	21	76				No
Sedal, 1973 [299]	Normal	Healthy volunteers	34	NR	47	18	77				Yes
Sedal, 1973 [299]	CTS	Complex objective standard	214	56	54	19	87				Yes
Welch, 1973 [223]	Other	Other	111	NR							No
Welch, 1973 [223]	Combined WRUEDs	Workers at risk	428	81							No
Casey, 1972 [300]	CTS	Unspecified diagnosis	16	94	55.9	35	70				Yes
Casey, 1972 [300]	Other	Other	18	33	53.5	30	77	178	72	444	Yes

Article	Disorder type	Patient selection	N patients	% female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (months)	Shortest duration (months)	Longest duration (months)	Are patient comorbidities reported?
Casey, 1972 [300]	Normal	Healthy volunteers	94	NR	51	20	80				Yes
Loong, 1972 [141]	Normal	Healthy volunteers	30	100		30	60				No
Loong, 1972 [141]	CTS	Unspecified diagnosis	18	100	43.7	31	60	12.7	1	48	No
Melvin, 1972 [147]	CTS	Symptoms/ presented	17	NR							No
Melvin, 1972 [147]	Normal	Healthy volunteers	24	NR							No
Buchthal, 1971 [301]	Normal	Healthy volunteers	10	50		32	57				No
Buchthal, 1971 [301]	CTS	Other	22	73		29	67			360	No
Loong, 1971 [148]	Normal	Healthy volunteers	30	100		30	60				Yes
Loong, 1971 [148]	CTS	Symptoms/ presented	15	100		31	60	7.6	1	24	Yes
Plaja, 1971 [142]	Normal	Healthy volunteers	20	NR							No
Plaja, 1971 [142]	CTS	Unspecified diagnosis	56	NR							No

[a]Reported median age instead of mean age
CTS—Carpal tunnel syndrome
DM—Diabetes mellitus

Table 46. Carpal Tunnel Syndrome–Reported Inclusion and Exclusion Criteria

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Finsen, 2001 [224]	Positive clinical diagnosis of carpal tunnel syndrome	Patients for whom the clinical diagnosis was considered equivocal. If more than one hand was treated, only the first was included.
Mondelli, 2001 [181]	Idiopathic CTS with reduction of distal conduction velocity of the median nerve. Unilateral CTS.	None reported
Atroshi, 2000 [225]	Respondents to a random survey who reported numbness and/or tingling in at least two radial fingers at least twice a week for previous four weeks	Previous CTS surgery, resolution of symptoms, symptoms not consistent with CTS, unwilling to take test
Bland, 2000 [200]	All patients in county referred for NCS with suspected CTS, also patients with other referrals who then had a positive NCS	None (authors report 100% inclusion)
Cuturic, 2000 [226]	Sensory symptoms and abnormal NCS, limited to mild or moderate disease	Certain EMG abnormalities (authors do not specify that these were in fact exclusion criteria--just that no patients had them)
Kearns, 2000 [204]	Pork processing employees who had worked for at least 2 months.	Pre-existing CTS or diabetes.
Loscher, 2000 [175]	Referred to the laboratory for neurophysiological assessment of median nerve	Traumatic nerve lesions
Montagna, 2000 [227]	Diagnosed with carpal tunnel syndrome or cubital tunnel syndrome.	None reported
Nakamichi, 2000 [228]	DML >4.2 ms and SCV >45 m/s	None reported
Raudino, 2000 [229]	Referred to lab. All were complaining of discomfort, paresthesias, or weakness in the territory of the median nerve occurring especially at night or after repetitive actions and relieved by changes in posture or shaking hands. Abnormal nerve conduction test as defined by one of the following three abnormalities: 1) DML >4 ms; 2) antidromic DSL to index finger >3 ms; wrist-to-palm sensory latency >1.8 ms for patients <45 years old or >2 ms for patients older than 45.	Metabolic diseases, radiculopathies, polyneuropathies, concomitant pathologies.
Resende, 2000 [184]	Clinical diagnosis of carpal tunnel syndrome and abnormal conventional motor and sensory conduction studies	None reported
Resende, 2000 [174]	Diagnosed with carpal tunnel syndrome by clinical and electrophysiological methods with conventional techniques. Normal bilateral sensory conduction studies of the ulnar nerve.	None reported
Sener, 2000 [186]	Symptoms and clinical signs suggesting carpal tunnel syndrome.	Peripheral nerve dysfunction or peripheral neuropathy other than CTS
Seror, 2000 [158]	Diagnosis of mild CTS	None reported
Stalberg, 2000 [230]	Patients referred to the lab with the presumptive diagnosis of carpal tunnel syndrome.	None reported
Weber, 2000 [108]	Suspected of having carpal tunnel syndrome.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Atroshi, 1999 [220]	Randomly selected from the population of Sweden.	Did not respond to mailed questionnaire, did not attend clinical exam, previous carpal tunnel surgery, declined nerve conduction testing, neurologic disease
Burke, 1999 [231]	Referred for splinting	None reported
Duncan, 1999 [232]	Positive NCS (decreased median SCV or prolonged DML) or two physicians agreeing that the symptoms and history are consistent with CTS. Did not give specific criteria for either.	Previous surgery or anatomic variation in the median nerve
Kabiraj, 1999 [233]	DML >4.02 m/sec [sic] (mean + 2 SD), MCV <47.57 m/s (mean – 2 SD), CMAP decreased by 1 SD, prolonged or absent median sensory action potential. Painful paresthesia with night worsening, appropriate distribution, thenar weakness, positive Tinel, positive Phalen.	None reported
Lee, 1999 [234]	Clinical diagnosis of CTS.	None reported
Missere, 1999 [205]	Male workers in a meat processing plant	None reported
Mongale, 1999 [235]	Diagnosed with carpal tunnel syndrome via NCS.	None reported
Murthy, 1999 [143]	Referred for electrodiagnostic evaluation for paresthesia	None reported
Rudolfer, 1999 [236]	Patients in database referred to electromyographer.	Non-CTS abnormality.
Sander, 1999 [237]	Both clinical and electrophysiological diagnosis of carpal tunnel. 1) Clinical: Two or more of the following primary symptoms in a median nerve distribution: numbness, tingling, clumsiness, or nocturnal symptom exacerbation. If only one of these symptoms was present, two of the following secondary symptoms were required: burning/cold, tightness, sore/ache/discomfort, or puffiness. 2) Electrodiagnostic confirmation: one of the following three abnormalities: A) an absent median palm-wrist mixed nerve action potential latency. B) a median palm-wrist mixed nerve action potential latency >1.7ms, C) if this same latency exceed the ipsilateral ulnar palm-wrist latency by more than 0.3ms.	Carpal tunnel patients: excluded if a history or physical exam suggestive of a neuromuscular disorder other than carpal tunnel syndrome.
Simovic, 1999 [183]	Referred to laboratory with hand or arm complaints including but not limited to numbness, tingling, or pain	Diabetes or the clinical or electrophysiological suggestion of a concomitant peripheral nerve disorder
Szabo, 1999 [152]	Diagnosed CTS	None reported
Thonnard, 1999 [117]	Severe CTS: small or absent sensory amplitude, DSL and DML >5 ms, and evidence of denervation in APB	Other (non-CTS) electrodiagnostic abnormalities

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Wang, 1999 [238]	Symptoms and at least 2 of the following 5 NCS criteria: 1) DML >4.2 ms 2) DSL to index >3.5 ms 3) Difference between median and ulnar mixed nerve latencies = 0.4 ms 4) Difference between median and ulnar sensory latency to ring finger = 0.5 ms 5) Difference between median motor latency to 2nd lumbrical and ulnar motor latency to first palmar interosseous = 0.5 ms	Additional neuromuscular disease, polyneuropathy, cervical radiculopathy, severe CTS, atypical histories.
Aurora, 1998 [239]	Referred to lab with clinically definite carpal tunnel syndrome.	None reported
Ferry, 1998 [221]	All participants were registered to receive primary care at a local general practice.	None reported
Fertl, 1998 [153]	Referred with pain	Polyneuropathy, ulnar nerve lesion, radiculopathy, arthropathy
Gerr, 1998 [31]	Any patient 18-70 years old with symptoms of pain, weakness, numbness, or tingling in the cutaneous distribution of the median nerve	Electrophysiological tests positive for a disorder other than CTS.
Ghavanini, 1998 [154]	Symptoms of CTS	Conditions other than CTS
Girlanda, 1998 [149]	Symptomatic hands with clinical evidence of idiopathic CTS. Examples of symptoms: nocturnal or activity-related pain and paresthesia in the hand, Phalen's, hypaesthesia limited to the distribution of the median nerve. Mild CTS required: No weakness or muscle atrophy present, DML in all patients was never slower than 4.0 ms which represented 2.5 SD below mean of controls in this laboratory.	Known causes of entrapment neuropathies or systemic diseases. Cervical radiculopathy, brachial plexopathy, thoracic outlet syndrome, multi-polyneuropathies.
Kabiraj, 1998 [240]	Patients had the following symptoms and signs: history of pain, numbness, paresthesia, nocturnal awakening due to pain and weakness with or without atrophy, decreased sensations, Tinel's signs and wrist flexion Phalen's signs	Evidence of peripheral neuropathy other than median nerve dysfunction
Kleindienst, 1998 [241]	Clinical diagnosis of CTS	None reported
Luchetti, 1998 [242]	Idiopathic CTS, defined as night pain and/or paresthesia, and median nerve sensory deficits. Motor deficits not required.	Diabetes, uremia, polyneuropathy, history of wrist trauma
Nathan, 1998 [202]	Industrial workers in four industries: steel mill workers, food processors, electronics workers, and plastics workers.	Previous carpal tunnel release surgery.
Rosen, 1998 [201]	Carpal tunnel patients: Clinically diagnosed. Vibration-exposure patients Symptomatic, with exposure to hand-held vibrating tools.	None reported
Scelsa, 1998 [243]	Clinically definite CTS as defined by: symptoms of numbness, paresthesia or pain in median nerve distribution and at least one of the following: hand clumsiness, nocturnal hand symptoms, sensory loss, weakness on exam in an appropriate median nerve distribution. Normal ulnar sensory and motor conduction studies	Cervical radicular pain or objective signs of cervical radiculopathy, or clinical evidence of polyneuropathy, or electrophysiological evidence of ulnar neuropathy

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Seror, 1998 [159]	Intermittent symptoms of burning, tingling, and paresthesia in the radial digits especially at night or upon awakening. Also patients had normal classical electrodiagnostic tests, i.e., DML to APB <4ms and palm-to-wrist orthodromic sensory conduction velocity >45m/s	None reported
Smith, 1998 [244]	Referred with suspected CTS	None reported
Tan, 1998 [206]	Working as carpet weaver	None reported
Terzis, 1998 [162]	CTS patients: Median distal motor latency required to be less than 4.2 ms. 18 months after the study, confirmation of CTS by sensory nerve latency on either digit 2 or digit 3 of >3ms.	Any history of peripheral nerve problems. Any other pathology, screened out by ulnar nerve and palmar stimulation studies
Tetro, 1998 [102]	CTS symptoms including median distribution of pain and paresthesia. Positive NCS including abnormal DML or DSL or DML 1.0 ms more than contralateral or DSL 0.5 ms more than contralateral	Proximal entrapment symptoms, thoracic outlet syndrome, acute CTS, paralysis, negative NCS (n = 7)
Werner, 1998 [207]	Workers were selected to be representative of a range of jobs typically found in contemporary manufacturing and clerical sites.	None reported
Wilson, 1998 [245]	Presence of carpal tunnel syndrome	History of significant hand trauma, or peripheral neuropathy, or radiculopathy, or Martin-Gruber anastomosis
Bak, 1997 [246]	Suspected CTS	Diabetes, severe renal disease, pregnancy within the last year, previously treated CTS, contraindications to MRI, polyneuropathy.
Brahme, 1997 [199]	Diagnosed by hand surgeon with work-related dynamic carpal tunnel syndrome (indicating that symptoms only occurred during repetitive motion).	None reported
Bronson, 1997 [163]	Patients: Pre-surgery, DML <4 ms, normal needle EMG of APB. Included in this group based on traditional clinical indications, as judged by physicians. Controls: positive Tinel's sign, but no symptoms. Negative on standard sensory and motor nerve conduction tests.	Diabetes, rheumatoid arthritis, hypothyroidism, cervical spine disease, pregnancy, cervical radiculopathy.
Del Pino, 1997 [104]	All of the following three criteria for diagnosis of CTS: 1) Symptoms of CTS, consisting of pain predominantly at night, paresthesias and dysaesthesias, numbness, sensory deficit in the territory of the median nerve, and weakness of the APB; 2) Abnormal sensitivity in the median nerve distribution compared to the ulnar territory of the same hand and/or cutaneous territory of the contralateral median nerve in cases of unilateral involvement; 3) Complete relief of pain and paresthesias within 15 days of open surgical release of the carpal tunnel.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Dellon, 1997 [107]	Already diagnosed with either carpal tunnel syndrome or cubital tunnel syndrome. Diagnosis was based on the clinical history and physical examination, which included positive provocative testing, positive Tinel's sign at the wrist or elbow, abnormal tuning fork perception.	Cervical radiculopathy, diabetes, thoracic outlet syndrome, thyroid disease, collagen vascular disease, using narcotics or antidepressants.
Franzblau, 1997 [208]	At least 6 months' tenure in jobs at a spark plug manufacturing plant	None reported
Guglielmo, 1997 [247]	Typical signs and symptoms of carpal tunnel syndrome (based on American Academy of Neurology Quality Standards Subcommittee)	None reported
Gunnarsson, 1997 [248]	Referred to lab with suspected CTS	Neuropathies
Horch, 1997 [249]	Surgical candidates with symptoms of CTS and median motor latency >4 ms	None reported
Jeng, 1997 [209]	Volunteers from food processing plant.	History of peripheral neuropathy, fractures, severe burns, arthritis, diabetes, carpal tunnel surgery
Kaneko, 1997 [250]	Group 01: Coexisting entrapment neuropathy and cervical cord compression demonstrated by MRI. Group 02: Diagnosed with carpal tunnel syndrome. Group 03: Diagnosed with cubital tunnel syndrome. Group 04: Control group, no subjective symptoms or neurologic findings associated with peripheral or central lesions.	None reported
King, 1997 [114]	CTS as confirmed by EMG or NCS. New referrals.	None reported
Pierre-Jerome, 1997 [251]	Typical signs and symptoms, DML >4.5 ms or sensory velocity <45 m/s	Previous surgery, comorbidity with "somatic connective tissue diseases" (radiculopathy?), alcoholism
Radack, 1997 [252]	All wrist MRI examinations, regardless of indication	None
Rosecrance, 1997 [253]	Recent (within two weeks) numbness and tingling, or one of those plus any two of: burning/cold, tightness, pain, symptoms worsening at night. Must have involved median nerve distribution (thumb to medial aspect of ring finger).	Disorders with similar presentation to CTS.
Simovic, 1997 [182]	1) Referral to laboratory for possible carpal tunnel syndrome; and 2) Completion of a median motor study including distal and proximal stimulation, sensory antidromic median conduction to the index finger, and mixed nerve median and ulnar conduction studies with palmar stimulation	1) Clinical symptoms or signs of other peripheral nerve disorders of the same limb. 2) Diabetes mellitus 3) Insufficient chart data
Werner, 1997 [210]	DSL prolonged by 0.5 ms or more, but asymptomatic	None reported
Andary, 1996 [196]	Referred to lab because of pain or numbness in the hand and wrist with histories and physical exam consistent with the possible diagnosis of CTS. Median antidromic sensory latency to index finger was required to be <4.0 ms to rule out "clear cut" CTS. Other nerve conduction tests (unspecified), however, were required to be positive.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Atroshi, 1996 [136]	Symptoms and signs consistent with carpal tunnel syndrome. Unsuccessful prior nonoperative treatment.	None reported
Bingham, 1996 [211]	All new applicants who had been offered jobs at meat packing, plastics assembly, food processing, furniture manufacturing, or grocery warehousing in a 17 county area in the southeastern US over an 18 month period. Applicants had worked for an average of 4.4 years in various settings.	None reported
Checkosky, 1996 [254]	Physician-diagnosed CTS	None reported
Cherniak, 1996 [190]	Referred to lab.	None reported
Foresti, 1996 [192]	Patients with suspected carpal tunnel referred to the laboratory	Other pathologies potentially causing polyneuropathy such as diabetes, iperuremia, acromegaly, etc.
Ghavanini, 1996 [255]	Paresthesia or numbness in fingers, and nocturnal hand pain or paresthesia, and excessive hand sweating or coldness, and positive Tinel sign or Phalen sign.	Diabetes, rheumatoid arthritis, thyroid dysfunction, history of trauma to neck or hands, cervical spondylosis, pregnancy, hand edema, obesity
Kleindienst, 1996 [256]	Pre-operative	None reported
Murata, 1996 [164]	Data entry operators.	None of the patients complained of nocturnal awakening with paresthesia or pain in hands, none had positive Tinel's sign or positive Phalen's sign. Also excluded prior pregnancy, occupational exposure to neurotoxic substances, endocrine disorders, neurological disorders, diabetes, acromegaly, myxedema, lupus, amyloidosis, rheumatoid arthritis, alcoholic dependency, hand injury, forearm injury.
Padua, 1996 [165]	Paresthesia, pain, hypotrophy of thenar eminence	Other neuropathies or signs of severe CTS (i.e., absence of SNAP at wrist).
Pierre-Jerome, 1996 [212]	Cleaners: Worked for at least three consecutive years and at least 19 hours a week.	Systemic diseases and psychiatric disorders including alcoholism.
Britz, 1995 [257]	select group of patients who had been clinically diagnosed as having CTS	None reported
De Smet, 1995 [101]	Presented as surgical candidate	None reported
Gerr, 1995 [118]	Age 18-70 with any hand symptoms	None reported
Glass, 1995 [28]	CTS symptoms	None reported
Golovchinsky, 1995 [258]	Referred to lab with complaints of neck pain and/or pain, numbness, or weakness in upper extremities.	Obvious injuries of the wrist, diabetes, hypothyroidism, renal failure.
Hamanaka, 1995 [259]	Clinical diagnosis of CTS based on symptoms, sensory disturbance of the median nerve distribution area, Tinel's sign, Phalen's sign, manual muscle testing, and APB atrophy. Carpal canal pressure in resting position >15 mm Hg or carpal canal pressure in power active flex >135 mmHg.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Hansson, 1995 [137]	Typical history (defined by sensory or motor symptoms like intermittent paresthesias, numbness, pain and weakness in the domain of the median nerve)	Diabetes, polyneuropathy, or rheumatic disease
Kothari, 1995 [260]	Clinical diagnosis of CTS, including arm or wrist pain, paresthesia or other median distribution symptoms, weakness, Tinel's, or Phalen's and positive NCS	Signs or symptoms of neuropathy
Lang, 1995 [109]	1) CTS-typical signs and symptoms; 2) DML >4.5 ms or orthodromic SCV palm-to-wrist <45 m/s 3) planned surgical treatment	Previous surgery on the same hand
Lesser, 1995 [261]	Typical signs and symptoms of carpal tunnel syndrome, AND one or more of the following: 1) median distal motor latency >4.4ms, 2)median sensory antidromic latency to peak >3.5ms, 3) median sensory palm to wrist latency at least 0.4ms longer than that latency for the analogous segment of the ulnar nerve.	Peripheral neuropathy or multiple mononeuropathy
Nakamichi, 1995 [262]	Clinical and electrophysiological diagnosis of bilateral CTS. Clinical evaluation included the presence of typical sensory symptoms, Phalen's test, two-point discrimination, muscle testing, and thenar atrophy. Electrophysiological criteria were either DML >4.2 ms or SCV <45 m/s.	Rheumatoid arthritis, chronic renal failure under hemodialysis, endocrine or metabolic disorders including diabetes, gout, amyloidosis, or hypothyroidism, Colles fracture, ganglion, calcium deposition, and osteoarthritis.
Seradge, 1995 [263]	None reported	None reported
Seror, 1995 [179]	Referred to lab based on a clinical diagnosis of carpal tunnel syndrome: Intermitted paresthesia, numbness, tingling, or hypoesthesia in the median nerve distribution, with nocturnal aggravation, with or without pain in the hand, wrist, and forearm, and rarely for thenar muscle atrophy.	None reported
Shafshak, 1995 [264]	Group 001: Positive Phalen's, positive Tinel's, DSL >4 ms, DML >4.7 ms, but normal ulnar nerve conduction studies Group 002: Definite polyneuropathy, DML >4.7 ms, slowed MCV at the forearm. Group 003: Severe unilateral CTS based on clinical findings, and unobtainable DML and DSL, but normal ulnar nerve conduction.	None reported
Sheean, 1995 [191]	Referred to lab based on suspected CTS.	None reported
Tassler, 1995 [115]	Symptomatic patients who had been diagnosed, had not been cured by nonoperative methods, and later received surgery for the condition.	Diabetes, alcoholism, other toxicity.
Valls-Sole, 1995 [265]	Referred to lab, and all of the following:1) Slowing of MCV in wrist to palm and normal DML to thenar and normal CV elbow to wrist2) Normal CMAP amplitude from wrist or elbow stimulation3) Slow median SCV from palm to wrist, but no reduced SNAP amplitude4) Normal ulnar SCV5) No significant limitation of joint movement because of pain, skin or joint diseases or fat.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Werner, 1995 [213]	Employees at an automobile parts manufacturing plant and a furniture assembly plant in southern Michigan.	None reported
Young, 1995 [166]	Workers at a poultry processing plant.	None reported
Clifford, 1994 [266]	Referred to lab from family physicians, rheumatologists, and neurologists. Symptoms of CTS (e.g. pain, numbness, tingling). Screening history and physical exam to ensure the referring diagnosis of CTS was warranted.	Peripheral neuropathy, or obvious entrapment other than the median nerve.
Durkan, 1994 [267]	Symptoms of CTS, particularly in median nerve distribution	None reported
Franzblau, 1994 [113]	Full-time employees of an automobile parts manufacturing plant which had reported problems with upper extremity cumulative trauma disorders.	None reported
Gerr, 1994 [197]	Referred to lab, age 18-70 with symptoms of pain, weakness, numbness, or tingling that involved either hand.	None reported
Kirschberg, 1994 [214]	Employees in repetitive jobs in the poultry industry who were referred to a neurologist with pain, numbness, or tingling.	None reported
Kuntzer, 1994 [144]	If patient reported a combination of hand and arm symptoms suggestive of CTS, with numbness, tingling, pins and needles, "sleeping" of the hands and fingers, nocturnal symptoms or clumsiness, weakness, puffiness, swelling, tightness, joint pain or aching of the hand or fingers.	Patients: Two were excluded due to absent distal reflexes in the lower extremities. Controls: Two were excluded due to presence of symptoms of CTS, or pregnancy.
Nathan, 1994 [215]	Japanese furniture factory workers. American workers from four industries.	None reported
Nilsson, 1994 [216]	Currently working as a platers, truck assembler, or office worker. Male, age <54, randomly selected from larger groups for participation in the study. Platers were required to be currently exposed to vibration, and were selected for nerve conduction based on consecutive cases.	None reported
Para, 1994 [103]	Paresthetic CTS: Has CTS, has normal distal motor latency. Slight CTS: Has CTS, has abnormal distal motor latency. Controls: no current or past subjective complaints about upper extremities and an entirely normal neurological exam.	None reported
Rossi, 1994 [178]	History and symptoms typical of idiopathic CTS. Reduction of median nerve SCV in one or more of the digit-wrist segments studied, with normal values of ulnar and radial nerve sensory conduction.	Working at manual jobs. None had signs or history of cervical radiculopathy or peripheral neuropathy.
Werner, 1994 [217]	Employees at an automobile parts manufacturing plant that had reported a significant problem with CTS. Consent to testing.	Significant exposures to vibration or low temperature.
Werner, 1994 [111]	Referred for evaluation of CTS, must have median nerve symptoms	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Eisen, 1993 [193]	One of three groups: 1) Clinical for CTS. Symptoms and clinical signs. Examinations included Tinel's and Phalen's, but these were not required for diagnosis of CTS; 2) Historical for CTS. Symptoms: pain, sensory discomfort, or numbness in the hand, nocturnal awakening because of hand pain, clumsiness and loss of dexterity; 3) Uncertain. Vague complaints without nocturnal awakening and no loss of hand dexterity, and normal neurological exam.	1) Clinical or electrophysiological evidence of other upper limb neuropathy such as proximal median neuropathy, ulnar neuropathy, or cervical radiculopathy. 2) Historical or clinical evidence of systemic disease such as diabetes or alcoholism. 3) Prior treatment with a wrist splint or carpal tunnel surgical release. 4) Inability to obtain a median CMAP elicited by stimulating the median nerve at the wrist or inability to obtain median or ulnar SNAPs by palmar stimulation
Johnson, 1993 [167]	Employees at one of six poultry processing plants.	None reported
Nakamichi, 1993 [268]	Diagnosed with carpal tunnel syndrome based on clinical signs and NCS tests. Clinical evaluation included the presence of typical sensory symptoms, Phalen's and Tinel's tests, sensory testing by 2-point discrimination on the middle finger, muscle testing, and thenar atrophy. NCS was abnormal if either DML >4.2 ms or SCV <45 m/s.	None reported
Nathan, 1993 [218]	Industrial workers from six industries: steel mill, meat/food processing, electronics, plastics, aluminum reduction, and cable plant. Workers' compensation patients had upper extremity complaints, primarily related to suspected CTS.	None reported
Rodriquez, 1993 [269]	History and physical, and abnormal NCS	Peripheral neuropathy, cervical radiculopathy, other entrapments
Rosen, 1993 [270]	Workers: Complaints of numbness and paresthesia and sometimes pain after long term exposure to vibrating tools. Carpal tunnel syndrome patients: Diagnosed with carpal tunnel syndrome, symptoms typical of CTS (numbness and paresthesia of radial fingers aggravated at night), not exposed to vibration	None reported
Rosén, 1993 [138]	Referred for diagnosis of suspected CTS. All had numbness and paresthesia that worsened at night	Any other explanation for symptoms, such as radiculopathy or polyneuropathy
Uncini, 1993 [160]	Clinical signs and symptoms suggestive of CTS, DML <4.2 ms (normal), SCV index-to-wrist >45 m/s (normal).	None reported
Buchberger, 1992 [271]	Patients with carpal tunnel syndrome. All had pain and sensory impairment in the distribution of the median nerve. All had prolonged DML (unspecified threshold).	None reported
Grant, 1992 [219]	Symptomatic: tingling, numbness, or decreased sensation in at least two fingers. Diagnosed: symptoms plus abnormal NCS	Arthritis, broken bones in hand/wrist, Raynaud's syndrome, previous wrist surgery, diabetes, kidney or metabolic disorders, heart or other circulatory disorders, pregnancy, use of OCs or hormones, history of heavy alcohol or tobacco use

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Imaoka, 1992 [272]	Any sensory disorder in the median nerve region, and either nocturnal acroparesthesia or positive Phalen's sign.	Marked atrophy of APB, peripheral nerve disorders, diabetes, or other polyneuropathies.
Kindstrand, 1992 [273]	NCS-confirmed CTS	None reported
Preston, 1992 [188]	Symptoms of CTS, "proven to have electrophysiologic CTS by standard nerve conduction criteria." Plus eight patients with possible CTS (symptomatic, but normal standard median studies, and at least one additional abnormal test)	None reported
Tchou, 1992 [274]	Referred to lab with symptoms and clinically diagnosed CTS, and confirmation of diagnosis via established criteria for nerve conduction studies. Developed symptoms within three months preceding examination.	None reported
Buchberger, 1991 [275]	Symptoms of CTS.	Unrelieved or recurrent CTS after surgical treatment.
Chang, 1991 [145]	History of carpal tunnel syndrome, with intermittent paresthesia occurring spontaneously at night or after repetitive use of the affected hand	Diabetes
Durkan, 1991 [155]	Suspected carpal tunnel syndrome based on pain, numbness, and paresthesias in the distribution of the median nerve. Either abnormal motor latency or sensory latency.	None reported
Jetzer, 1991 [168]	One of four different groups: computer assemblers, meat processors, keyboard workers, controls.	None reported
Katz, 1991 [276]	Pain or paresthesia in the upper extremity who were referred to the lab, and whose symptoms were caused by work.	Patients whose symptoms were not caused by work.
Lauritzen, 1991 [185]	Symptoms and signs compatible with CTS, and slowing of SCV along the median nerve from digit 1 or 3,or both, to the wrist, and prolonged DML from wrist to APB.	None reported
Luchetti, 1991 [169]	Nocturnal paresthesia in the median nerve territory. Normal motor function, sensory function, quantitative sensory examination, cutaneous trophism, distal sensory latency, distal motor latency.	Polyneuropathy, metabolic diseases with involvement of peripheral nerves.
Radwin, 1991 [116]	Diagnosis of CTS. Sensory complaints including tingling or numbness in the thumb, index, or middle finger and nocturnal exacerbation of the paresthesias. Either positive Tinel's sign, positive Phalen's sign, or positive Semmes-Weinstein monofilaments test.	Polyneuropathy, evidence of Raynaud's phenomenon.
Charles, 1990 [170]	For carpal tunnel syndrome patients: Clinical diagnosis of CTS by referring physician, and at least one of the following: 1) DML = 4.5 ms; 2) median orthodromic sensory nerve conduction in the second finger <45 m/s; 3) difference between median and ulnar orthodromic distal sensory latencies in the ring finger = 0.5ms.	For controls: Diabetes, peripheral neuropathy, no symptoms suggestive of CTS For the cervical spondylitic radiculopathy group: hand paresthesia mainly in the second and third fingers
DeKrom, 1990 [222]	Randomly selected from the general population of Maastricht (The Netherlands) and surrounding villages.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Fitz, 1990 [277]	APB motor latency = 4.2 ms, or digit 1 radial sensory latency = 3.1 ms, or median sensory latency = 3.2 ms or difference = 0.5 ms or similar abnormalities on digit 3	None reported
Gilliatt, 1990 [278]	Patients had carpal tunnel syndrome	None reported
MacDonell, 1990 [90]	Patients had at least two of five criteria: 1) DML >4.2ms; 2) SNAP amplitude <10μV; 3) SNAP conduction velocity <40m/s; 4) SNAP amplitude less than that of the ipsilateral ulnar nerve at the wrist; 5) median motor or sensory latencies at the wrist more than 0.5 ms longer than opposite hand	Normal ulnar nerve motor and sensory conduction studies in both arms
Merchut, 1990 [279]	Symptomatic CTS referred to the lab. Electrophysiological confirmation via at least one of four NCS tests: 1) Prolonged sensory latency; 2) Prolonged DML; 3) Slowed median SCV; 4) prolonged difference between median sensory latency from ring finger and ulnar sensory latency from ring finger.	Excluded if any clinical signs, symptoms, or EMG findings suggested the possibility of another cause of paresthesia or numbness in their hands such as polyneuropathy, radiculopathy, or CNS lesion.
Palliyath, 1990 [171]	Symptoms of CTS, but little change on routine NCS	None reported
Pease, 1990 [177]	Symptoms and abnormal nerve conduction testing (vague).	Abnormalities or radial or ulnar nerves. Abnormal EMG of any muscle except the thenar muscles.
Rojviroj, 1990 [280]	Symptoms, positive Phalen's and positive Tinel's, and carpal tunnel was confirmed by DSL >3.5 ms or DML >4.5 ms or both.	None reported
Tzeng, 1990 [180]	Diagnosed by both clinical and electromyographic findings	None reported
Uncini, 1990 [135]	Typical CTS symptoms but normal DML and normal or borderline SCV	None reported
Winn, 1990 [281]	Responded to ad on bulletin board	None reported
Braun, 1989 [282]	Symptoms of dynamic carpal tunnel syndrome.	Evidence of long-standing fixed compression neuropathy or with contributory diseases such as rheumatoid arthritis. Thenar atrophy or profound fixed anesthesia.
Cioni, 1989 [146]	Signs and symptoms suggestive of carpal tunnel syndrome. Referred to laboratory for electrophysiological confirmation of carpal tunnel syndrome.	History or physical evidence of peripheral neuropathy or cervical radiculopathy.
Jackson, 1989 [150]	Referred to the lab for symptoms of CTS.	Peripheral neuropathy, or obvious entrapment other than median nerve.
Meyers, 1989 [283]	History and physical consistent with CTS, characteristic electrophysiologic abnormalities	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
So, 1989 [173]	Patients were selected from referrals to the lab. Carpal tunnel syndrome: Confident clinical diagnosis based on history of pain and paresthesias in the hand and fingers, and physical findings that localized the pathology to the median nerve, e.g. sensory alteration or weakness in a median nerve distribution, Tinel's, or Phalen's. Cubital tunnel syndrome: Confident clinical diagnosis based on paresthesias or numbness in an ulnar nerve distribution, usually accompanied by weakness in ulnar-innervated muscles. In those patients without weakness on examination, the diagnosis of ulnar neuropathy at the elbow was not made unless there was percussion sensitivity at the cubital tunnel or the ulnar groove, or exacerbation of symptoms with elbow flexion.	None reported
Szabo, 1989 [284]	CTS patients about to have carpal tunnel release surgery. Clinical and electrophysiological evidence of CTS. Electrophysiological evidence based on either DML >4.5 ms or DSL >3.5 ms.	None reported
Uncini, 1989 [161]	Symptoms and signs of carpal tunnel syndrome	Severe carpal tunnel (DML >4.2 ms or SNAPs were absent or SNAPs were very low amplitude)
De Léan, 1988 [285]	Paresthesia in median nerve distribution, regardless of Tinel's or Phalen's signs	Polyneuropathy, medicolegal cases, workers' comp
Koris, 1988 [198]	Accepted signs and symptoms including paresthesia, but did not have to be limited to the median nerve distribution	None reported
Molitor, 1988 [110]	Referred to lab for the diagnosis of carpal tunnel.	None reported
Mortier, 1988 [286]	Prolonged distal motor latency of median nerve or prolonged distal sensory latency of median nerve	Generalized peripheral neuropathy, other peripheral entrapment neuropathies, cervical radiculopathy.
Pease, 1988 [287]	Diagnosed with CTS based on clinical and electrodiagnostic findings	None reported
Carroll, 1987 [288]	Referred to lab, symptoms suggestive of CTS	Abnormal ulnar sensory amplitude or latency.
Jessurun, 1987 [289]	Suffering from primary CTS	None reported
Johnson, 1987 [290]	Antidromic DSL to middle finger >4 ms and DML >4.3 ms.	None reported
Liang, 1987 [291]	None reported	None reported
Macleod, 1987 [292]	Symptomatic NCS confirmed with abnormal sensory latency	Signs of other neurologic disorder
Seror, 1987 [156]	Pathological wrists	Radicular signs
Borg, 1986 [293]	Referred to lab with suspicion of CTS. Patients had digital paresthesias.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Gellman, 1986 [106]	Carpal tunnel group syndrome: Three requirements: 1) Symptoms indicative of median-nerve compression in the carpal canal; 2) Either positive Semmes-Weinstein test or positive two-point discrimination test; 3) Positive nerve conduction results as indicated by any of four abnormalities: A) DML >4.5 ms B) DML on symptomatic hand more than 1 ms slower than DML on asymptomatic hand C) Sensory latency >3.5 ms D) Sensory latency on symptomatic hand more than one millisecond slower than on asymptomatic hand. Diverse lesion group: Abnormal results on clinical sensibility testing other than carpal tunnel syndrome	None reported
Escobar, 1985 [151]	Patients: Referred to lab for evaluation of numbness, tingling, weakness, and/or pain in the hand or arm. Controls: DSL <3.7 ms.	Endocrine disorders or peripheral nerve disease.
Kimura, 1985 [189]	Referred to lab with frank clinical signs and symptoms suggestive of CTS	Other disease that predispose toward peripheral neuropathy.
Mills, 1985 [194]	Tentative diagnosis of CTS	None reported
Borg, 1984 [294]	Patients with CTS. Some patients' conditions had been neurophysiologically confirmed (undefined).	None reported
Pryse-Phillips, 1984 [105]	Group 01: Carpal tunnel syndrome: Symptoms of paresthesia, numbness and/or weakness in the hand in digits I-II or I-V, with or without hand and arm pain, usually with nocturnal or early morning accentuation, ± clinical signs of thenar motor or median nerve territory sensory deficit. DML >4.5 ms or a difference of 1 ms between right and left or 1.5 median/ulnar difference. Median SNAP amplitude <ulnar or <10 μV or latency to onset >3.5 ms. Group 02: Cubital tunnel syndrome: Symptoms of hand weakness, ± digit V (IV) hypoesthesia, not extending into palm: and/or electrical signs of interosseous or hypothenar wasting, with proportionate weakness. Eisen score (undefined) greater than 5/10. Group 03: Other median nerve pathologies: Digital neuropathy affecting digits I-III or arm pain/paresthesia without nocturnal predominance, or clinically apparent weakness of long forearm flexors, ± palmar hypoesthesia. EMG evidence of acute/chronic denervation in forearm flexor muscles, ± delay in motor conduction across the point above the wrist with absence of electrical evidence of median nerve compression at the carpal tunnel. Group 04: Thoracic outlet syndrome. Group 05: Cervical radiculopathy	Carpal tunnel syndrome: Martin-Gruber anastomosis, other median nerve pathologies: cases of anterior interosseous syndrome
Satoh, 1984 [295]	No symptoms, normal ulnar sensory and motor conduction and one of three nerve conduction abnormalities: 1) orthodromic SCV digit-to-palm <42 m/s; 2) terminal latency >4.2 ms; 3) absent SNAP and absent CMAP.	None reported

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Szabo, 1984 [30]	Patients with objectively proved abnormalities of median nerve conduction who had carpal tunnel release surgery.	None reported
Goddard, 1983 [296]	Diagnosed with CTS and referred to the department	None reported
Kim, 1983 [195]	Signs and symptoms highly suggestive of CTS but with borderline or normal DSL.	None reported
Marin, 1983 [139]	Patients had previously undergone routine NCS studies for carpal tunnel syndrome	None reported
Wongsam, 1983 [172]	Symptoms suggesting early CTS	None reported
Johnson, 1981 [297]	Diagnosed CTS: history and NCS	None reported
Dekel, 1980 [21]	Diagnosed with carpal tunnel using history, clinical exam, and nerve conduction studies.	Any of the recognized diseases associated with carpal tunnel syndrome.
Messina, 1980 [120]	Signs and symptoms suggestive of CTS	None reported
Gelmers, 1979 [29]	Diagnosis of carpal tunnel based on three findings: 1) Acroparesthesia in the distribution of the median nerve; 2) Thenar muscle wasting or weakness or failure to detect an action potential of the thenar muscles by needle electromyography; 3) Prolongation of distal latency of the median nerve to more than 4.7 ms, or a difference in distal latency of more than 1 ms between symptomatic and asymptomatic hands, even though both latencies were within normal limits	Signs of generalized neuropathy
Kimura, 1979 [140]	Clinical impression (history and symptoms, not NCS), relatively mild symptoms	Polyneuropathy
Schwartz, 1979 [187]	Referred to lab based on sensory symptoms in a median distribution.	Generalized neuropathy
Stewart, 1978 [157]	In addition to ipsilateral ulnar sensory amplitude = 8.5 μV and ulnar sensory latency <2.8 ms, three or more of the following were required: 1) Sensory signs in the distribution of the median nerve.; 2) Thenar wasting or weakness; 3) DML >4.5 ms; 4) sensory onset latency >2.7 ms; 5) Sensory amplitude <8.6 μV	Diabetes, peripheral neuropathy. CTS secondary to trauma or other localized or generalized disease.

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Eisen, 1977 [298]	Carpal tunnel patients: Sensory symptoms limited to one or both hands, normal ulnar sensory latency (<2.8 ms), normal ulnar sensory amplitude (>8.4 μV), and at least three of the following five criteria: 1) Sensory signs restricted to median distribution; 2) Weakness or wasting of the APB muscle; 3) Median DML >4.5 ms; 4) Median DSL >2.7 ms; 5) Median SNAP amplitude <8.6 μV or median SNAP duration >2.4 ms. Cubital tunnel patients: Sensory symptoms limited to one or both hands, normal median sensory latency (<2.7 ms), normal median sensory amplitude (>8.6 μV), and at least three of the following six criteria: 1) Sensory signs restricted to ulnar distribution; 2) Weakness or wasting of the ulnar-innervated muscles of the hand; 3) Ulnar DML >4.0 ms; 4) Ulnar proximal motor latency (stimulation just above the elbow) >8.9 ms; 5) Ulnar DSL >2.8 ms; 6) Ulnar SNAP amplitude <8.4 μV or ulnar SNAP duration >2.1 ms. Patients with proximal lesions: Sensory symptoms limited to one or both hands, but did not meet criteria for either carpal tunnel or cubital tunnel.	Subjects were excluded from the control group if there was neuromuscular disease, diabetes, alcoholism, peripheral neuropathy, or systemic dysfunction.
Sedal, 1973 [299]	Presented as idiopathic carpal tunnel.	Excluded if CTS was an incidental finding in the investigation of a generalized peripheral neuropathy, OR if they had diabetes or alcoholism or chronic renal disease, or if there was clinical evidence of either radial or nerve lesions
Welch, 1973 [223]	Workers at a factory employed on repetition work producing domestic appliances. The other group consisted of job applicants who had not yet started work.	None reported
Casey, 1972 [300]	Carpal tunnel syndrome: Classical symptoms. Also 10 of the 16 patients had hypalgesia in the fingers of the involved hand supplied by the median nerve. Abnormal (or at the lower limit of normal) median SNAP recorded at the wrist after digital stimulation. Diabetics: Reflex changes and distal sensory abnormalities in the lower limbs, consisting of pain and paresthesia with sensory loss. In addition, 10 of the 18 diabetics had sensory changes in the upper limbs	None reported
Loong, 1972 [141]	Clinical diagnosis of CTS with typical history of intermittent paresthesia at night or after use.	None reported
Melvin, 1972 [147]	Referred to the laboratory as possible cases of carpal tunnel syndrome.	None reported
Buchthal, 1971 [301]	None reported	Normal ulnar SCV and latency to ADM to exclude generalized neuropathy

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Loong, 1971 [148]	Referred to lab with clinical diagnosis of carpal tunnel syndrome. Typical history of the syndrome with intermittent paresthesia occurring spontaneously at night or after use of the affected hand.	Diabetes
Plaja, 1971 [142]	None reported	"We excluded misleading diagnosis by controlling at the same time different levels and nerve trunks."

Question #2: What are the specific indications for surgery for carpal tunnel syndrome?

Published evidence does not directly address the specific indications for surgery for carpal tunnel syndrome. Therefore, we describe the reported characteristics of patients who have received surgery for carpal tunnel syndrome in published studies. The extent to which these patients represent typical surgical candidates is not certain. Patients included in published studies of a procedure are frequently a subset of patients who are candidates for that procedure. They may represent an unusual group of interest, or a group thought most likely to benefit from the procedure. Therefore, the data presented here, while informative, may not accurately reflect the overall patient population. It does, however, represent the best data available, and is the most comprehensive description of those carpal tunnel syndrome patient characteristics who receive surgery that has yet been compiled.

Evidence Base

To answer this question, we examined 141 studies (controlled trials and case series) describing a total of 15,993 patients.

Age

Patients who received surgery for carpal tunnel syndrome were predominantly of middle age. The mean of mean ages from the 124 studies that reported this information was 50.5 years, with a standard deviation of 5.7. Ages of individual patients ranged from 17 to 100 years. Mean ages and ranges from individual studies are given in Table 47, and are depicted in Figure 16. The vertical line in Figure 16 represents the mean age for all studies.

Very few studies (4%) reported that patients were excluded on the basis of age. Two studies excluded patients under the age of 18,[302,303] and one excluded patients under 16.[304] In contrast, one excluded patients over the age of seventy,[305] and another excluded patients over 75.[306]

Sex

Patients receiving surgery for carpal tunnel syndrome were more likely to be female than male, as can be seen in Figure 17. One hundred twenty eight studies provided sufficient information to calculate the male-to-female patient ratio. The average study reported that 73% of patients were female, with a standard deviation of 0.2. Patients in two studies were 100% female, and 100% male in one study. Numbers of male and female patients in individual studies are reported in Table 47.

No study reported sex to be a criterion for exclusion or inclusion. However, both studies in which men were the majority recruited their patients from male-majority populations. One recruited exclusively from a veteran's hospital population,[307] and one

recruited patients who worked with heavy, vibrating machinery.[308] These patients do not represent typical carpal tunnel syndrome patients.

Signs and Symptoms

Signs and symptoms of carpal tunnel syndrome among patients receiving surgery for carpal tunnel syndrome were incompletely reported. This is illustrated by Figure 18, which depicts the percentage of studies reporting the number of patients with an individual sign or symptom. This percentage never exceeds 15% of all studies. Rather than report the number of patients with a given sign or symptom, the common practice among studies of carpal tunnel syndrome is to report that patients had one or more symptoms from a given list. Some studies that included patients with bilateral carpal tunnel syndrome report symptoms per affected hand rather than per patient, reflecting the fact that the same patient can have different symptoms in each hand. The number and percent of patients reporting each sign or symptom is given in Table 48. These data are summarized in Figure 19. "Error" bars in Figure 19 represent the range of percentages reported by individual studies. Because so few (always less than 15%) studies reported this information, the extent to which the available data reflect the signs and symptoms of typical patients receiving surgery cannot be determined.

Eight studies excluded patients with thenar atrophy, while four included only patients with thenar atrophy. Seven studies required their patients to have Tinel's sign, Phalen's sign or both, and an indeterminate number included tests for these signs as part of their diagnostic procedure. The exact number of such studies can not be determined because some describe their patients as having "signs and symptoms of carpal tunnel syndrome" without providing further description or enumeration. The extent to which use of these criteria influence the overall description of the typical patient with carpal tunnel syndrome cannot be determined, because it is unclear whether or to what extent criteria for surgery may differ from criteria for study inclusion.

The duration of symptoms prior to surgery was reported by 35 studies (24% of total). These are listed in Table 49. The mean of means among these 35 studies was 29.9 months, with a standard deviation of 16.5 and a range of zero to 480 months. The means and ranges of individual studies are depicted in Figure 20. The vertical line in Figure 20 represents the mean of means.

Neuroelectrical characteristics

Of the 145 studies that reported on surgery for carpal tunnel syndrome and met inclusion criteria, 83 stated that electrodiagnostic tests were part of their inclusion criteria, but did not provide any further information as to the nature of these tests. An additional 26 did not provide any diagnostic information. Eleven studies did not include electrodiagnostic studies in their description of their diagnostic and inclusion criteria, and two specifically stated that electrodiagnostics were not part of their diagnostic protocol. Electrodiagnostic criteria in the remaining studies are reported in Table 50. Because the majority of studies excluded some patients based on their

neuroelectrical characteristics without providing information as to which patients were excluded or why, the impact of these exclusion criteria on the characteristics of the patients described in these studies cannot be determined.

Employment Characteristics

Of the 145 studies describing patients receiving surgery for carpal tunnel syndrome that met inclusion criteria, only 20 (14%) reported data on the types of employment of their patients. The occupations of patients receiving surgery for carpal tunnel syndrome and the percent of patients in each study possessing that occupation are given in Table 51.

No consistent categorization was used in these studies. The distinction between groups may be unclear. For example, the study by Worseg, et al. distinguished between "Workers" and "Employees".[44] The difference between the two groups was not described. As a result, it is difficult to make generalizations about typical characteristics of patients with carpal tunnel syndrome. The number of studies reporting each occupational category is given in Figure 21, and the percent of patients with each occupation among studies reporting that occupation is given in Figure 22.

Comorbidities

The number of patients with comorbidities is incompletely reported in published studies of surgical treatment for carpal tunnel syndrome, as can be seen in Figure 23. The number of studies reporting the presence of a given comorbidity never exceeds 20% of the available studies. Further confounding analysis is the fact that many studies excluded patients with comorbidities, and not all studies reported a precise list of excluded comorbidities. Because comorbidities are underreported and because patients with them are frequently excluded, it is difficult to draw conclusions about the presence of comorbidities among patients receiving surgery for carpal tunnel syndrome or how these comorbidities affect whether a patient is a candidate for surgery.

Conclusions

Patients who have undergone surgery for carpal tunnel syndrome are predominantly middle aged and female. Because of underreporting, no firm evidence-based conclusions can be drawn regarding the signs, symptoms, neuroelectrical characteristics and comorbidities of these patients.

Table 47. Age and sex of patients receiving surgery for carpal tunnel syndrome

Trial	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Finsen, 2001 [224]	79	18	61	77.2%	Median	48	21	86
Mondelli, 2001 [181]	28	4	24	85.7%	Mean	52.8	35	75
Avci, 2000 [309]	25	1	24	96.0%	Mean	43	21	72
Khan, 2000 [310]	44	11	33	75.0%	Mean	55	29	88
Mondelli, 2000 [311]	110	13	97	88.2%	Mean	56	20	82
Muller, 2000 [312]	148	28	120	81.1%	Mean	51.8	NR[a]	NR
Porras, 2000 [313]	85	8	77	90.6%	Mean	52	18	81
Vartimidis, 2000 [314]	15	6	9	60.0%	Mean	52	28	75
Alderson, 1999 [315]	26	5	21	80.8%	Mean	44.4	22	79
Braun, 1999 [316]	225	36	189	84.0%	Mean	41.0	NR	NR
Chen, 1999 [317]	948	212	736	77.6%	Mean	48	21	79
Erhard, 1999 [318]	124	15	109	87.9%	Mean	54.3	19	84
Finsen, 1999 [319]	82	22	60	73.2%	Mean	49.4	21	86
Hasegawa, 1999 [320]	82	0	82	100.0	Mean	54.1	NR	NR
Hirooka, 1999 [321]	37	4	33	89.2%	Mean	58	40	78
Lindau, 1999 [322]	140	17	123	87.9%	Mean	55.4	NR	NR
Olney, 1999 [323]	211	46	165	78.2%	Mean	44.8	NR	NR
Senda, 1999 [324]	26	1	25	96.2%	Mean	56.8	19	93
Straub, 1999 [305]	67	47	20	29.9%	Median	40	19	70
Vartimidis, 1999 [325]	22	8	14	63.6%	Mean	52	21	77
Atroshi, 1998 [326]	103	35	68	66.0%	Mean	52	21	88
Aulisa, 1998 [327]	45	8	37	82.2%	Mean	47	26	68
Buckhorn 1998 [328]	50	21	29	58.0%	Mean	51.3	27	61
Choi, 1998 [329]	154	6	148	96.1%	Mean	52	30	82
Davies, 1998 [330]	239	NR	NR	NR	Mean	43.5	20	82
Lee, 1998 [331]	525	134	391	74.5%	Mean	50.7	21	88
Nakamichi, 1998 [332]	130	16	114	87.7%	Mean	58	35	85

Trial	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Papageorgiou, 1998 [333]	76	18	58	76.3%	Mean	48	NR	NR
Schuind. 1998 [334]	13	6	7	53.8%	Mean	47	45	77
Tomaino, 1998 [335]	29	6	23	79.3%	Mean	52	28	82
Armstrong, 1997 [336]	176	35	141	80.1%	Mean	50.5	30	86
Atroshi, 1997 [337]	204	56	148	72.5%	Mean	49.3	19	94
Baguneid, 1997 [338]	75	11	64	85.3%	Mean	56	24	85
Chia, 1997 [339]	62	13	49	79.0%	Mean	47.7	29	73
Citron, 1997 [340]	47	8	39	83.0%	Mean	52.1	26	80
Higgs, 1997 [341]	93	30	63	67.7%	Mean	43	23	69
Karlsson, 1997 [48]	74	15	59	79.7%	Median	54.5	24	88
Katz, 1997 [302]	135	42	93	68.9%	NR	NR	NR	NR
Leinberry, 1997 [342]	44	18	26	59.1%	Mean	64.9	38	100
Rosen, 1997 [343]	102	18	84	82.4%	Mean	51.0	24	82
Serra, 1997 [344]	112	16	96	85.7%	Mean	47	31	70
Stahl, 1997 [345]	50	16	34	68.0%	Mean	49.5	NR	NR
Tucci, 1997 [346]	27	6	21	77.8%	Mean	48.6	NR	NR
Weber, 1997 [347]	74	26	48	64.9%	Median	41.4	26	80
Wheatly, 1997 [307]	126	114	12	9.5%	NR	NR	NR	NR
Cobb, 1996 [348]	235	44	191	81.3%	Mean	51	20	79
Elmaraghy. 1996 [349]	69	21	48	69.6%	Mean	51	24	97
Franzini, 1996 [350]	50	11	39	78.0%	Mean	52	32	60
Gibbs, 1996 [351]	46	16	30	65.2%	Mean	56.2	31	86
Glowacki, 1996 [352]	167	35	132	79.0%	Mean	42	17	84
Jacobsen, 1996 [353]	32	9	23	71.9%	Mean	44.9	24	59
Kluge. 1996 [354]	66	18	48	72.7%	Mean	51	36	93
Lee, 1996 [355]	275	76	199	72.4%	Mean	50.7	21	88
Mclaughlin, 1996 [356]	102	26	76	74.5%	Mean	52	NR	NR
Nagle, 1996 [357]	506	134	372	73.5%	Mean	48	13	91
Nygaard, 1996 [306]	29	7	22	75.9%	Mean	53	32	75
Okutsu, 1996 [41]	43	2	41	95.3%	Mean	55.1	31	87

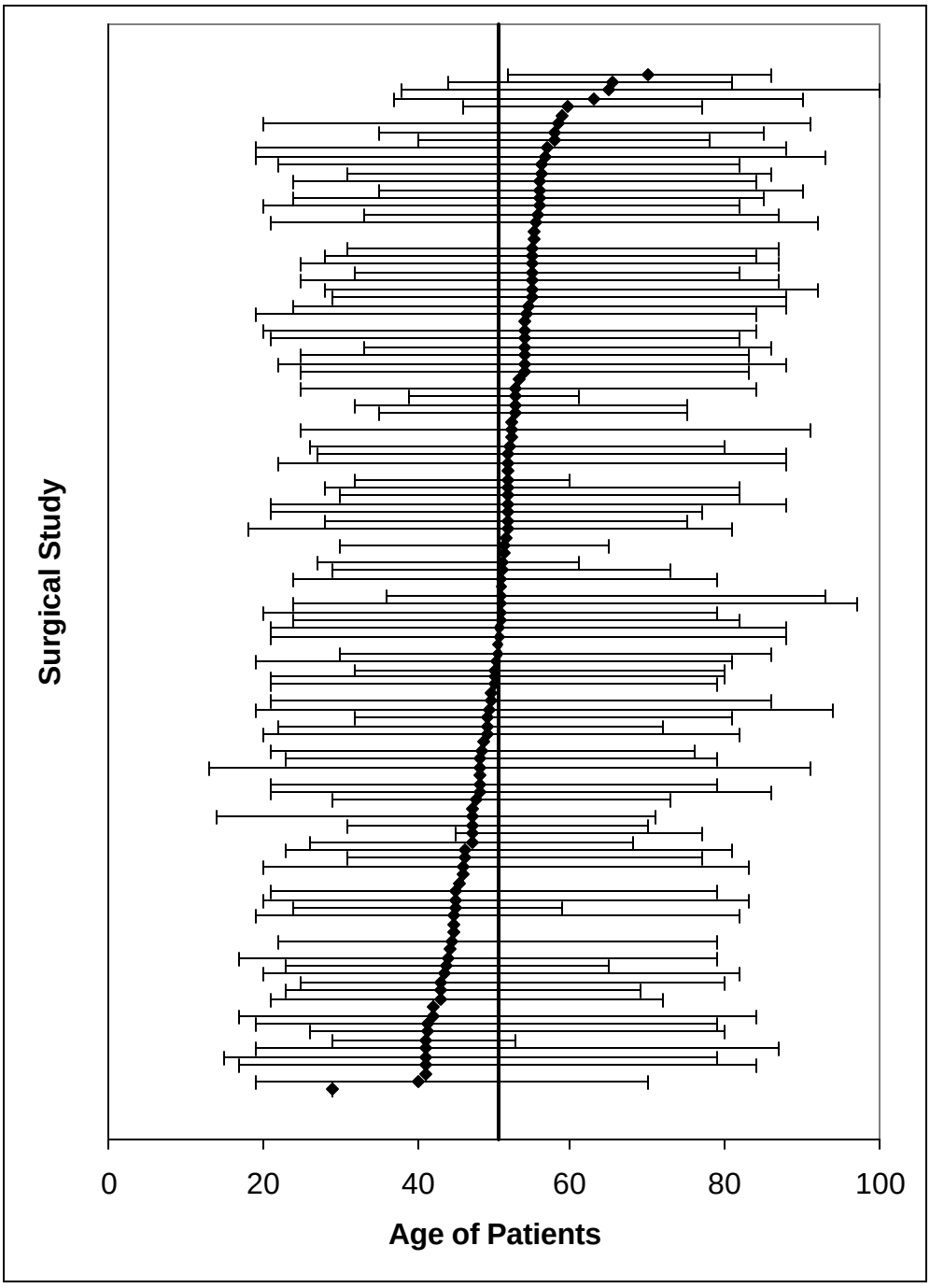
Trial	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Padua, 1996 [358]	33	7	26	78.8%	Mean	47.2	NR	NR
Pennino, 1996 [359]	124	NR	NR	NR	Mean	55	28	92
Povlsen, 1996 [360]	51	23	28	54.9%	NR	NR	NR	NR
Strickland, 1996 [361]	62	16	46	74.2%	Mean	52	22	88
Wintman, 1996 [362]	50	NR	NR	NR	Mean	54	25	83
Worseg, 1996 [44]	126	38	88	69.8%	Mean	56.0	35	90
Abdullah, 1995 [363]	100	19	81	81.0%	Mean	41.4	19	79
Bury, 1995 [364]	43	4	39	90.7%	Mean	52.3	NR	NR
Dumontier, 1995 [365]	96	11	85	88.5%	Mean	41.1	29	53
El-Zahaar, 1995 [43]	41	12	29	70.7%	Mean	53	39	61
Futami, 1995 [366]	10	1	9	90.0%	Mean	51	NR	NR
Gross, 1995 [367]	44	16	28	63.6%	Mean	44.2	NR	NR
Hallock, 1995 [368]	100	26	74	74.0%	Mean	59	NR	NR
Katz, 1995 [369]	50	6	44	88.0%	Mean	51.4	NR	NR
Lang, 1995 [109]	23	5	18	78.3%	Mean	53	25	84
LoVerme, 1995 [370]	42	4	38	90.5%	Mean	29	NR	NR
Mirza, 1995 [371]	236	74	162	68.6%	Mean	44	17	79
Nancollas, 1995 [372]	93	17	76	81.7%	Mean	52.5	NR	NR
Sennwald, 1995 [373]	47	12	35	74.5%	Mean	54	22	88
Shinya, 1995 [374]	88	16	72	81.8%	Mean	49	20	82
Al-Qattan, 1994 [375]	112	28	84	75.0%	Mean	54	25	83
Chow, 1994 [42]	815	289	526	64.5%	NR	NR	NR	NR
Erdmann, 1994 [304]	96	26	70	72.9%	Mean	53.4	NR	NR
Foulkes, 1994 [376]	33	16	17	51.5%	Mean	45.4	NR	NR
Katz, 1994 [377]	104	31	73	70.2%	Mean	55	25	87
Kelly, 1994 [378]	69	16	53	76.8%	Mean	50	21	79
Kerr, 1994 [379]	85	37	48	56.5%	Mean	44.8	19	82
Menon, 1994 [380]	87	28	59	67.8%	Mean	48.3	21	76

Trial	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Pascoe, 1994 [381]	28	12	16	57.1%	Mean	55	32	82
Payne, 1994 [382]	16	6	10	62.5%	NR	NR	NR	NR
Roth. 1994 [383]	94	35	59	62.8%	Mean	52.4	25	91
Singh, 1994 [384]	357	56	301	84.3%	NR	NR	NR	NR
Skoff, 1994 [385]	1994	NR	NR	NR	Mean	56.0	24	84
Slattery, 1994 [40]	215	69	146	67.9%	Mean	41	17	84
Strasberg, 1994 [386]	45	16	29	64.4%	Mean	50.6	NR	NR
Wolson, 1994 [387]	30	10	20	66.7%	Mean	47	14	71
Biyani, 1993 [388]	56	7	49	87.5%	Mean	65.4	44	81
Brown, 1993 [45]	145	46	99	68.3%	Mean	55	25	87
Chang, 1993 [389]	30	6	24	80.0%	Mean	46.2	31	77
Feinstein, 1993 [390]	55	21	34	61.8%	Mean	45	21	79
Jiminez, 1993 [391]	24	6	18	75.0%	Mean	46	NR	NR
Leach, 1993 [392]	25	11	14	56.0%	Mean	43	25	80
Levine, 1993 [393]	39	17	22	56.4%	Median	57	19	88
Nakamichi, 1993 [394]	41	8	33	80.5%	Mean	54	33	86
Nathan, 1993 [395]	238	80	158	66.4%	Mean	41	15	79
Okutsu, 1993 [396]	27	0	27	100.0%	Mean	55.9	33	87
Palmer, 1993 [397]	173	73	100	57.8%	Mean	44.9	20	83
Waegeneers, 1993 [398]	76	21	55	72.4%	Mean	54	21	82
Nolan, 1992 [399]	22	7	15	68.2%	Mean	70	52	86
Pagnanelli, 1992 [400]	228	65	163	71.5%	Mean	55.2	NR	NR
Viegas, 1992 [401]	71	17	54	76.1%	Mean	48	23	79
Young, 1992 [402]	21	NR	NR	NR	Mean	49	22	72
Yu, 1992 [403]	53	22	31	58.5%	Median	46	20	83
Flaschka, 1991 [404]	99	18	81	81.8%	Mean	56.4	22	82
Foucher, 1991 [405]	83	17	66	79.5%	Mean	59.6	46	77
Hagberg, 1991 [308]	41	41	0	0.0%	Mean	42.0	NR	NR

Trial	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Jakab, 1991 [406]	73	25	48	65.8%	Mean	52	27	88
Mackimmon, 1991 [407]	59	11	48	81.4%	Mean	58.5	20	91
Resnick, 1991 [408]	65	17	48	73.8%	Mean	46.2	23	81
Schuind, 1990 [409]	21	2	19	90.5%	Mean	49	32	81
Gellman, 1989 [410]	21	2	19	90.5%	Mean	51.5	30	65
Okutsu, 1989 [411]	45	15	30	66.7%	Mean	51.1	29	73
Richman, 1989 [412]	12	6	6	50.0%	NR	NR	NR	NR
Seiler, 1989 [413]	10	2	8	80.0%	Mean	43.6	23	65
Seradge, 1989 [414]	500	218	282	56.4%	Median	41	19	87
Szabo, 1989 [284]	22	6	16	72.7%	Mean	51	24	79
Gelberman, 1987 [415]	29	17	12	41.4%	Mean	55	28	84
Holmgren, 1987 [416]	48	15	33	68.8%	Mean	50	21	80
Gartsman, 1986 [417]	50	14	36	72.0%	NR	NR	NR	NR
Kulick, 1986 [418]	167	30	137	82.0%	Mean	55.5	21	92
Leblhuber , 1986 [419]	47	10	37	78.7%	Mean	50.2	19	81
Shurr, 1986 [420]	36	8	28	77.8%	Mean	44.6	NR	NR
Wadstroem, 1986 [421]	36	10	26	72.2%	Mean	50	32	80
Rhodes, 1985 [422]	32	21	11	34.4%	Mean	63	37	90
Litchman, 1984 [423]	135	28	107	79.3%	Mean	54	20	84
van Rossum, 1980 [424]	37	6	31	83.8%	NR	NR	NR	NR

a: Not reported

Figure 16. Distribution of patient ages in studies of surgical treatment for carpal tunnel syndrome



The solid vertical line denotes the mean age for all studies

Figure 17. Sex distribution in surgical trials of surgical treatment for carpal tunnel syndrome

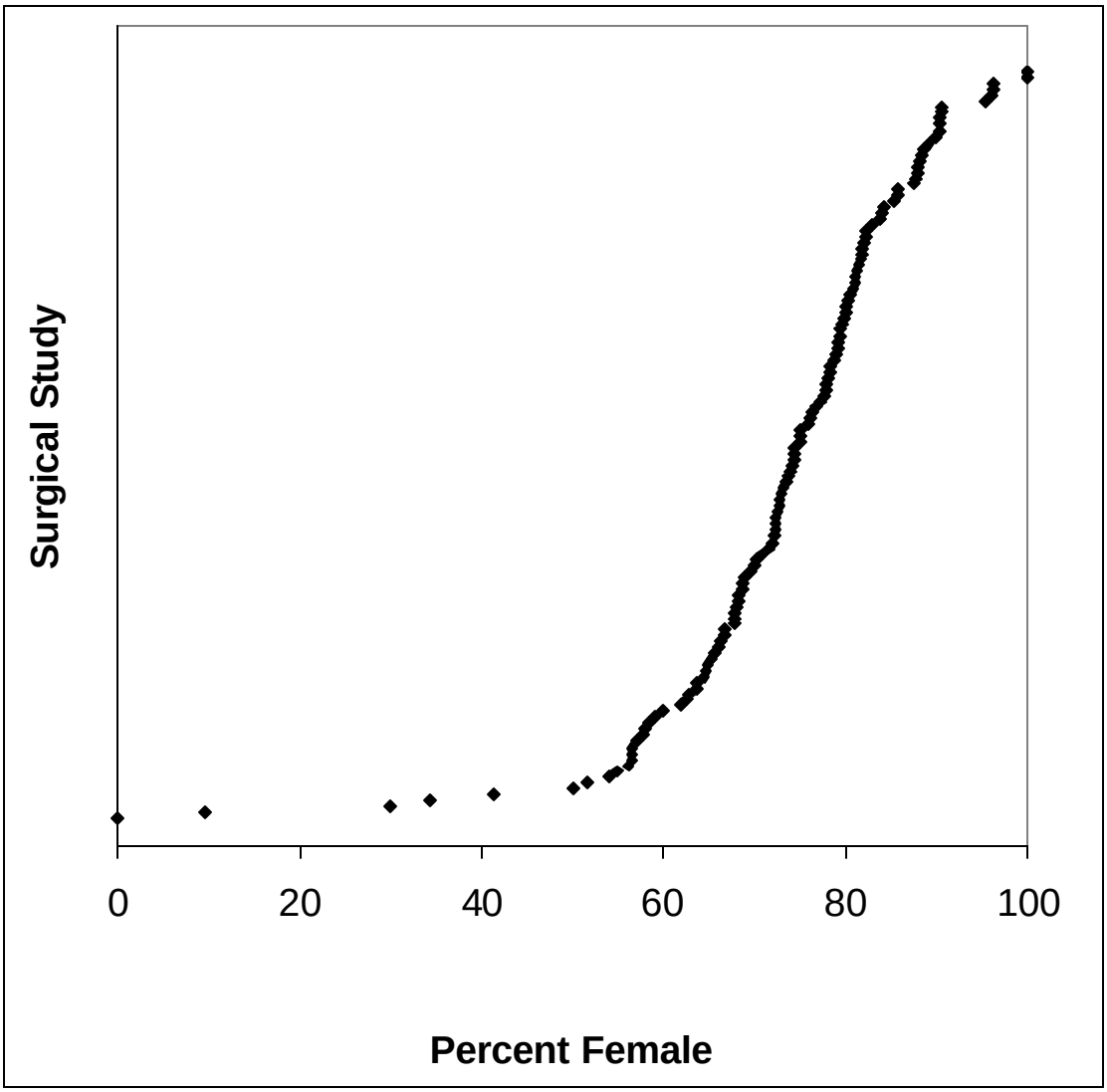


Figure 18. Reporting of symptoms in studies of surgical treatment for carpal tunnel syndrome

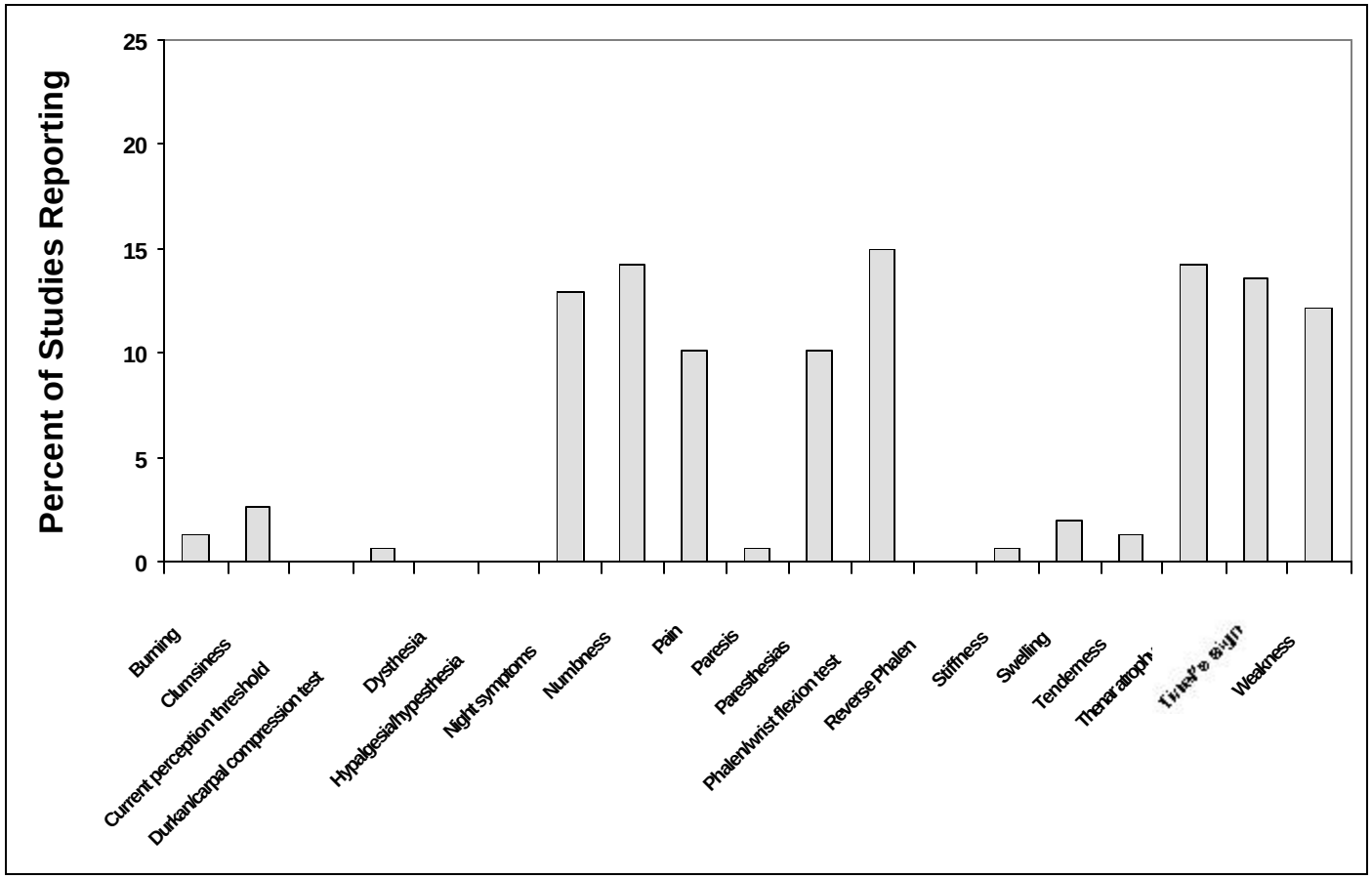


Table 48. Symptoms of patients treated with surgery for carpal tunnel syndrome

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
McLaughlin, 1996 [356]	102	Burning	70	68.6%
Mirza, 1995 [371]	56	Burning	6	10.7%
Finsen, 2001 [224]	79	Clumsiness	42	53.2%
Atroshi, 1997 [337]	255 Hands	Clumsiness	155	60.8%
Cobb, 1996 [348]	235	Clumsiness	81	34.5%
Lee, 1996 [355]	275 Hands	Clumsiness	207	75.3%
Lascar, 2000 [425]	71	Clumsiness	6	8.5%
Porras, 2000 [313]	85	Durkan/carpal compression test	50	58.8%
Finsen, 2001 [224]	79	Night symptoms	56	70.9%
Straub, 1999 [305]	100 Hands	Night symptoms	93	93.0%
Aulisa, 1998 [327]	45	Night symptoms	44	97.8%
Buchhorn, 1998 [328]	50	Night symptoms	50	100.0%
Atroshi, 1997 [337]	255 Hands	Night symptoms	237	92.9%
Cobb, 1996 [348]	235	Night symptoms	71	30.2%
Elmaraghy, 1996 [349]	69	Night symptoms	56	81.2%
Glowacki, 1996 [352]	167	Night symptoms	114	68.3%
Kluge, 1996 [354]	66	Night symptoms	50	75.8%
Lee, 1996 [355]	275 Hands	Night symptoms	226	82.2%
McLaughlin, 1996 [356]	102	Night symptoms	78	76.5%
Nygaard, 1996 [306]	29	Night symptoms	20	69.0%
Strickland, 1996 [361]	58	Night symptoms	58	100%
Worseg, 1996 [44]	126	Night symptoms	111	88.1%
Singh, 1994 [384]	357	Night symptoms	104	29.1%
Palmer, 1993 [397]	173	Night symptoms	148	85.5%
Pagnanelli, 1992 [400]	456 Hands	Night symptoms	424	93.0%
Resnick, 1991 [408]	75 Hands	Night symptoms	66	88.0%

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
Freshwater, 1978 [426]	22	Night symptoms	22	100%
Provinciali, 2000 [427]	100	Numbness	62	62.0%
Vartimidis, 2000 [314]	15	Numbness	15	100.0%
Straub, 1999 [305]	100 Hands	Numbness	71	71.0%
Aulisa, 1998 [327]	45	Numbness	7	15.6%
Armstrong, 1997 [336]	208 Hands	Numbness	160	76.9%
Atroshi, 1997 [337]	255 Hands	Numbness	178	69.8%
Blair, 1996 [428]	75	Numbness	71	94.7%
Cobb, 1996 [348]	235	Numbness	88	37.4%
Elmarghy, 1996 [349]	69	Numbness	68	98.6%
Kluge, 1996 [354]	66	Numbness	35	53.0%
Lee, 1996 [355]	275 Hands	Numbness	240	87.3%
McLaughlin, 1996 [356]	102	Numbness	71	69.6%
Futami, 1995 [366]	10	Numbness	10	100%
LoVerme, 1995 [370]	42	Numbness	28	66.7%
Mirza, 1995 [371]	56	Numbness	53	94.6%
Singh, 1994 [384]	357	Numbness	283	79.3%
Strasberg, 1994 [386]	45	Numbness	45	100.0%
Waegeneers, 1993 [398]	100 Hands	Numbness	28	28.0%
Pagnanelli, 1992 [400]	456 Hands	Numbness	264	57.9%
Wadstroem, 1986 [421]	36	Numbness	25	69.4%
Freshwater, 1978 [426]	11	Numbness	11	100%
Provinciali, 2000 [427]	100	Pain	80	80.0%
Vartimidis, 2000 [314]	15	Pain	15	100%
Armstrong, 1997 [336]	208 Hands	Pain	185	88.9%
Atroshi, 1997 [337]	255 Hands	Pain	198	77.6%
Blair, 1996 [428]	75	Pain	67	89.3%
Cobb, 1996 [348]	131	Pain	80	61.1%

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
Elmaraghy, 1996 [349]	69	Pain	59	85.5%
Lee, 1996 [355]	275 Hands	Pain	232	84.4%
Mirza, 1995 [371]	56	Pain	46	82.1%
Strasberg, 1994 [386]	45	Pain	39	86.7%
Waegeneers. 1993 [398]	100 Hands	Pain	96	96.0%
Nolan, 1992 [399]	22	Pain	11	50.0%
Richman, 1989 [412]	12	Pain	10	83.3%
Lowry, 1988 [429]	50	Pain	47	94.0%
Freshwater, 1978 [426]	22	Pain	6	27.3%
Nygaard, 1996 [306]	29	Paresis	8	27.6%
Provinciali, 2000 [427]	100	Paresthesias	82	82.0%
Straub, 1999 [305]	100 Hands	Paresthesias	100	100%
Buchholm, 1998 [328]	50	Paresthesias	49	98.0%
Armstrong, 1997 [336]	208 Hands	Paresthesias	195	93.8%
Atroshi, 1997 [337]	255 Hands	Paresthesias	242	94.9%
Cobb, 1996 [348]	235	Paresthesias	82	34.9%
Elmaraghy, 1996 [349]	69	Paresthesias	59	85.5%
Kluge, 1996 [354]	66	Paresthesias	3	4.5%
Lee, 1996 [355]	275 Hands	Paresthesias	233	84.7%
Worseg, 1996 [44]	126	Paresthesias	120	95.2%
Mirza, 1995 [371]	56	Paresthesias	56	100%
Palmer, 1993 [397]	173	Paresthesias	171	98.8%
Waegeneers, 1993 [398]	100 Hands	Paresthesias	99	99.0%
Pagnanelli, 1992 [400]	456 Hands	Paresthesias	424	93.0%
Wadstroem, 1986 [421]	36	Paresthesias	32	88.9%
Finsen, 2001 [224]	79	Phalen's sign	58	73.4%
Porras, 2000 [313]	85	Phalen's sign	64	75.3%

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
Straub, 1999 [305]	100 Hands	Phalen's sign	87	87.0%
Aulisa, 1998 [327]	45	Phalen's sign	32	71.1%
Atroshi, 1997 [337]	255 Hands	Phalen's sign	214	83.9%
Serra, 1997 [344]	112	Phalen's sign	98	87.5%
Glowacki, 1996 [352]	167	Phalen's sign	115	68.9%
McLaughlin, 1996 [356]	102	Phalen's sign	90	88.2%
Nygaard, 1996 [306]	29	Phalen's sign	22	75.9%
Strickland, 1996 [361]	62	Phalen's sign	45	72.6%
Worseg, 1996 [44]	126	Phalen's sign	74	58.7%
Bury, 1995 [364]	43	Phalen's sign	43	100.0%
Futami, 1995 [366]	10	Phalen's sign	10	100.0%
Lang, 1995 [109]	23	Phalen's sign	19	82.6%
Erdmann. 1994 [304]	96	Phalen's sign	80	83.3%
Payne, 1994 [382]	16	Phalen's sign	16	100.0%
Roth, 1994 [383]	94	Phalen's sign	94	100.0%
Palmer, 1993 [397]	211 Hands	Phalen's sign	196	92.9%
Waegemeers, 1993 [398]	100 Hands	Phalen's sign	84	84.0%
Resnick, 1991 [408]	75 Hands	Phalen's sign	69	92.0%
Richman, 1989 [412]	12	Phalen's sign	10	83.3%
Freshwater, 1978 [426]	22	Phalen's sign	17	77.3%
Armstrong, 1997 [336]	208 Hands	Stiffness	174	83.7%
Lascar, 2000 [425]	71	Stiffness	7	9.9%
Aulisa, 1998 [327]	45	Swelling	27	60.0%
Mirza, 1995 [371]	280	Swelling	3	1.1%
Freshwater, 1978 [426]	22	Swelling	0	0.0%
Strickland, 1996 [361]	58	Tenderness	54	93.1%
Pagnanelli, 1992 [400]	456 Hands	Tenderness	18	3.9%

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
Porras, 2000 [313]	85	Thenar atrophy	15	17.6%
Aulisa, 1998 [327]	45	Thenar atrophy	3	6.7%
Buchhorn, 1998 [328]	50	Thenar atrophy	11	22.0%
Atroshi, 1997 [337]	255 Hands	Thenar atrophy	36	14.1%
Serra, 1997 [344]	112	Thenar atrophy	16	14.3%
McLaughlin, 1996 [356]	102	Thenar atrophy	16	15.7%
Nygaard, 1996 [306]	29	Thenar atrophy	8	27.6%
LoVerme, 1995 [370]	42	Thenar atrophy	8	19.0%
Singh, 1994 [384]	357	Thenar atrophy	110	30.8%
Waegeneers, 1993 [398]	100 Hands	Thenar atrophy	8	8.0%
Nolan, 1992 [399]	22	Thenar atrophy	11	50.0%
Pagnanelli, 1992 [400]	456 Hands	Thenar atrophy	112	24.6%
Foucher, 1991 [405]	83	Thenar atrophy	83	100.0%
Mackimmon, 1991 [407]	59	Thenar atrophy	41	69.5%
Resnick, 1991 [408]	75 Hands	Thenar atrophy	12	16.0%
Richman, 1989 [412]	12	Thenar atrophy	3	25.0%
Gelberman, 1987 [415]	61	Thenar atrophy	38	62.3%
Kulick, 1986 [418]	167	Thenar atrophy	20	12.0%
Leblhuber, 1986 [419]	55 Hands	Thenar atrophy	14	25.5%
Wadstroem, 1986 [421]	36	Thenar atrophy	17	47.2%
Freshwater, 1978 [426]	22	Thenar atrophy	2	9.1%
Finsen, 2001 [224]	79	Tinel's sign	46	58.2%
Porras, 2000 [313]	85	Tinel's sign	51	60.0%
Straub, 1999 [305]	100 Hands	Tinel's sign	73	73.0%
Buchhorn, 1998 [328]	50	Tinel's sign	46	92.0%
Atroshi, 1997 [337]	255 Hands	Tinel's sign	176	69.0%

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
Serra, 1997 [344]	112	Tinel's sign	5	4.5%
Glowacki, 1996 [352]	96	Tinel's sign	66	68.8%
McLaughlin, 1996 [356]	102	Tinel's sign	69	67.6%
Nygaard, 1996 [306]	29	Tinel's sign	9	31.0%
Strickland, 1996 [361]	62	Tinel's sign	45	72.6%
Worsegm 1996 [44]	126	Tinel's sign	100	79.4%
Futami, 1995 [366]	10	Tinel's sign	10	100.0%
Lang, 1995 [109]	23	Tinel's sign	7	30.4%
Erdmann, 1994 [304]	96	Tinel's sign	74	77.1%
Roth, 1994 [383]	94	Tinel's sign	94	100.0%
Palmer, 1993 [397]	211	Tinel's sign	181	85.8%
Waegeneers, 1993 [398]	100 Hands	Tinel's sign	77	77.0%
Resnick, 1991 [408]	75 Hands	Tinel's sign	57	76.0%
Richman, 1989 [412]	12	Tinel's sign	7	58.3%
Freshwater, 1978 [426]	22	Tinel's sign	15	68.2%
Provinciali, 2000 [427]	100	Weakness	75	75.0%
Straub, 1999 [305]	100 Hands	Weakness	63	63.0%
Aulisa, 1998 [327]	45	Weakness	9	20.0%
Armstrong, 1997 [336]	208 Hands	Weakness	156	75.0%
Atroshi, 1997 [337]	255 Hands	Weakness	79	31.0%
Cobb, 1996 [348]	235	Weakness	97	41.3%
Elmaraghy, 1996 [349]	69	Weakness	35	50.7%
Kluge, 1996 [354]	66	Weakness	5	7.6%
Lee, 1996 [355]	275 Hands	Weakness	220	80.0%
McLaughlin, 1996 [356]	102	Weakness	17	16.7%
Singh, 1994 [384]	357	Weakness	120	33.6%
Strasberg, 1994 [386]	45	Weakness	42	93.3%

Study	Number of patients (or hands)	Sign or symptom	Number of patients with sign or symptom	Percent of patients (or hands)
Palmer, 1993 [397]	173	Weakness	152	87.9%
Waegeneers, 1993 [398]	100 Hands	Weakness	43	43.0%
Pagnanelli, 1992 [400]	456 Hands	Weakness	210	46.1%
Richman, 1989 [412]	12	Weakness	7	58.3%
Kulick, 1986 [418]	167	Weakness	20	12.0%
Freshwater, 1978 [426]	22	Weakness	17	77.3%

Figure 19. Symptoms of patients with carpal tunnel syndrome

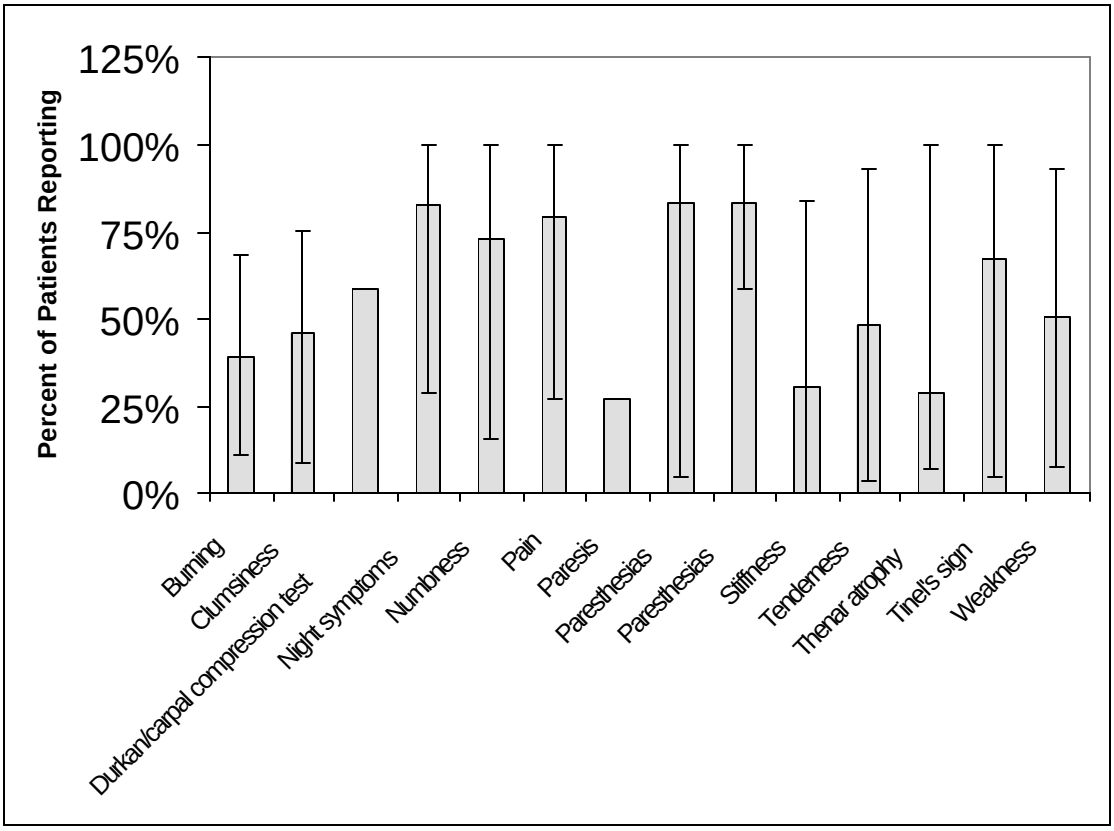
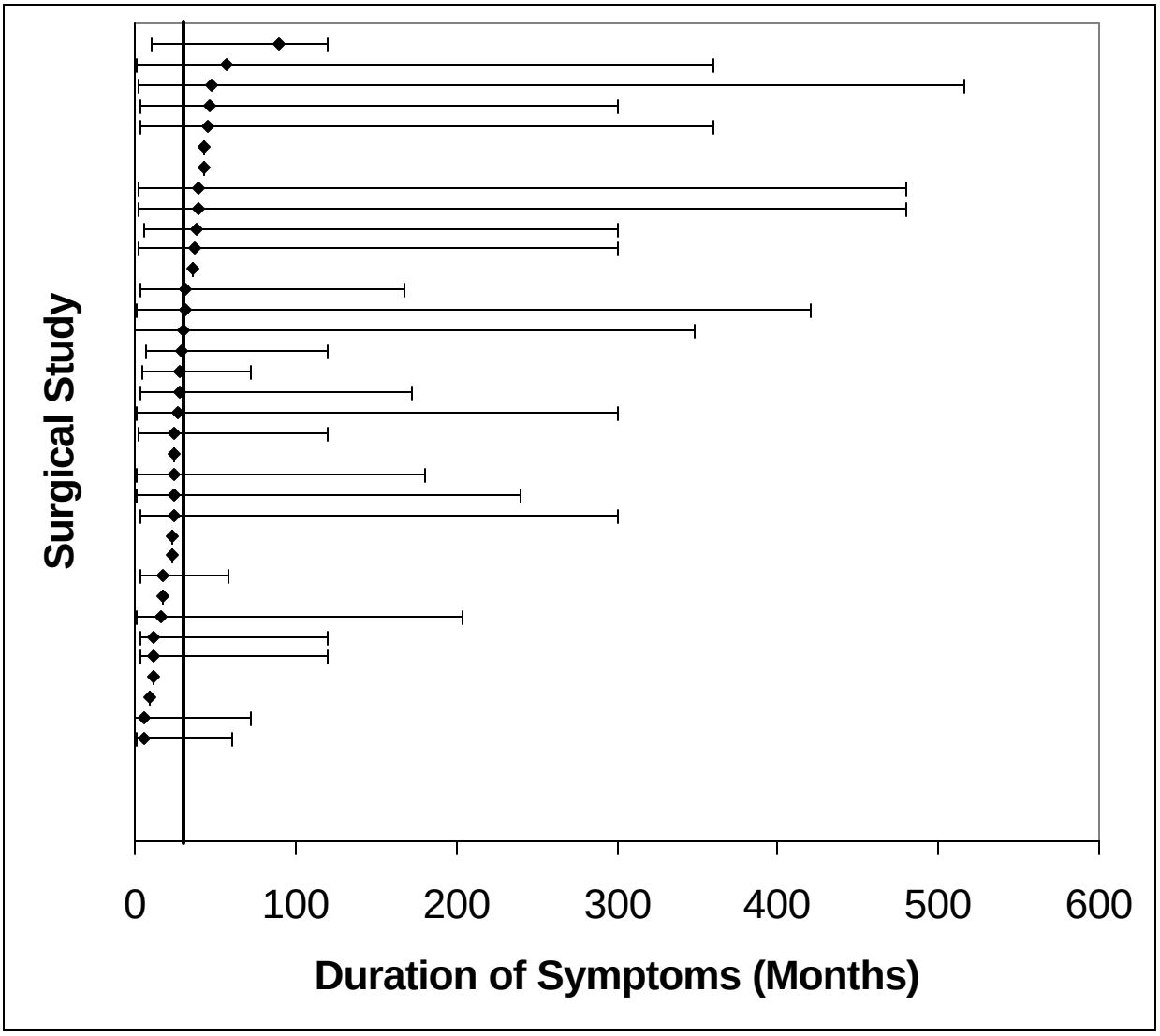


Table 49. Duration of symptoms among patients treated with surgery for carpal tunnel syndrome

Trial	N	Is duration of condition reported as Mean or Median?	Duration of condition before treatment (months)	Shortest period of duration before treatment (months)	Longest period of duration before treatment (months)
Porras, 2000 [313]	85	Mean	39	6	300
Straub, 1999 [305]	67	Median	24	3	300
Buchhorn, 1998 [328]	50	Mean	43	Not reported	Not reported
Lee, 1998 [331]	525	Mean	40.1	2	480
Atroshi, 1997 [337]	204	Mean	24	1	240
Karlsson, 1997 [48]	74	Median	6	1	60
Leinberry, 1997 [342]	44	Mean	31.8	3	168
Wheatly, 1997 [307]	126	Mean	90	10	120
Gibbs, 1996 [351]	46	Mean	57.0	1	360
Glowacki, 1996 [352]	96	Mean	17.8	Not reported	Not reported
Lee, 1996 [430]	525	Mean	40.1	2	480
Nagle, 1996 [357]	506	Mean	31	1	420
Wintman, 1996 [362]	50	Mean	28	3	173
Worseg, 1996 [44]	126	Mean	23.4	Not reported	Not reported
Mirza, 1995 [371]	236	Mean	23	Not reported	Not reported
Nancollas, 1995 [372]	93	Mean	26.5	1	300
Sennwald, 1995 [373]	47	Mean	9.2	Not reported	Not reported
Erdmann, 1994 [304]	96	Mean	24.1	Not reported	Not reported
Roth, 1994 [383]	94	Mean	46.8	4	300
Brown, 1993 [45]	145	Mean	25	2	120
Clarke, 1993 [431]	37	Mean	37	2	300
Levine, 1993 [393]	39	Median	18	3	58
Palmer, 1993 [397]	173	Mean	35.6	Not reported	Not reported
Pagnanelli, 1992 [400]	228	Mean	45.6	3	360
Yu, 1992 [403]	53	Median	6	0	72

Trial	N	Is duration of condition reported as Mean or Median?	Duration of condition before treatment (months)	Shortest period of duration before treatment (months)	Longest period of duration before treatment (months)
Flaschka, 1991 [404]	99	Mean	24	1	180
Hagberg, 1991 [308]	41	Mean	43.6	Not reported	Not reported
Jakab, 1991 [406]	73	Mean	48	2	516
Resnick, 1991 [408]	65	Mean	16.8	1	204
Richman, 1989 [412]	12	Mean	28	5	72
Szabo, 1989 [284]	22	Mean	29	7	120
Kulick, 1986 [418]	167	Mean	30	0	348
Shurr, 1986 [420]	36	Mean	12	Not reported	Not reported
Freshwater, 1978 [426]	11	Mean	12	3	120

Figure 20. Duration of symptoms in studies of surgery for carpal tunnel syndrome



Solid vertical line denotes the mean duration of symptoms

Table 50. Electrodiagnostic criteria among patients treated with surgery for carpal tunnel syndrome

Trial	Electrodiagnostic criteria
Hasegawa, 1999 [320]	Patients with grade I (mild) symptoms were accepted for surgery if they also had distal motor latency >7.1ms or distal motor latency >5.2ms and 3 months of failed conservative treatment
Hirooka, 1999 [321]	Patients with grade 1 (mild) symptoms received surgery only if they had a distal motor latency of at least 7.0 ms.
Aulisa, 1998 [327]	Patients fit into one of the following categories: Mild: Sensory conduction velocity, first digit to wrist <42m/s, third digit to wrist <44m/s Moderate: Sensory conduction velocity as in mild, plus median distal motor latency >4ms Severe: Absent sensory or motor median response.
Jacobsen, 1996 [353]	Patients fit into one of the following categories: Slight CTS: >3 sensory responses delayed 2-4 standard deviations (SD). Intermediate CTS: All sensory responses delayed >3SD+decreased sensory amplitudes. Pronounced CTS: Several or all sensory responses lacking and rest are delayed >4SD with low amplitudes, motor delay >4SD with low amplitude or no motor response. The "normal" values to which these diagnostics were compared, and the size of a standard deviation were not reported.
Cook, 1995 [432]	Distal motor latency >4.5 ms and/or sensory antidromic latency >3.5 ms.
Lang, 1995 [109]	Either distal motor latency >4.5 ms or orthodromic sensory conduction velocity palm-to-wrist <45 m/s
Foulkes, 1994 [376]	Distal sensory latency of at least 3.6ms or motor latency of 4.4ms were considered supportive of diagnosis.
Pascoe, 1994 [381]	Difference between median and palmar sensory latency of more than 0.4ms
Brown, 1993 [45]	Electrophysiological confirmation was established when distal motor latency was 4.5 ms or there was a difference of 1 ms or more between the affected and unaffected hand or sensory latency was more than 3.5 ms or there was a difference of more than 0.5 ms between the affected and unaffected hand.
Nakamichi, 1993 [394]	Distal motor latency >4.2ms or sensory nerve conduction velocity <45ms
Hagberg, 1991 [308]	A positive phalen test or distal motor latency of at least 4.5
Schuind, 1990 [409]	Distal motor latency >4ms or distal sensory latency >3.5ms
Richman, 1989 [412]	Distal motor latency >4.5ms or distal sensory latency >3.5ms
Szabo, 1989 [284]	Distal motor latency >4.5 ms or distal sensory latency >3.5 ms.
Lowry, 1998 [429]	Distal antidromic sensory latency >5ms or unobtainable at 13cm.
Holmgren-Larssen, 1985 [433]	Sensory nerve conduction velocity <50 ms and distal latency >4.5 ms.
Rhoades, 1985 [422]	Fibrillations in the abductor pollicis or opponens pollicis muscles detectable by EMG.
Van Rossum, 1980 [424]	Distal motor latency >4.5 ms
Freshwater, 1978 [426]	No patients had normal motor latency (4.5ms or less), but this was not stated to have been an inclusion criterion.

Table 51. Reported occupations of patients receiving surgery for carpal tunnel syndrome

Study	Occupation	Number of Patients	Number of patients with occupation	Percent of patients with occupation
Mirza, 1995 [371]	Blue Collar	56	9	16.1%
Olney, 1999 [323]	Clerical	211	89	42.2%
Weber, 1997 [347]	Clerical	74	29	39.2%
Cobb, 1996 [348]	Clerical	235	38	16.2%
Mirza, 1995 [371]	Clerical	56	6	10.7%
Kelly, 1994 [378]	Clerical	69	10	14.5%
Palmer, 1993 [397]	Clerical	173	35	20.2%
Pagnanelli, 1992 [400]	Clerical	228	71	31.1%
Dumontier, 1995 [365]	Clerical, unoccupied or retired	96	47	49.0%
Wintman, 1996 [362]	Disabled	50	1	2.0%
Worseg, 1996 [44]	Employee	126	19	15.1%
Buchhorn, 1998 [328]	Employee- average work	50	21	42.0%
Olney, 1999 [323]	Factory	211	30	14.2%
Nagle, 1996 [357]	Heavy work	506	27	5.3%
Yu, 1992 [403]	Heavy work	53	23	43.4%
Porras, 2000 [313]	High manual activity	85	14	16.5%
Kelly, 1994 [378]	High manual activity	69	7	10.1%
Cobb, 1996 [348]	Homemaker	235	19	8.1%
Wintman, 1996 [362]	Homemaker	50	12	24.0%
Worseg, 1996 [44]	Homemaker	126	8	6.3%
Mirza, 1995 [371]	Homemaker	56	5	8.9%
Chow, 1994 [42]	Homemaker	815	63	7.7%
Kelly, 1994 [378]	Homemaker	69	14	20.3%
Yu, 1992 [403]	Homemaker	53	3	5.7%
Palmer, 1993 [397]	Industrial	173	90	52.0%
Katz, 1997 [302]	Laborer/machine operator	135	25	18.5%
Nagle, 1996 [357]	Light work	506	72	14.2%
Buchhorn, 1998 [328]	Light work	50	16	32.0%
Yu, 1992 [403]	Light work	53	8	15.1%
Wintman, 1996 [362]	Light labor with repetitive tasks or clerical work	50	15	30.0%
Nagle, 1996 [357]	Light-repetitive work	506	42	8.3%
Porras, 2000 [313]	Low manual activity	85	37	43.5%
Kelly, 1994 [378]	Low manual activity	69	21	30.4%
Katz, 1997 [302]	Management	135	22	16.3%
Weber, 1997 [347]	Management	74	14	18.9%
Lindau, 1999 [322]	Manual Worker	140	29	20.7%
Buchhorn, 1998 [328]	Manual Worker	50	8	16.0%
Weber, 1997 [347]	Manual Worker	74	25	33.8%
Cobb, 1996 [348]	Manual Worker	235	60	25.5%
Dumontier, 1995 [365]	Manual Worker	96	45	46.9%
Erhard, 1999 [318]	Manual worker- heavy lifting	124	12	9.7%
Olney, 1999 [323]	Manual worker- heavy lifting	211	40	19.0%

Study	Occupation	Number of Patients	Number of patients with occupation	Percent of patients with occupation
Buchhorn, 1998 [328]	Manual worker- heavy lifting	50	5	10.0%
Wintman, 1996 [362]	Manual worker- heavy lifting	50	5	10.0%
Chow, 1994 [42]	Manual worker- heavy lifting	815	322	39.5%
Pagnanelli, 1992 [400]	Manual worker- heavy lifting	228	60	26.3%
Erhard, 1999 [318]	Manual worker- light lifting	124	12	9.7%
Chow, 1994 [42]	Manual worker- light lifting	815	215	26.4%
Pagnanelli, 1992 [400]	Manual worker- light lifting	228	97	42.5%
Olney, 1999 [323]	Meat packing	211	15	7.1%
Palmer, 1993 [397]	Medical	173	7	4.0%
Porras, 2000 [313]	Medium manual activity	85	35	41.2%
Nagle, 1996 [357]	Medium work	506	46	9.1%
Yu, 1992 [403]	Medium strenuous work	53	13	24.5%
Lindau, 1999 [322]	Nonmanual worker	140	41	29.3%
Chow, 1994 [42]	Other	815	68	8.3%
Katz, 1997 [302]	Other	135	81	60.0%
Cobb, 1996 [348]	Other	235	14	6.0%
Worseg, 1996 [44]	Other	126	3	2.4%
Kelly, 1994 [378]	Other	69	1	1.4%
Palmer, 1993 [397]	Other	173	15	8.7%
Wintman, 1996 [362]	Professional	50	6	12.0%
Mirza, 1995 [371]	Professional	56	11	19.6%
Palmer, 1993 [397]	Professional	173	16	9.2%
Palmer, 1993 [397]	Education	173	8	4.6%
Lindau, 1999 [322]	Retired	140	21	15.0%
Weber, 1997 [347]	Retired	74	6	8.1%
Wintman, 1996 [362]	Retired	50	7	14.0%
Worseg, 1996 [44]	Retired	126	60	47.6%
Hallock, 1995 [368]	Retired	100	15	15.0%
Mirza, 1995 [371]	Retired	56	5	8.9%
Strasberg, 1994 [386]	Retired	45	4	8.9%
Yu, 1992 [403]	Retired	53	6	11.3%
Palmer, 1993 [397]	Retired or Homemaker	173	40	23.1%
Olney, 1999 [323]	Retired or light employment	211	57	27.0%
Chow, 1994 [42]	Retired or unemployed	815	147	18.0%
Kelly, 1994 [378]	Retired or unemployed	69	16	23.2%
Erhard, 1999 [318]	Sedentary	124	18	14.5%
Nagle, 1996 [357]	Sedentary	506	69	13.6%
Strasberg, 1994 [386]	Student	45	2	4.4%
Wintman, 1996 [362]	Unemployed	50	4	8.0%
Worseg, 1996 [44]	Unemployed	126	19	15.1%
Strasberg, 1994 [386]	Unemployed	45	28	62.2%
Worseg, 1996 [44]	Worker	126	17	13.5%

Figure 21. Number of studies reporting occupations of patients receiving surgery for carpal tunnel syndrome

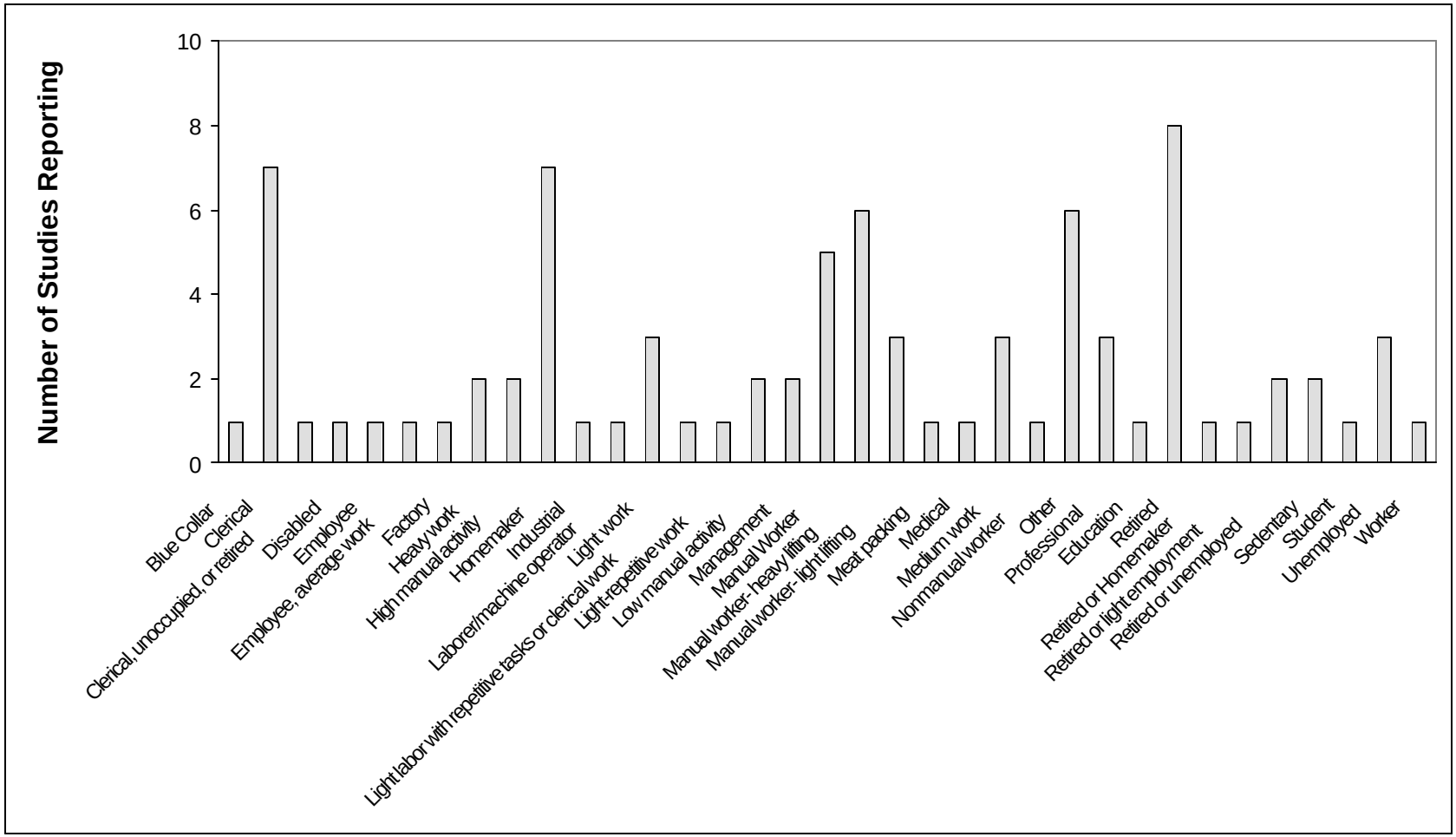


Figure 22. Percent of patients with reported occupations receiving surgery for carpal tunnel syndrome

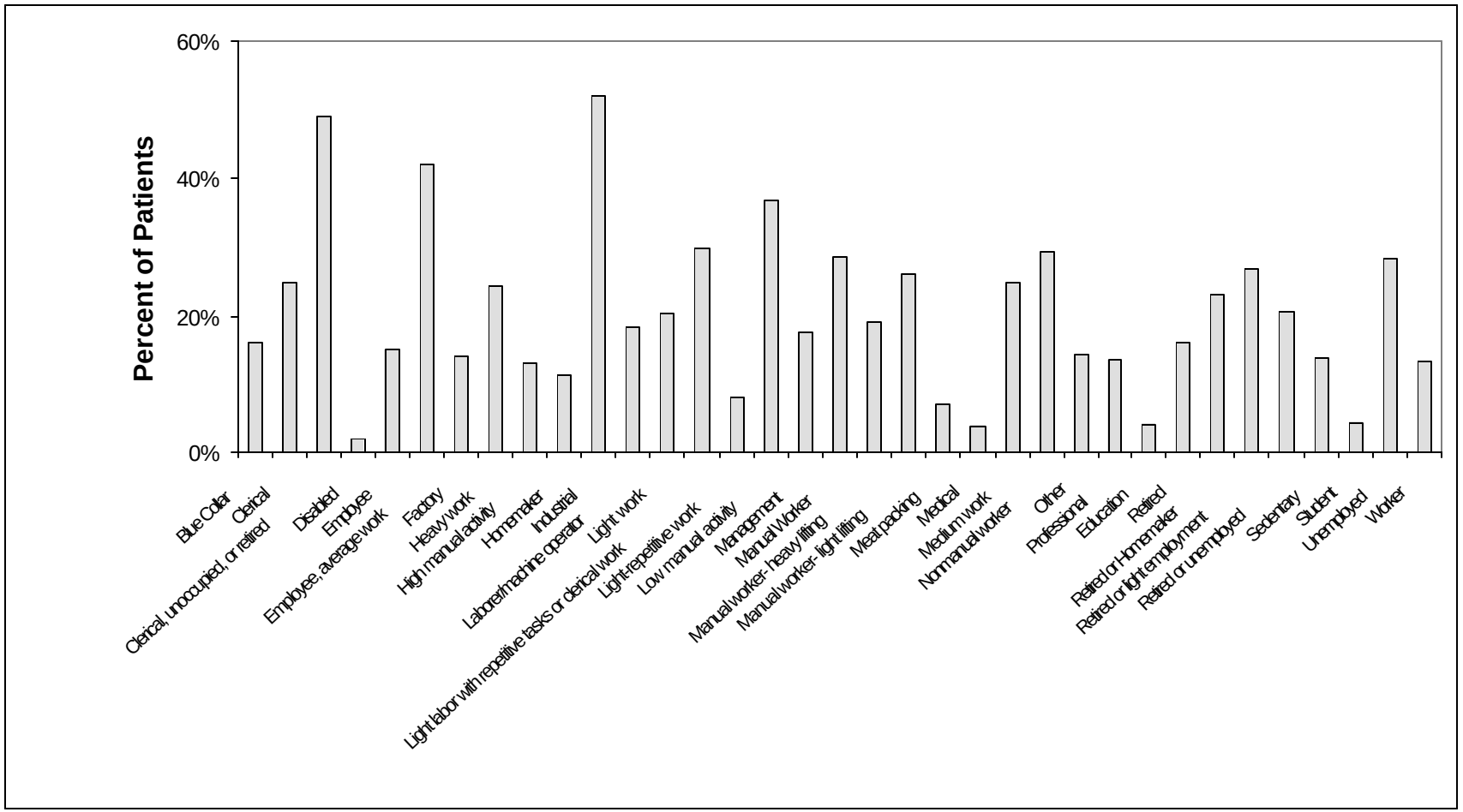
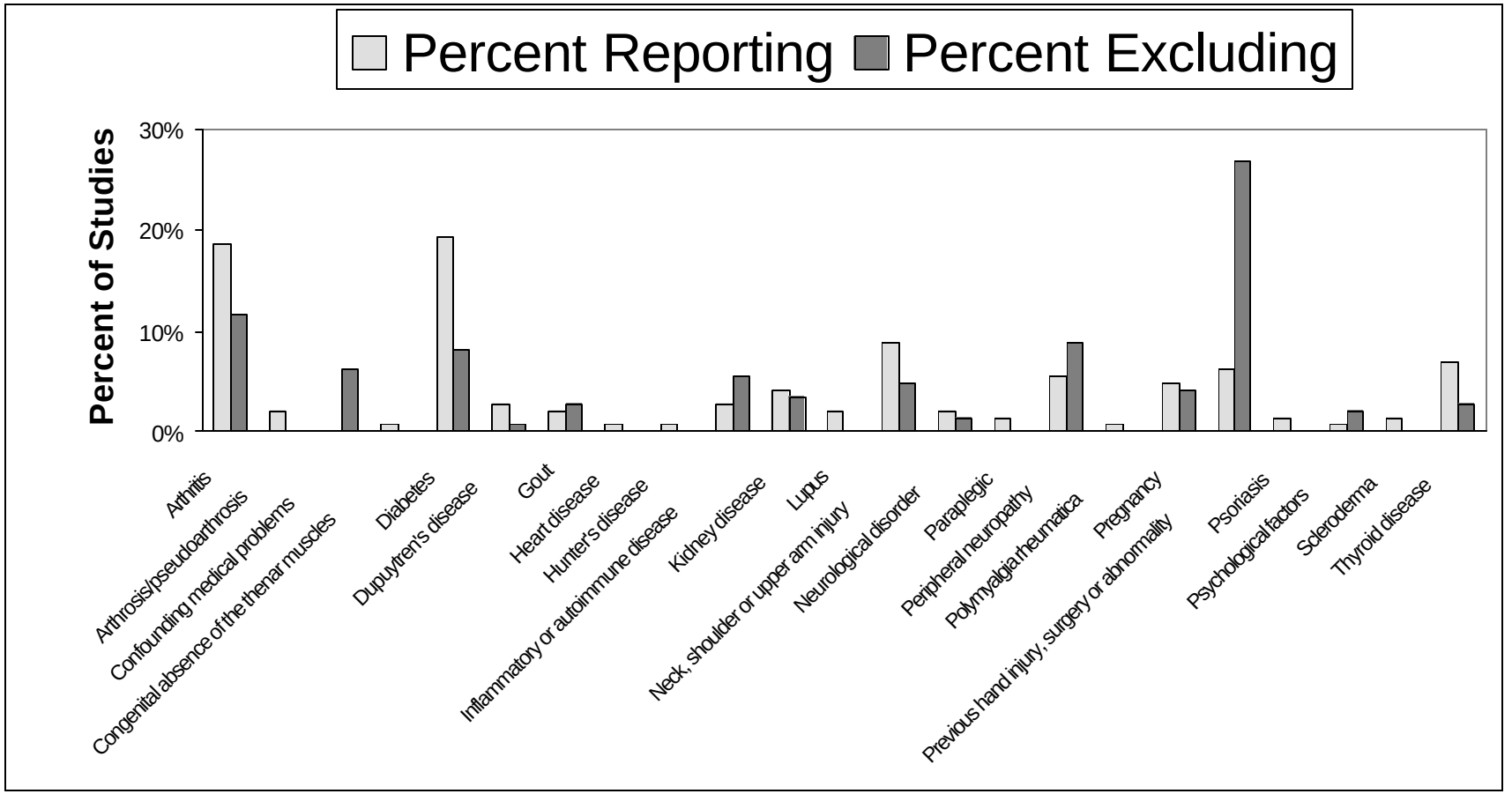


Figure 23. Percent of studies reporting and excluding comorbidities



Question #3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with carpal tunnel syndrome?

Evidence Base

In addressing this question, we consider only data from controlled trials. Controls are needed to account for changes that can occur over time that are not due to treatment. These changes could be caused by rest, changes in patient activity, or other factors. CTS is often a progressive disease, but remissions occur, even in untreated patients.[434]

As described in the methodology section of this evidence report, we only evaluate patient-oriented outcomes. These are the outcomes of primary interest to the patient. They include pain, functional activity, quality of life, return to work, and global measures of treatment outcome such as patient satisfaction and overall relief of symptoms. Functional activity includes the measures of functional ability as well as measures of activities of daily living (ADL), including time to return to ADL. Outcomes that are not directly experienced by the patient, such as change in nerve conduction velocity, are not assessed. Surrogate outcomes, such as two-point discrimination or grip strength, are important only to the extent that they correlate with patient-oriented outcomes. Because no measures of correlation between changes in surrogate outcomes and changes in patient-oriented outcomes have been published, we did not analyze surrogate outcomes.

To determine the benefits and harms of various treatments for carpal tunnel syndrome, we retrieved 58 controlled trials. Seventeen of these were excluded for reasons stated in Table 52, leaving 41 studies to be assessed. Four (10%) of these trials were multicenter, 27 (66%) were randomized, and 34 (83%) were prospective. Sixteen (39%) of the studies were double or single blinded and 16 (39%) either used intent-to treat analysis to account for patients lost to followup or had no reported loss to followup.

No published trials compared surgery to no treatment or placebo, making it difficult to determine, in strict scientific terms, whether surgery benefits patients. Although absence of evidence is not evidence of absence of efficacy, the lack of trials that incorporate these controls complicates evaluation of the effectiveness of surgery. However, differences between the effects of various surgical treatments can in some cases be assessed. The existence of differences in effect size between treatments may itself constitute evidence that some treatments are, to some extent, effective.

The 41 studies are divided below into groups of studies comparing similar treatments. Internal validity and generalizability are discussed separately for each group of studies. The former term describes the potential for bias in the studies. Randomization and blinding help to eliminate potential sources of bias, providing stronger evidence that any observed differences between groups are the result of differences in treatment. Patient attrition and threats to statistical validity may also affect internal validity.

Generalizability refers to the extent to which the results of a trial may be applied to the overall population of candidates for treatment. If the patients described in a trial are unusual or specialized, the generalizability of the trial is limited. The results of a study that includes only elderly patients, for example, may not be generalizable to a population of younger patients.

Table 52. Excluded trials

Study	Reason for Exclusion
Todnem, 2000 [435]	Retrospective comparison of operated and nonoperated patients. Groups were significantly different in several electrodiagnostic parameters prior to surgery.
Atherton, 1999 [436]	Did not report any patient characteristics or patient-oriented outcomes.
Brüser, 1999 [437]	A single study comparing two very similar treatments.
Davis, 1998 [438]	Utilized a combination of treatments, rendering it impossible to determine the effect of a single treatment.
Ebenbichler, 1998 [439]	There were significant differences between groups at baseline. Although patients were described as having bilateral carpal tunnel syndrome, five patients in the treated group and seven in the placebo group had no wrist complaints.
Garfinkel, 1998 [440]	The treatment received by the control group was not standardized and was not described.
Netscher, 1998 [47]	Did not report any patient-oriented outcomes.
Rozmaryn, 1998 [32]	Patients received an assortment of nonstandardized treatments in addition to the experimental treatment.
Braithwaite, 1997 [441]	Compares minor variations in surgical technique. No patient-oriented outcome measures were reported other than perioperative pain. No patient characteristics were reported.
Jones, 1997 [442]	A single study comparing two very similar treatments.
Monge, 1995 [443]	No patient-oriented outcomes were reported for the controls; only for treated patients. Reported no information on the source of control data or the comparability of controls and treated patients.
Bande, 1994 [444]	Groups were not comparable. Patients with comorbidities (e.g. synovitis, diabetes, rheumatoid arthritis) were all placed in the open release group. There was no indication as to how many such patients were included.
Biyani, 1993 [388]	A single study comparing two very similar treatments.
Nathan, 1993 [395]	A single study comparing two very similar treatments.
Spooner, 1993 [445]	Did not report any patient-oriented outcomes.
Groves, 1989 [446]	Compared outcomes at two separate clinics. There was no indication that the patient populations treated by the two clinics were comparable. This study had no internal validity.
Wolaniuk, 1983 [447]	Did not report any patient-oriented outcomes.
Ellis, 1979 [447]	Describes a double-blind crossover study of a single patient.

What are the relative benefits and harms of open and endoscopic carpal tunnel release for persons with carpal tunnel syndrome?

Seventeen published controlled trials addressing this question met inclusion criteria. These trials described a total of 2,598 patients.

Internal validity

Six of these trials were randomized; two of which were blinded. One RCT was incompletely randomized, as some patients with bilateral CTS requested endoscopic release for their second procedure after undergoing endoscopic release in the initial hand.[46] Blinding of patients and posttreatment examiners in trials of surgical treatments is often impractical, if not impossible. In the two blinded studies, only raters and not patients were blinded. In addition to the prospective trials, there were four retrospective comparisons between patient groups. Patient attrition ranged from zero to more than 80%. No studies with patient attrition performed intent-to-treat analyses performed. In at least two reports, investigators had a financial stake in the results of their studies. Neither of these studies were blinded. Study characteristics affecting internal validity are listed in Table 53.

Randomization is necessary to ensure that patients in the different groups of a study are as similar as possible. One particularly important feature of randomization is that important but unknown patient characteristics are equally distributed among groups. Finally, randomization reduces the chance of bias being introduced as a result of the personal preferences or expectations of the patient or the physician. Similarly, lack of blinding can introduce bias.

Patient attrition may skew the results of a study in the direction of seeming more favorable toward a treatment, because patients who are dissatisfied with their treatment may be less likely to return for followup examinations. Wherever possible, we have recalculated data from studies with patient attrition. In doing so, we apply the conservative assumption that treatment failed for all patients lost to followup. If statistical significance is obtained under this assumption, one can be more confident that the effect of patient attrition is not severe enough to overturn a statistically significant result.

An additional threat to internal validity common in studies of carpal tunnel syndrome is the presence of bilateral procedures. Carpal tunnel syndrome often occurs in both hands, leading some researchers to report outcome data per procedure rather than per patient. Using procedures rather than patients as the unit of analysis violates statistical assumptions of independence between and within groups and compromises the statistical validity of the study if more than one procedure is performed on a single patient. Four studies included patients with bilateral procedures, but did not violate assumptions of independence between groups because all patients had the same procedure in each hand.[351,368,379,448] An additional study implied, but did not explicitly state, that no patient underwent both open and endoscopic release.[317] Two studies included patients with

bilateral procedures, but analyzed their data using the Wilcoxon rank-sum test, which does not assume independence between groups.[304,353] The study by Sennwald also analyzed some data by this method, but did not specify which comparisons utilized this test.[373] In all cases, assumptions of independence within groups were violated.

Violating the assumption of independence within groups leads to underestimation of standard errors and spurious statistically significant results (Type I errors). Four studies had no bilateral procedures and therefore did not violate the independence assumption. Among the remaining studies, the extent of the violation depends on the percentage of patients with bilateral procedures. The more bilateral patients, the more severe the violation. To guage the severity of this violation, we note the percentage of patients on whom bilateral procedures were performed for each study. Four of the studies (Chen, Gibbs, Futami and Erdman) had a fairly high percentage of patients who received bilateral procedures (>30%), and are particularly prone to statistical biases in their results.

The power of a statistical test to detect differences between groups is also an internal validity issue. However, statistical power is different for each outcome. Therefore, power is addressed as part of the discussion of each outcome, below.

Generalizability

The average age of patients in the 13 studies that provided this information is 49.0 years. Mean ages ranged from 44 to 56 years, while individual ages ranged from 19 to 90 years. The majority of patients (56% to 100%) were female. This is consistent with available epidemiological data on carpal tunnel syndrome,[22,25] as well as with data on surgical patients compiled in answer to question 2 of this evidence report. This indicates that the results of these studies are broadly generalizable to the overall carpal tunnel population. These and other patient characteristics are listed in Table 54.

The presence of various comorbidities associated with CTS is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 54 by a zero under that comorbidity. This somewhat limits the generalizability of these studies, as comorbidities are not exclusion criteria for surgery. An exception is rheumatoid arthritis, which can sometimes interfere with endoscopic carpal tunnel release. Five studies excluded patients with severe CTS. While this exclusion may limit our ability to generalize to other severe CTS patients, it may render the results more generalizable to average patients. Eight studies excluded patients with mild CTS. The effect of this exclusion on generalizability is unknown, because we do not know whether the criteria applied were unique to these studies or if they are normally applied to surgical candidates in general clinical practice.

Patient employment characteristics (Table 55) are incompletely reported in these studies. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall CTS patient population cannot be determined from the information available.

Table 53. Internal validity of studies comparing open and endoscopic carpal tunnel release

Study	Number of patients	Percent of patients with bilateral procedures	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?
Concannon, 2000 [449]	191	NR[a]	Single	Not reported	Retro	No	0	Yes
Chen, 1999 [317]	948	At least 34.8%[b]	Single	Not reported	Retro	No	24	No
Hasegawa, 1999 [320]	82	2.4%	Single	Not reported	Retro	No	0	Yes
Povlsen, 1997 [450]	120	0%	Multiple (<5)	Not reported	CT	No	4	No
Gibbs, 1996 [351]	46	23.9%	Single	Not reported	Retro	No	3	No
Jacobsen, 1996 [353]	29	10.3%	Single	Not reported	RCT	Rater	0	Yes
Worseg, 1996 [44]	126	0%	Single	Not reported	CT	No	0	Yes
Dumontier, 1995 [365]	103	0%	Single	Not reported	RCT	No	83	No
Futami, 1995 [366]	10	100%	Single	Not reported	CT	No	0	Yes
Hallock, 1995 [368]	96	37%	Single	Not reported	CT	No	0	No[c]
Sennwald, 1995 [373]	47	0%	Single	Not reported	RCT	No	0	Yes
Erdmann, 1994 [304]	71	47.9%	Single	Not reported	RCT	No	0	Yes
Kerr, 1994 [379]	157	At least 17.4%[b]	Single	Not reported	CT	No	13	No
Brown, 1993 [45]	151	13.2%	Multiple (<5)	No	RCT	Rater	22	No
McDonough, 1993 [448]	88	23.5%	Single	Yes	Retro	No	7	No
Palmer, 1993 [397]	211	29.4%	Single	No	CT	No	0	Yes
Agee, 1992 [46]	122	20.5%	Multiple (>5)	Yes	RCT	No	NR	No

[a]: This report describes the results of 191 procedures. The number of patients was not reported.
[b]: The number of bilateral procedures among those patients who underwent open procedures was not reported.
[c]: Four patients whose endoscopic procedures were, for various technical reasons, converted to open procedures, are included in the Open group.

Table 54. Generalizability of studies comparing open and endoscopic carpal tunnel release

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Concannon, 2000 [449]	191	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Chen, 1999 [317]	948	48 (21-79)	78.5	NR	0.6	2.4	0	NR	0	0.3	0	Yes	No
Hasegawa, 1999 [320]	82	54.1	100	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Povlsen, 1997 [450]	120	NR	NR	NR	NR	NR	NR	NR	0	NR	NR	No	No
Gibbs, 1996 [351]	46	56.2 (31-86)	89.1	57.0 (1-360)	0	0	NR	0	NR	NR	NR	No	No
Jacobsen, 1996 [353]	29	(24-59)	NR	NR	NR	NR	NR	NR	NR	NR	NR	Yes	Yes
Worseg, 1996 [44]	126	56.0 (35-90)	69.8	23.4	NR	0	NR	NR	0	NR	NR	Yes	Yes
Dumontier, 1995 [365]	103	52.3	82.5	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Futami, 1995 [366]	10	53 (39-61)	90.0	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Hallock, 1995 [368]	96	44.2	77.1	NR	NR	NR	0	NR	NR	NR	NR	No	No
Sennwald, 1995 [373]	47	52.5	80.9	9.2	0	0	NR	NR	NR	NR	NR	No	Yes
Erdmann, 1994 [304]	71	53.4	98.6	27.3	2.8	28.2	0	NR	NR	NR	NR	Yes	No
Kerr, 1994 [379]	157	44.8 (19-82)	56.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Brown, 1993 [45]	151	55 (25-87)	65.6	25 (2-120)	NR	0	NR	NR	0	0	NR	No	No
McDonough, 1993 [448]	88	46.0 (21-79)	62.5	35.6	NR	NR	NR	NR	NR	NR	NR	No	Yes
Palmer, 1993 [397]	211	44.9 (20-83)	65.4	35.7	1.4	0	NR	NR	NR	NR	NR	No	Yes

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Agee, 1992 [46]	122	NR	NR	NR	0	0	0	NR	0	NR	0	Yes	Yes

Table 55. Patient employment characteristics in studies comparing open and endoscopic carpal tunnel release

Study	Number of patients	% Patients employed	% Patients receiving workers' compensation	% Patients retired	% Patients Homemakers	Reported occupations
Concannon, 2000 [449]	191	Not reported	44.0	Not reported	Not reported	Not reported
Chen, 1999 [317]	948	Not reported	Not reported	Not reported	Not reported	Not reported
Hasegawa, 1999 [320]	82	Not reported	Not reported	Not reported	Not reported	Not reported
Povlsen, 1997 [450]	120	Not reported	Not reported	Not reported	Not reported	Not reported
Gibbs, 1996 [351]	46	84.8	15.2	Not reported	Not reported	16 Retired, homemaker or unemployed
Jacobsen, 1996 [353]	29	100	0	0	0	Not reported
Worseg, 1996 [44]	126	31.0	87.3	47.6	6.3	19 Employee 17 Worker 60 Retired 19 Unemployed 8 Homemaker 3 Other
Dumontier, 1995 [365]	103	89.3	Not reported	Not reported	Not reported	45 Manual workers 47 Clerical, unoccupied or retired
Futami, 1995 [366]	10	Not reported	Not reported	Not reported	Not reported	Not reported
Hallock, 1995 [368]	96	Not reported	54.2	15.6	Not reported	Not reported
Sennwald, 1995 [373]	47	Not reported	Not reported	Not reported	Not reported	Not reported
Erdmann, 1994 [304]	71	Not reported	Not reported	Not reported	Not reported	Not reported
Kerr, 1994 [379]	157	Not reported	Not reported	Not reported	Not reported	Not reported
Brown, 1993 [45]	151	53.6	4.6	Not reported	Not reported	41 Professional, management or business 29 Clerical or technical support 11 Manual labor
McDonough, 1993 [448]	88	Not reported	27.3	Not reported	Not reported	Not reported

Study	Number of patients	% Patients employed	% Patients receiving workers' compensation	% Patients retired	% Patients Homemakers	Reported occupations
Palmer, 1993 [397]	211	73.9	57.8	Not reported	Not reported	8 Education 90 Industrial 7 Medical 16 Professional 35 Clerical 40 Retired or Homemaker 15 Other
Agee, 1992 [46]	122	Not reported	Not reported	Not reported	Not reported	Not reported

Results

Global outcome

A global outcome is any score that attempts to encompass the overall success or failure of the treatment. It may be a numerical rating of overall symptom relief or patient satisfaction, a categorical rating such as excellent, good, fair or poor, or a dichotomous rating such as the answer to the question "Would you undergo this procedure again?." Such outcomes were reported in seven controlled trials, two of which were randomized and two of which were retrospective. The results are presented in Table 56.

Five studies reported sufficient data for an effect size to be calculated. This number was sufficient for us to perform a meta-analysis. In this analysis, a positive effect size indicates that the study favors endoscopic release over open release, and a negative effect size indicates the converse. The results of the meta-analysis of the five studies are summarized in Table 57.

The combined fixed effect size from the meta-analysis is modest (d = 0.19), but statistically significant. The individual and combined effect sizes are illustrated in Figure 24. The magnitude of the effect size is further illustrated in Figure 25 which demonstrates that there is a high degree (85.7%) of overlap in the global outcome scores of the two treatment groups.

Four of the five studies were neither randomized nor blinded. Two were retrospective. Although there is a trend in favor of endoscopic release, the suboptimal quality of the studies incorporated into this analysis means that these results are suggestive rather than definitive. In addition, the difference is not robust. The incorporation of a single study showing no difference between groups into the meta-analysis would render the overall effect size nonsignificant. On the other hand, the two studies reporting global outcomes that were not incorporated into the meta-analysis all found slightly more favorable results in the endoscopic groups. Addition of these studies would likely reduce the impact of a "no-effect" study on the summary effect size. Therefore, our analysis suggests that although there may be a difference in the global outcome of patients who receive open surgery and those who receive endoscopic surgery, any such difference is small, and its exact value is uncertain.

Table 56. Global outcome in patients treated with open or endoscopic carpal tunnel release

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Hasegawa et al., 1999 [320]	40 Open 42 Endoscopic	Global outcome rating at 12 Months 28 Excellent 8 Good 3 Fair 1 Poor 29 Excellent 13 Good 1 Fair 1 Poor	Not significantly different by chi square test conducted by ECRI, p = 0.57
Gibbs et al., 1996 [351]	43 Open 14 Endoscopic (Hands)	Mean change in symptom severity score 3-33 Months -12.5±5.6 -12.2±5.3	Not significantly different by t-test conducted by ECRI, p = 0.86
Worseg et al., 1996 [44]	62 Open 64 Endoscopic	Mean symptom rating, verbal scale This outcome was reported using a 3-dimensional graph, making it difficult to estimate values.	Scores were not significantly different between groups at any time point (p >0.05, Wilcoxon rank sum test)
Futami 1995 [366]	10 Open 10 Endoscopic (Hands of 10 patients)	Weeks until relief of symptoms 2.5 Weeks 2.4 Weeks	Not reported
Hallock 1995 [368]	71 Open 66 Endoscopic (Hands)	Number of hands with complete relief of symptoms (Time not reported) 63 61	Not significantly different by chi square test conducted by ECRI, p = 0.46
Erdmann, 1994 [304]	52 Open 53 Endoscopic	Days until relief of symptoms 1.75 Days 1.1 Days	Not significantly different by Mann-Whitney test. The p value determining significance was not reported.
Brown, 1993 [45]	82 Open 78 Endoscopic (Hands)	Mean patient satisfaction rating, 0-100 84 Days: 84±26 84 Days: 89±18	Not significantly different by t-test conducted by ECRI, p = 0.15

Table 57. Results of meta-analysis of the effect of open or endoscopic treatment on global outcome

Author	Year	N	Effect Size	95% CI	p-value	Standardized Residual	Outlier by Std Resid?
Hasegawa [320]	1999	82	0.362	-0.07-0.80	0.105	0.83	No
Gibbs [351]	1996	57	-0.054	-0.66-0.55	0.862	-0.84	No
Worseg [44]	1996	126	0.12[a]	-0.23-0.41.	0.502	-0.49	No
Hallock [368]	1995	137	0.240	-0.41-0.89	0.466	0.15	No
Brown [45]	1993	160	0.222	-0.09-0.53	0.163	-0.22	No
		Summary Effect Size		95% CI	p-value	Q Statistic	p of Q
Fixed Effects Model		0.19		0.01-0.38	0.041	1.44	0.838

a: Estimated from published data by assuming that the p-value of the Wilcoxon test was 0.5

Figure 24. Results of meta-analysis of effect of treatment on global outcome

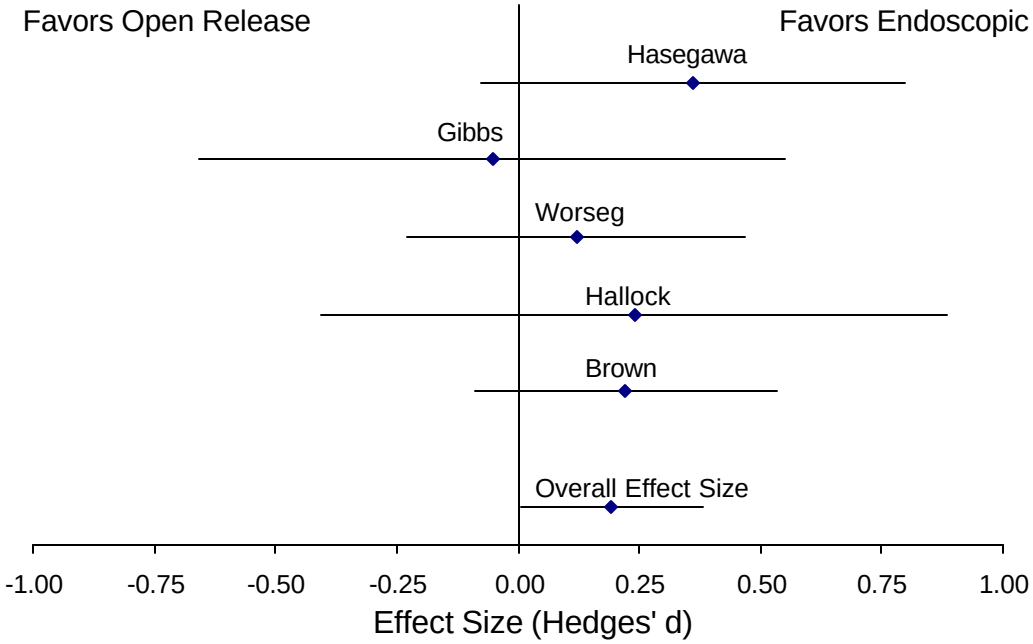
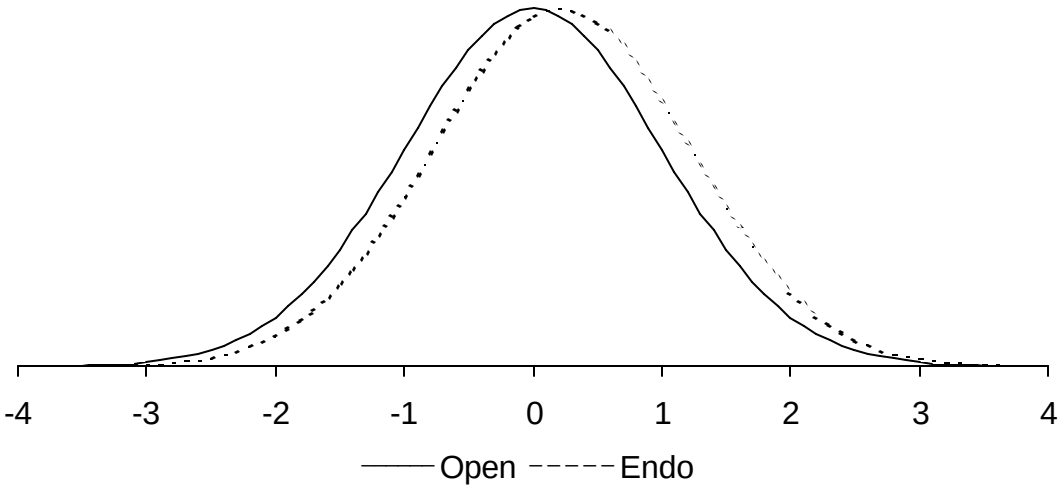


Figure 25. Degree of overlap between outcomes



Return to work

Return to work was reported in 12 controlled trials, six of which were randomized and two of which were retrospective. Only two studies reported sufficient data for an effect size to be calculated. Results from such a small fraction (16.7%) of the available studies do not constitute a sufficient sampling of the available information. For this reason, we did not perform a meta-analysis on these data. The results of the trials are given in Table 58. Data are reported as means plus or minus standard deviations (when available) unless otherwise stated.

Table 59 summarizes return to work data by indicating whether patients treated with endoscopic or open carpal tunnel release had a faster reported return to work, and whether that difference was statistically significant. As can be seen in Table 59 and Figure 26, only one trial found that patients receiving open release returned to work faster than those receiving endoscopic release, and that difference was not statistically significant. Examination of the study designs, patient and employment characteristics (Table 53, Table 54, and Table 55) does not suggest a reason why this study found a trend opposite that observed in the other studies. In contrast, 11 trials found that endoscopic release led to faster return to work. This difference was statistically significant in six trials.

Table 59 also indicates the power of each study to detect differences between groups. In all three of the studies for which power could be calculated, there was insufficient power to detect small (less than 10%) differences between groups. Two of the studies that did not detect a significant effect lacked the power to detect moderate (less than 25%) differences. The addition of more patients to these studies might have increased the statistical power to detect differences between groups enough so that the detected differences would have become statistically significant.

Effect sizes (Hedges' d) could be calculated for only two studies. These are given in Table 59 and Figure 27.

Because no meta-analysis could be conducted on the available studies, we base our conclusions on a semi-quantitative analysis. Data from 11 of 12 trials suggest that patients undergoing endoscopic surgery show a tendency toward faster return to work than patients who have open surgery. However, because no quantitative analysis was possible, no reliable conclusions can be drawn as to how much faster they may return.

Table 58. Time to return to work in patients treated with open or endoscopic surgery

Study	n (units)	Time Until Return to Work	Statistical Significance of Difference Between Groups
Gibbs, 1996 [351]	Open Endoscopic Total N = 28 Group n not reported	Time at which 50% of patients had returned to work 4 Days (Range 1->1003)[a] 14 Days Range (1-91)	Groups were not significantly different by log rank test , p = 0.63
Jacobsen, 1996 [353]	16 Open 16 Endoscopic (Hands)	Open 18.94±10.25 Days (Range 0-42) Endoscopic 17.06±9.11 Days (Range 0-31)	Groups not significantly different, p >0.05, Fisher Exact test
Dumontier, 1995 [365]	Open Endoscopic Numbers of patients not reported	Percent of patients returning to work within: 2 Weeks: 29%; 1 Month: 70%; 3 Months: 89%[b] 2 Weeks: 30%; 1 Month 45%; 3 Months 70%	Groups were not significantly different at any time by chi square test . At 1 month, p = 0.13. p-values were not reported for the other two time points.
Futami, 1995 [366]	Open 3 Endoscopic 3	7 Weeks 6 Weeks	Not reported
Hallock, 1995 [368]	Open 39 Endoscopic 25	46.3±36.9 Days[c] 39.8±19.3 Days	Groups were not significantly different, p = 0.373. The test used was not reported.
Sennwald, 1995 [373]	22 Open 25 Endoscopic (Patients)	41.95±13.18 Days[d] 24.13±7.69 Days	Groups were significantly different by t-test calculated by ECRI, p = 0.000001
Erdmann, 1994 [304]	23 Open (Patients) 27 Open (Hands)[e] 23 Endoscopic (Patients) 28 Endoscopic (Hands)	39 Days Open 14 Days Endoscopic	Groups were significantly different, p <0.005 unpaired Mann-Whitney U test

Study	n (units)	Time Until Return to Work	Statistical Significance of Difference Between Groups
Kerr, 1994 [379]	72 Open 72 Endoscopic	Patients treated endoscopically returned to work 10.6 days sooner than those treated openly.	Groups were significantly different by paired t-test (p = 0.0015)
Brown, 1993 [45]	85 Open 84 Endoscopic (Hands)	Median 28 Days Open[a] Median 14 Days Endoscopic	Groups were statistically significant, p <0.05, log-rank test
McDonough, 1993 [448]	28 Open 27 Endoscopic (Patients)	50.4 Days (Range 11-103) 28.5 Days (Range 4-67)	Not reported
Palmer, 1993 [397]	Open Endoscopic-Agee method Endoscopic-Chow method n not reported	44.1±37.3 20.7±12.8 27.9±16.9	Open was significantly different from the other two groups by t-test, p <0.05
Agee, 1992 [46]	30 Open 49 Endoscopic (Patients)	Median 46.5 Days[a] Median 25 Days	Statistically significant difference between groups, p <0.01, survival analysis version of the Wilcoxon test

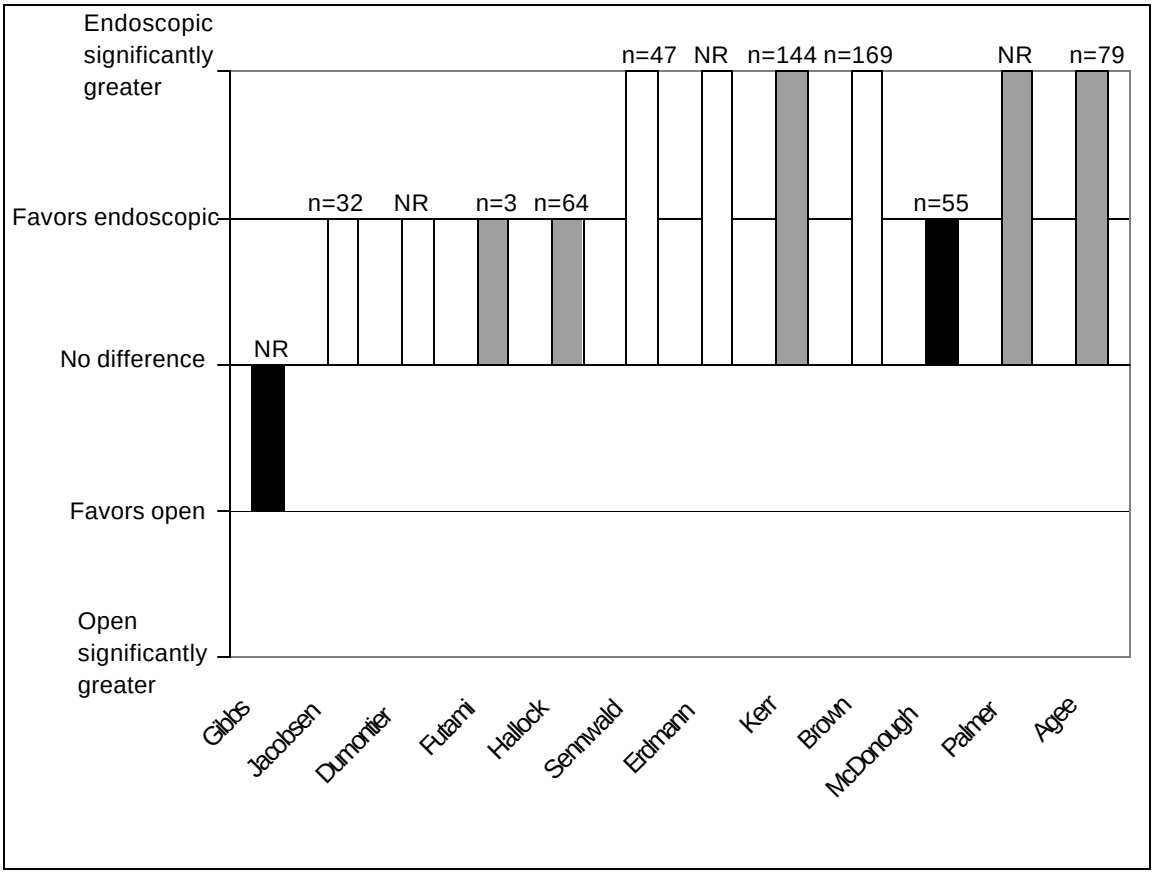
a: Calculated by Kaplan-Meier survival analysis
b: Percentages estimated from a published chart. They cannot be converted to numbers of patients because it is unclear whether they are percentages of all patients or of patients employed prior to surgery.
c: Some patients in each group did not return to work. The numbers reported therefore do not constitute an accurate representation of time to return to work.
d: Estimated by ECRI from a published chart.
e: Unclear whether data is reported per patient or per treated hand. Therefore, we did not calculate an effect size for this study.

Table 59. Summary of effect of treatment type on return to work

Study	Which Procedure Yielded Faster Return to Work?	Was the Difference Statistically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Gibbs, 1996 [351]	Open	No	Not calculable	Not calculable
Jacobsen, 1996 [353]	Endoscopic	No	25%	0.19 (-0.51 – 0.88)
Dumontier, 1995 [365]	Endoscopic at 2 weeks Open at 1 month and 3 months	No	Not calculable	Not calculable
Futami, 1995 [366]	Endoscopic	No	Not calculable	Not calculable
Hallock, 1995 [368]	Endoscopic	No	32.6%	Not calculable
Sennwald, 1995 [373]	Endoscopic	Yes	15.1%	1.65 (0.99 –2.31)
Erdmann, 1994 [304]	Endoscopic	Yes	Not calculable	Not calculable
Kerr, 1994 [379]	Endoscopic	Yes	Not calculable	Not calculable
Brown, 1993 [45]	Endoscopic	Yes	Not calculable	Not calculable
McDonough, 1993 [448]	Endoscopic	Not reported	Not calculable	Not calculable
Palmer, 1993 [397]	Endoscopic	Yes	Not calculable	Not calculable
Agee, 1992 [46]	Endoscopic	Yes	Not calculable	Not calculable

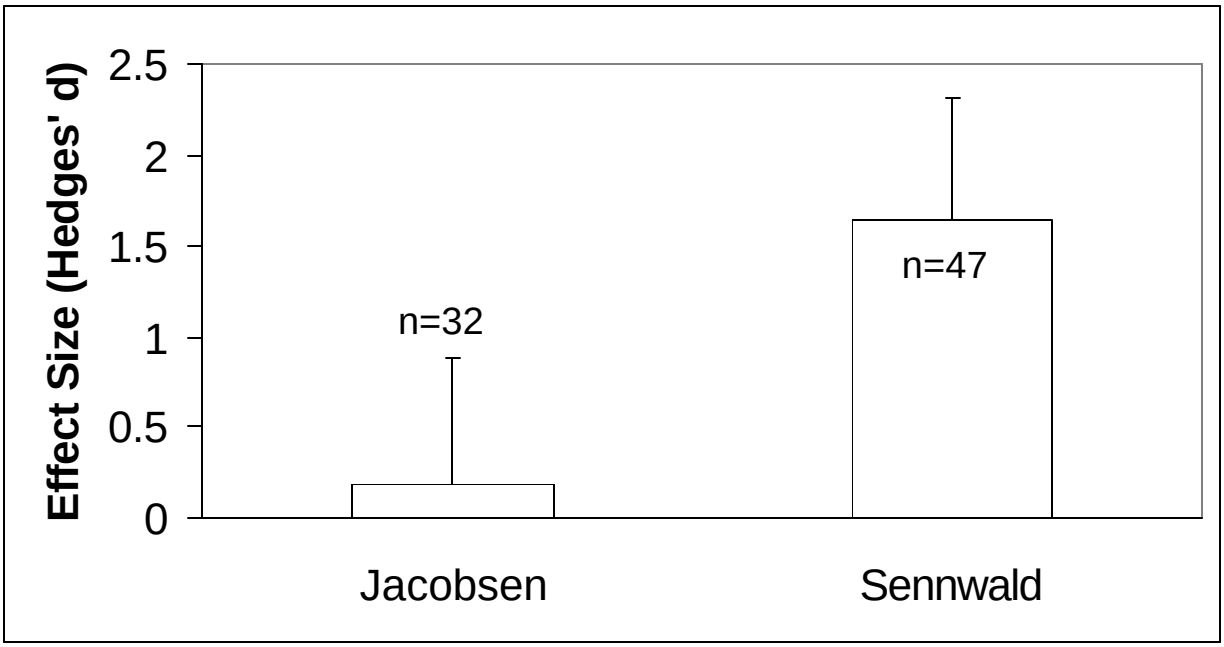
a. Calculated by ECRI

Figure 26. Summary of effect of treatment on return to work



An open bar denotes an RCT, a striped bar a CT, and a filled bar a retrospective trial.
NR indicates that the authors did not report the number of patients for whom this outcome was recorded.

Figure 27. Calculable effect sizes for effect of treatment type on return to work



Time to return to activities of daily living

This outcome was reported in five controlled studies, three of which were randomized. Data from these studies are presented in Table 60. Unless otherwise stated, data are presented as mean times to return to activities of daily living (ADLs). Only one study reported sufficient data for a valid effect size to be calculated. Therefore, no meta-analysis could be performed. Instead, Table 61 summarizes trends in the data available from the controlled trials.

Four trials found a faster return to daily activities in the group treated with endoscopic release. Three of these found the difference to be statistically significant. A chi square test conducted by ECRI found that in the study by Brown, the difference between groups at 84 days was statistically significant despite the fact that it was reported as insignificant.[45] The effect size calculated from the same data was significantly different from zero. The study that did not favor endoscopic release was the only retrospective study. It found that both groups returned to daily activities in the same amount of time. This is illustrated in Figure 28.

The amount of time required for return to ADLs varies among studies. Futami reported that all patients treated with endoscopic release returned to daily activities "with full use of the hand" within 18 days, while Brown reported that only a fraction of endoscopic patients (11%) returned to ADLs within 21 days. Gibbs reported that half of the patients in the endoscopic group returned to work in 21 days, while Agee reported a median of 9 days. The reasons for these differences are unknown.

As was the case for return to work, the data show a trend toward faster return to daily activities for patients treated with endoscopic carpal tunnel release than with open surgery. However, because one cannot perform a meta-analysis on the data, the magnitude of the difference cannot be precisely determined.

Table 60. Time to return to activities of daily living in patients treated with open or endoscopic surgery

Study	Number of Patients	Time to Return to Activities of Daily Living	Statistical Significance of Difference Between Groups
Gibbs, 1996 [351]		Time until 50% of patients had returned to ADL[a]	Groups not significantly different by log-rank test
	43 Open	21 Days (Range 1->911)	
	14 Endoscopic	21 Days (Range 7->425)	
Futami, 1995 [366]	10 Open[b]	41 Days (Range 28-51)	Groups significantly different by t-test, p <0.01
	10 Endoscopic	12 Days (Range 4-18)	
Erdmann, 1994 [304]	23 Open (Patients) 27 Open (Hands)	39 Days	Groups significantly different (p <0.005, Mann-Whitney test)
	23 Endoscopic (Patients)[c] 28 Endoscopic (Hands)	14 Days	
Brown, 1993 [45]	21 Days, N = 149 Hands Group n not reported[d]	Number of patients (hands) with no impairment of ADL	
	Open	3 (5)	Groups were not significantly different by Kaplan-Meier survivorship analysis.
	Endoscopic	8 (8)	
	42 Days, N = 147 Hands		
	Open	(12)	Groups were not significantly different by Kaplan-Meier survivorship analysis.
	Endoscopic	(14)	
	84 Days, N = 160 Hands		
	82 Open	28 (29)	Groups were not significantly different by Kaplan-Meier survivorship analysis. However, they were significantly different by chi square test conducted by ECRI, p = 0.019
	78 Endoscopic	39 (42)	

Study	Number of Patients	Time to Return to Activities of Daily Living	Statistical Significance of Difference Between Groups
Agee, 1992 [46]	63 Open 81 Endoscopic (Hands)	Median 13 Days, estimated by Kaplan-Meier Median 9 Days, estimated by Kaplan-Meier	Groups not significantly different according to a survival analysis version of the Wilcoxon test.

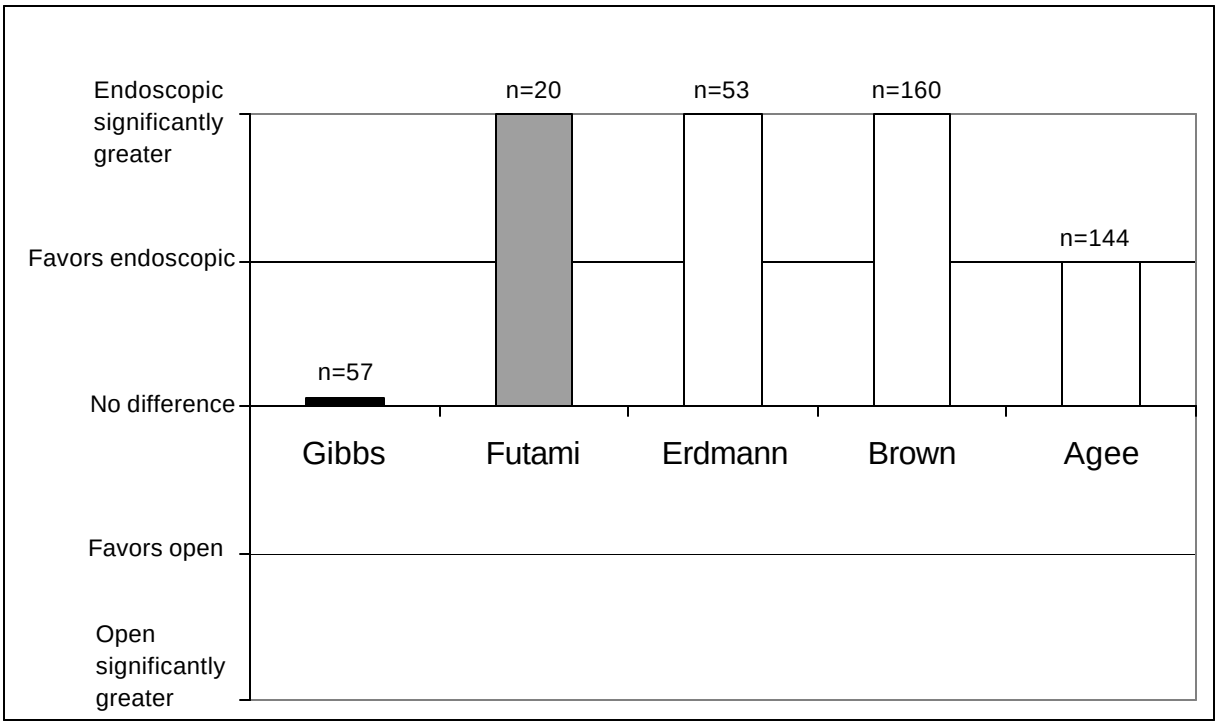
[a]: Calculated by Kaplan-Meier survival analysis
[b]: 20 hands in 10 patients
[c]: Unclear whether means were calculated as per patient or per hand.
[d]: Sum of group ns calculated by ECRI from published data did not match reported total Ns.

Table 61. Summary of effect of treatment (open or endoscopic) on time to return to ADLs

Study	Which Procedure Yielded Faster Return to Daily Activities?	Was the Difference Statistically Significant?	Power (Minimum percent difference detectable[a]	Effect Size (95% Confidence Interval)[a]
Gibbs, 1996 [351]	Both groups were equal	No	Not calculable	Not calculable
Futami, 1995 [366]	Endoscopic	Yes	Not calculable	Not calculable
Erdmann, 1994 [304]	Endoscopic	Yes	Not calculable	Not calculable
Brown, 1993 [45]	Endoscopic	21 days: No 42 days: No 84 days: Yes	21 days: Not calculable 42 days: Not calculable 84 days: 18.3%	21 Days: Not calculable 42 days: Not calculable 84 days: 0.42 (0.065-0.77)
Agee, 1992 [46]	Endoscopic	No	Not calculable	Not calculable

[a]: Calculated by ECRI

Figure 28. Summary of effect of treatment on return to ADLs



Open bars represent RCTs, striped bars CTs, and dark bars retrospective trials.

Pain

In this question, we address pain as a symptom of carpal tunnel syndrome, distinct from postsurgical pain, scar tenderness or pillar pain. This outcome was reported in four controlled trials, two of which were randomized. Again, because effect sizes could be calculated for only two studies, we did not perform a meta-analysis. Therefore, we examine the data for trends. Data describing the relative effect of open and endoscopic treatment on pain are presented in Table 62.

To address this outcome, we perform three separate analyses. First, we assess differences between patient groups prior to treatment. If there are differences in pain prior to treatment, this may influence whether there are differences after treatment. In randomized controlled trials, the process of randomization is used to eliminate this concern.

The second analysis we performed is a comparison of short-term results. This is because the rationale behind endoscopic treatment is that it is less invasive, leading to faster recovery. Whether this also means faster relief of symptoms has not been determined. For this analysis, we are defining short-term results to be those obtained one month or less after surgery. Finally, in our third analysis, we evaluated long-term (longer than one month) results.

Data relevant to these three analyses are summarized in Table 63. There were no statistically significant differences between groups before treatment. All three studies reporting pain at early (1 month or less) times after treatment found less pain in the endoscopic groups, with one RCT finding a statistically significant difference. At later time points, all but the one retrospective study found less pain in the endoscopic groups. However, none of the differences were statistically significant.

The statistically nonsignificant results may indicate that these studies were too small (i.e., underpowered to detect differences. Only Gibbs provided sufficient data for power to be calculable. After treatment, the study only had the power to detect large (>40%) differences between groups. If the true difference between groups is less than this, the study is uninformative. However, the two calculable post-treatment effect sizes are not large (See Figure 31), suggesting that low power is not exclusively responsible for these non-significant results.

The data show a trend toward greater pain relief for patients treated with endoscopic carpal tunnel release at both early and later times after surgery (See Figure 29, Figure 30, and Figure 31). However, there is some circumstantial evidence to suggest that the effect is not large at both early and late followup times. At early followup times, only one of three studies found a statistically significant effect, despite all three studies being of reasonable size (>100 patients). At later followup times, no studies found a statistically significant effect. Similarly, the only calculable effect size from a prospective trial (an RCT) was not large. Thus, while the precise effect size cannot be calculated, evidence suggests it is small.

Table 62. Symptomatic pain in patients treated with open or endoscopic carpal tunnel release

Study	Number of Hands	Pain	Statistical Significance of Difference Between Groups
Gibbs, 1996 [351]		Pain rating	Groups not significantly different before or after treatment by t-test, p = 0.78 and 0.21 respectively.
	43 Open	Preop:: 3.3±1.0 18.9 Months: 1.2 ±0.52	
	14 Endoscopic	Preop: 3.3±0.87 16 Months: 1.5±0.96	
Erdmann, 1994 [304]		Mean VAS, 0-10 Scale[a]	Groups significantly different at 1 week only (Mann-Whitney test, p <0.05)
	52 Open	Preop: 5.6; 1 Week: 3.9 1 Year: 0.95	
	53 Endoscopic	Preop, 5.7; 1 Week: 2.4 1 Year: 0.1	
Palmer, 1993 [397]		Percent of patients[b] reporting nocturnal pain	Groups not significantly different at any time point by chi square test, p >0.05
	42 Patients, 49 Hands Open	Preop: 88.7% 2 Weeks: 23.3% 6 Months: 25.0%	
	70 Patients, 90 Hands Endoscopic (Agee method)	Preop: 80.0% 2 Weeks: 16.7% 6 Months: 12.5%	
	62 Patients, 72 Hands Endoscopic (Chow method)	Preop: 89.8% 2 Weeks: 21.7% 6 Months: 28.9%	
Agee, 1992 [46]		Percent of patients[b] with symptomatic pain	Not reported
	65 Open	Preop: 89; 1 Week: 59 26 Weeks: 27	
	82 Endoscopic	Preop: 85; 1 Week: 43 26 Weeks: 25	

a: Estimated by ECRI from a published chart

b: The report states that outcomes are reported as percent of patients. However, as some patients had a different procedure in each hand, it is likely that the outcome is actually percent of hands. Thus, the true n is unclear.

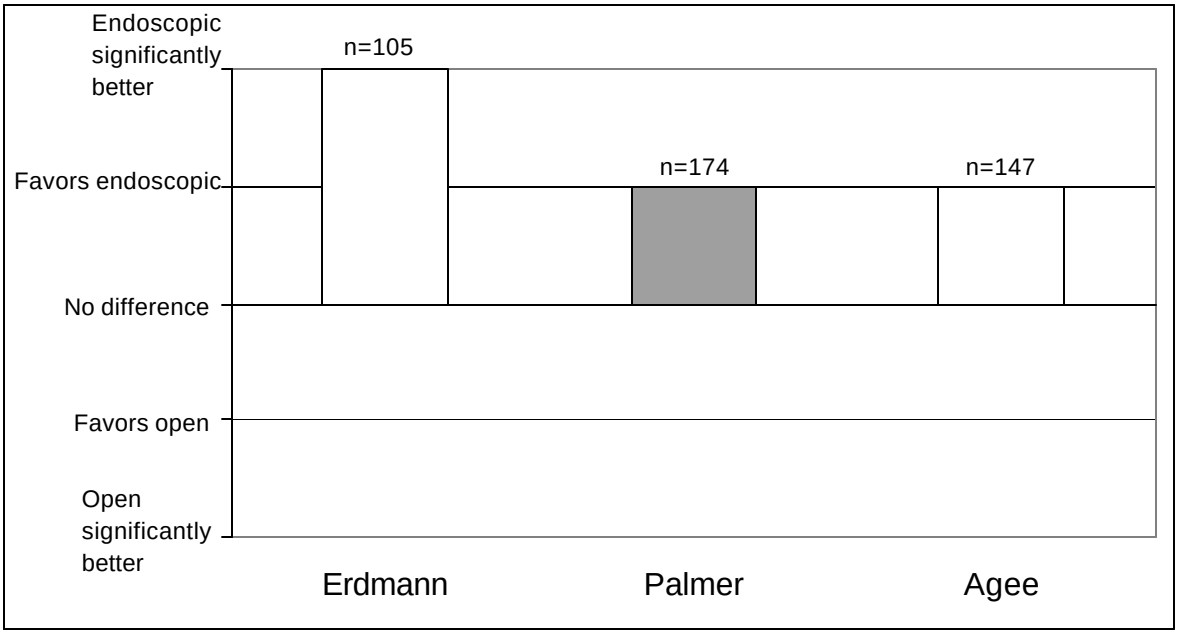
Table 63. Summary of effect of treatment (open or endoscopic) on pain

Study	Which Procedure Had Less Pain?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable 80% of the time)[a]	Effect Size (95% Confidence Interval)[a]
Gibbs, 1996 [351]	Preop: No difference Early: Not reported Late: Open	Preop: No Early: Not reported Late: No	Preop: 17.5% Early: Not reported Late: 40.0%	Preop: 0.0 (-0.60–0.60) Early: Not reported Late: -0.45 (-1.06-0.15)
Erdmann, 1994 [304]	Preop: Open Early: Endoscopic Late: Endpscopic	Preop: No Early: Yes Late: No	Not calculable	Preop: Not calculable Early: 0.39 (0.00-0.77)[b] Late: Not calculable
Palmer, 1993 [397]	Preop: Endoscopic Early: Endoscopic Late: Endoscopic	Preop: No Early: No Late: No	Not calculable	Not calculable
Agee, 1992 [46]	Preop: Endoscopic Early: Endoscopic Late: Endoscopic	Preop: Not reported Early: Not reported Late: Not reported	Not calculable	Not calculable

a: Calculated by ECRI

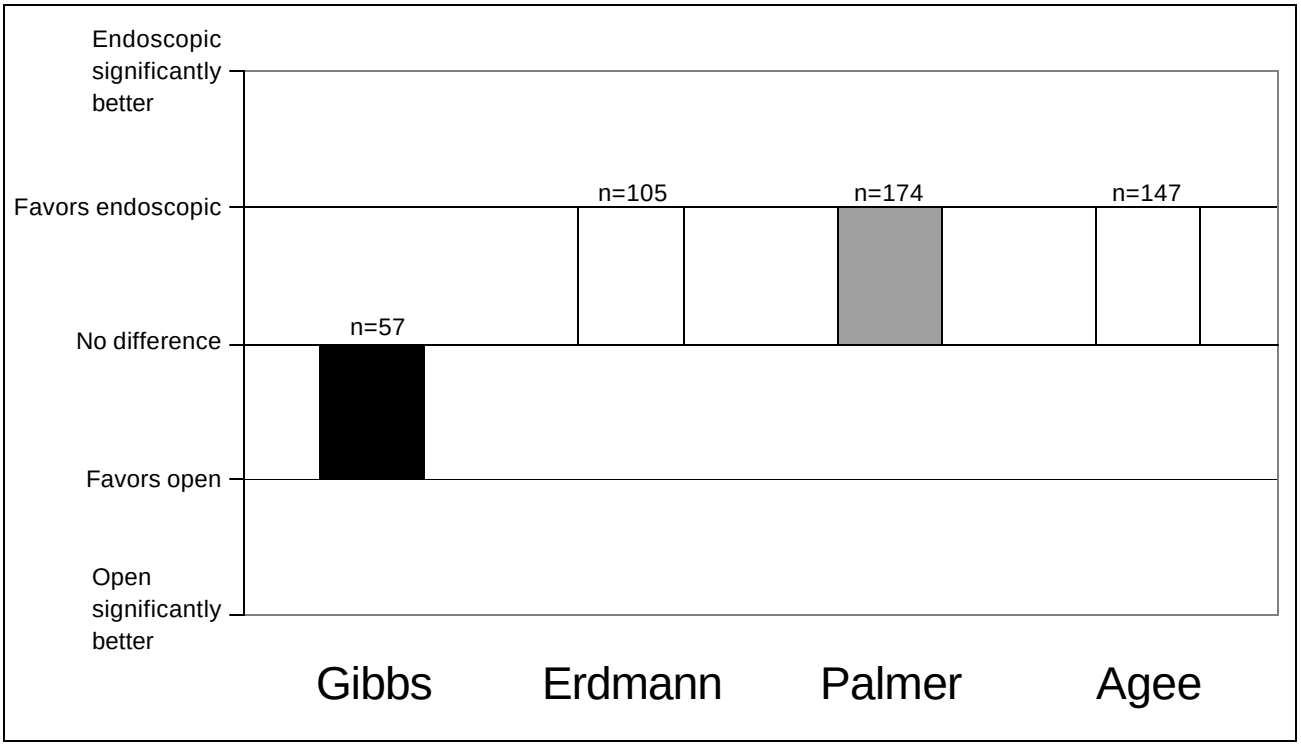
b: Calculated by ECRI based on the conservative assumption that p = 0.049)

Figure 29. Summary of the effect of treatment on pain at early time points



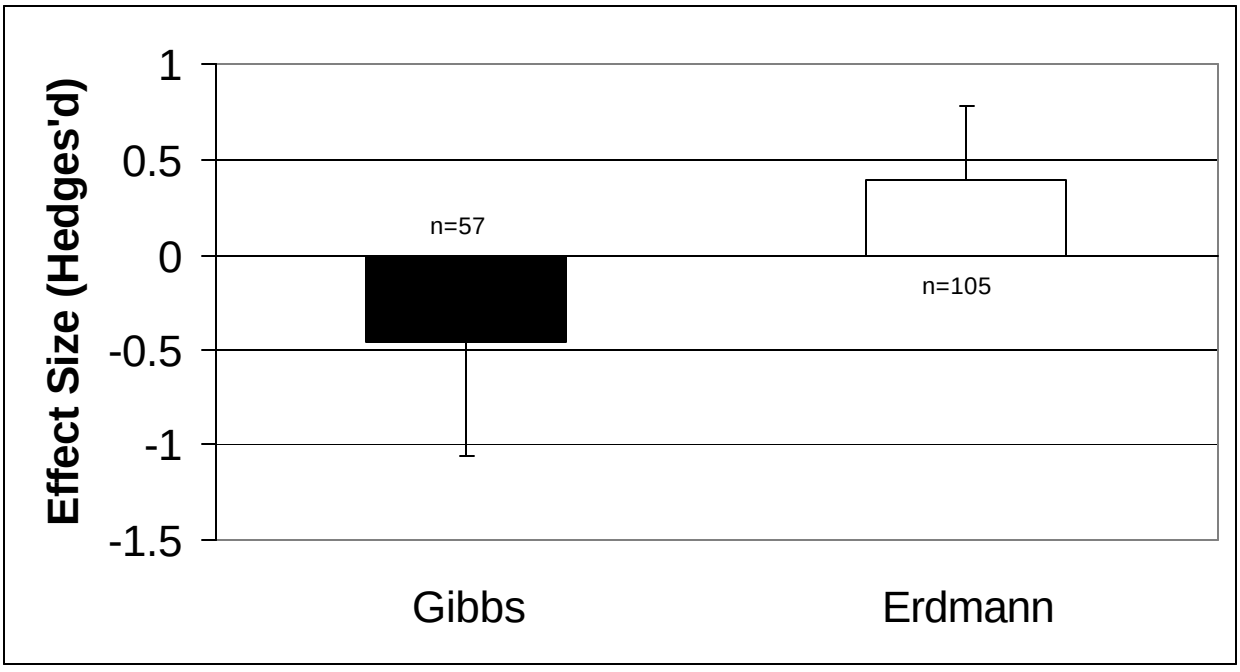
An open bar indicates an RCT, a striped bar a CT. The study by Gibbs does not appear because it did not report early time ponts.

Figure 30. Summary of the effect of treatment on pain at late time points



An open bar indicates an RCT, a striped bar a CT, and a dark bar a retrospective study.

Figure 31. Calculable effect sizes for pain



An open bar indicates an RCT and a dark bar a retrospective study.

Function

Function refers to the ability of the patient to perform various tasks and activities with their affected limb(s). It is measured using any of a number of tests.

Only one nonrandomized controlled trial, that by Worseg, reported a measure of function. This outcome is described in Table 64 and summarized in Table 65. Worseg's global function was the mean of the difficulty ratings (scale of 1-5) of eight individual activities (writing, buttoning clothes, holding a book, gripping a telephone, opening jars, household chores, carrying a grocery bag, and bathing and dressing).

The endoscopic group experienced superior function one week after surgery, but there were no statistically significant differences in the long term. This is consistent with the idea that the less invasive treatment leads to more rapid recovery. Because, however, function was examined in only one study (which was not randomized), it is difficult to draw firm evidence-based conclusions about the relative effects of open and endoscopic surgery on function.

Table 64. Function in patients treated with open or endoscopic carpal tunnel release

Study	Number of Patients	Function	Statistical Significance of Difference Between Groups
Worseg et al., 1996 [44]		Mean of function scores[a]	Between group differences were significant at 1 Week only ($p < 0.05$, Wilcoxon rank sum test).
	Open 62	Preop: 3.14 ; 1 Week: 3.33; 24 Weeks: 1.29	
	Endoscopic 64	Preop: 3.16 ; 1 Week: 2.29; 24 Weeks: 1.20	

a: Lower score indicates superior function

Table 65. Summary of the effect of treatment on function

Study	Which Procedure Had Superior Function at Followup?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Worseg, 1996 [44]	Endoscopic	At 1 week only	Not calculable	Preop: 0.12 (-0.23 – 0.47)[b] 1 Week: 0.35 (0.00 – 0.70) 24 Weeks: 0.12 (-0.23 – 0.47)

a: Calculated by ECRI
b: Calculated by ECRI based on the conservative assumption that p = 0.49 at one week and p = 0.50 at the other time points.

Quality of Life

No studies reported this outcome.

Harms

Analysis of differences in incidence of adverse events between endoscopic and open surgery is hindered by incomplete reporting. Figure 32 shows the percent of studies reporting each adverse effect. Only one complication, transient sensory disturbance, was reported by more than half of the studies. It is not possible to determine whether in the remaining studies complications did not occur or were not reported in the remaining studies. Six studies did not report any complications. A complete listing of reported complications may be found in Evidence Table 12.

The following analysis is based on the assumption that major, severe complications are more likely to be reported than minor ones. This analysis is therefore limited to reports of the accidental severing of a nerve, tendon or blood vessel. This type of injury requires repair and is presumably serious enough to warrant mention. Incidence of accidental laceration is reported in Table 66.

Incomplete transection of the carpal ligament is a technical failure that can lead to recurring or continuing symptoms of carpal tunnel syndrome and may require reoperation. The number of incomplete transections reported in studies comparing open and endoscopic carpal tunnel release are presented in Table 67.

Ten studies reporting on 490 open releases reported one nerve injury. Among 1,774 Endoscopic releases, there were five nerve, tendon or blood vessel lacerations. The difference between groups was not statistically significant by a chi square test ($p=0.767$) conducted by ECRI.

An incomplete transection of the carpal ligament is unlikely when performing open release, because the ligament is fully visualized. Since the rate of incomplete release is essentially zero when performing open release, the rate for endoscopic release (9 incomplete transections in 378 procedures) is higher. Endoscopic release may therefore have a higher reoperation rate than open release.

Figure 32. Studies reporting minor complications

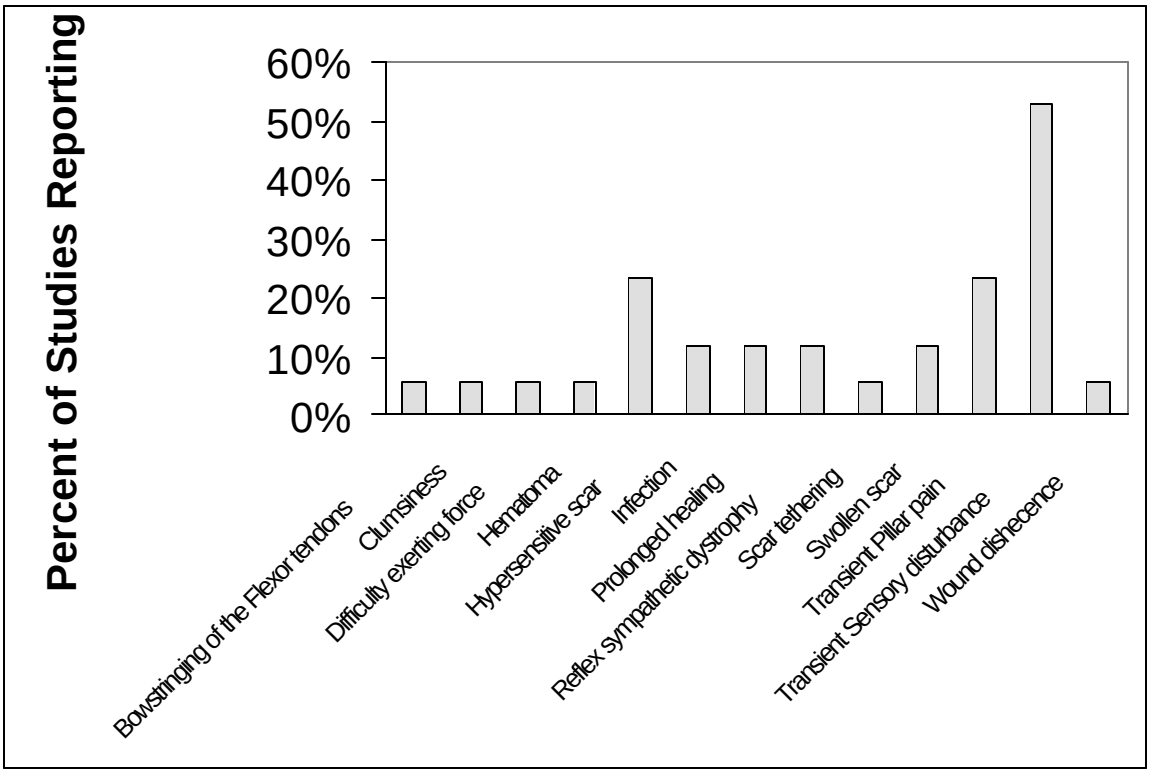


Table 66. Blood vessel, nerve and tendon lacerations during open and endoscopic carpal tunnel release

Study	Procedures	Endoscopic Lacerations	Open Lacerations
Chen, 1999 [317]	Open 64 Endo 1214	1 Motor nerve	0
Povlsen, 1997 [450]	Open 50 Endo 50	0	0
Jacobsen, 1996 [353]	Open 16 Endo 16	0	0
Worseg, 1996 [44]	Open 62 Endo 64	1 Transection of the superficial palmar arch	0
Dumontier, 1995 [365]	Open 40 Endo 56	1 Ulnar artery injury	0
Sennwald, 1995 [373]	Open 22 Endo 25	0	0
Erdmann, 1994 [304]	Open 52 Endo 53	0	1 Palmar cutaneous nerve
Brown, 1993 [45]	Open 85 Endo 84	1 Superficial palmar arch	0
McDonough, 1993 [448]	Open 50 Endo 50	1 Digital tendon	0
Palmer, 1993 [397]	Open 49 Endo (Agee) 90 Endo (Chow) 72	0	0
Total		1774 Procedures 5 Lacerations	490 Procedures 1 Laceration

Table 67. Incomplete transections of the carpal ligament

Study	Procedures	Endoscopic Incomplete Transections	Open Incomplete Transections
Concannon et al., 2000 [449]	Open 103 Endo 88	5	0
Sennwald and Benedetti, 1995 [373]	Open 22 Endo 25	0	0
Erdmann, 1994 [304]	Open 52 Endo 53	1	0
McDonough et al., 1993 [448]	Open 50 Endo 50	1	0
Palmer et al., 1993 [397]	Open 49 Endo (Agee) 90 Endo (Chow) 72	1 Agee 1 Chow	0
Total		378 Procedures 9 Incomplete transections	276 Procedures 0 Incomplete transections

Conclusions

Endoscopic release allows faster return to work and to activities of daily living. In addition, it leads to superior global outcome and reduced pain. However, the effects on pain and global outcome may be small. Presently available data do not allow one to reach firm evidence-based conclusions about the relative effect of open and endoscopic surgery on function. Because of incomplete transection of the transverse carpal ligament, endoscopic release has a higher rate of reoperation. Although there is insufficient data to draw firm conclusions, endoscopic release may also have a higher complication rate.

What are the relative benefits and harms of open carpal tunnel release with and without neurolysis for persons with carpal tunnel syndrome?

Eight published studies comparing open carpal tunnel release with carpal tunnel release combined with neurolysis met the inclusion criteria. These studies enrolled a total of 494 cases. One of these, the study by Gelberman et al.,[415] compared their data to an earlier case series, that of Rhodes et al.[451] Therefore, the study of Rhodes et al. may be considered an historical control for the study by Gelberman et al. Six of the remaining trials are prospective, randomized controlled trials. Four are single- or double-blinded. One is double-blinded, but not randomized.[426] Long-term outcomes for one study are reported in a separate publication.[416,433]

Internal validity

Factors affecting internal validity of controlled trials of neurolysis are described in Table 68. Three studies had no attrition, and the remaining five had attrition ranging from 6% to 50%. None of the studies with patient attrition reported results on an intent-to-treat basis. Wherever possible, we compensated for attrition using the conservative assumption that treatment had failed for all patients not accounted for. All but one of the studies violated statistical assumptions of independence by including patients with bilateral CTS.[433] The impact of this violation in terms of the number of times an erroneous conclusion of statistical significance was drawn is unknown, but it does affect one's confidence in the results of our analyses.

Generalizability

The average age of the patients in the five studies reporting mean ages was 55.7, with a range of 20-100. This is consistent with the reported epidemiology of CTS as well as with the ages observed under question 2 of this evidence report. Two of the studies included somewhat fewer than 50% female patients, but this percentage is not so low that it would greatly limit the generalizability of the data reported. These and other patient characteristics are listed in Table 69.

Except in cases where patients with comorbidities were excluded (noted in Table 69 by a zero under the comorbidity), patient comorbidities were not described in these studies. Similarly, employment characteristics are not described, as can be seen in Table 70. No conclusions about the generalizability of these results to the general CTS population is possible.

One study (Leinberry, et al.) included only patients with severe disease.[342] It may therefore be inappropriate to combine the study by Leinberry with the remaining studies, and this study may not be generalizable to the CTS population at large. All but one of the studies excluded patients with mild disease.[426] The extent to which this criterion differs from criteria for surgical candidates in ordinary clinical practice is not known. Therefore, the impact of this exclusion on generalizability is not known.

Table 68. Internal validity of studies comparing open carpal tunnel release with and without neurolysis

Study	Number of patients	Percent of patients with bilateral procedures	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?
Leinberry, 1997 [342]	44	13.6%	Single	No	RCT	Rater	0	Yes
Blair, 1996 [428]	117	36.0%	Single	No	RCT	Rater	42	No
Foulkes, 1994 [376]	46	8.7%	Single	No	RCT	Rater	23	No
Mackinnon, 1991 [407]	59	6.8%	Single	No	RCT	Double	20	No
Lowry, 1988 [429]	50	22.0%	Single	Not reported	RCT	Double	3	No
Gelberman, 1987 [415]	61	13.1%	Multiple (<5)	No	Retro	No	0	Yes
Holmgren-Larsson, 1985 [433] Holmgren, 1987 [416]	48	0.0%	Single	Not reported	RCT	No	7	No
Freshwater, 1978 [426]	22	18.2%	Single	Not reported	CT	Double	0	Yes

Table 69. Generalizability of studies comparing open carpal tunnel release with and without neurolysis

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Leinberry, 1997 [342]	44	65 (38-100)	59.1	31.8 (1-360)	6.8	NR	NR	NR	NR	NR	NR	No	Yes
Blair, 1996 [428]	86	49 (23-82)	72.1	NR	NR	NR	NR	0	0	NR	NR	No	Yes
Foulkes, 1994 [376]	46	NR	37.0	NR	NR	NR	NR	NR	NR	0	NR	No	Yes
Mackinnon, 1991 [407]	79	58.5 (20-91)	60.8	NR	0	NR	0	0	0	NR	NR	No	Yes
Lowry, 1988 [429]	50	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Gelberman, 1987 [415]	61	59.2 (28-90)	37.7	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Holmgren, 1987 [416]	48	50 (21-80)	68.8	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Holmgren-Larsson, 1985 [433]	48	50 (21-80)	68.8	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Freshwater, 1978 [426]	22	NR; (32-74)	NR	12 (3-120)	NR	0	NR	NR	NR	NR	NR	NR	NR

Table 70. Patient employment characteristics in studies comparing open carpal tunnel release with and without neurolysis

Study	Number of patients	% Patients employed	% Patients receiving workers' compensation	% Patients retired	% Patients Homemakers	Reported occupations
Leinberry, 1997 [342]	44	Not reported	Not reported	Not reported	Not reported	Not reported
Blair, 1996 [428]	86	Not reported	Not reported	Not reported	Not reported	Not reported
Foulkes, 1994 [376]	46	Not reported	Not reported	Not reported	Not reported	Not reported
Mackinnon, 1991 [407]	79	Not reported	12.7	Not reported	Not reported	Not reported
Lowry, 1988 [429]	50	Not reported	Not reported	Not reported	Not reported	Not reported
Gelberman, 1987 [415]	61	Not reported	Not reported	Not reported	Not reported	Not reported
Holmgren, 1987 [416]	48	Not reported	Not reported	Not reported	Not reported	Not reported
Holmgren-Larsson, 1985 [433]	48	Not reported	Not reported	Not reported	Not reported	Not reported
Freshwater, 1978 [426]	22	Not reported	Not reported	Not reported	Not reported	Not reported

Results

Global outcome

This outcome was reported by all eight controlled trials, six of which were randomized and one of which was retrospective. Of the six randomized trials, five were blinded. Data from these trials are summarized in Table 71. The study by Blair employed three different measures of global outcome.[428] We did not consider patient perceptions about symptom relief because these authors presented their results in a manner that is difficult to quantify. For example, they reported that some patients experience permanent partial relief while others experienced temporary total relief. It is difficult to determine which of these outcomes the patients considered superior.

Of the remaining two outcomes in the report by Blair et al., both could be used to calculate an effect size. The number of patients stating they would have surgery again gave an effect size of d = 0.067, while the number of patients happy or satisfied with their treatment led to an effect size of d = 0.94. It is unclear which of these is the more accurate measure of global effect. We chose to use the smaller effect size in our meta-analysis. This conservative approach, which is biased against finding a significant effect, adds credibility to the resulting significant effect.

The report by Foulkes [376] provided two measures of global outcome, only one of which could be used to calculate an effect size. We were able to compensate for 13 of the 27 hands lost to followup by using the conservative assumption that they were unimproved at followup. The remaining 14 hands could not be accounted for because their group assignment was not reported. Similarly, the 42 hands not reported in the study by Blair and twenty in the study by Mackinnon could not be accounted for because their group assignment was not reported.

The report by Holmgren et al. is a long-term followup of Holmgren-Larsson et al. that does not account for five patients (10.4%) who did not return for followup examinations.[416,433] Because the original report by Holmgren-Larsson did not report the number of patients assigned to each group, the group assignments of these five patients is not known. Thus, these patients cannot be accounted for when calculating effect sizes. The two patients known to have died were not included in our calculations. Three patients were not accounted for in the study by Lowry. Two of them were in the no neurolysis group and one in the neurolysis group. We accounted for them using the conservative assumption that treatment had failed for all of them.

Eight studies provided sufficient data for meta-analysis. The results may be found in Table 72. The calculated effect sizes are not heterogenous (Q = 5.20; p = 0.64) and the overall effect size is significantly different from zero (d = 0.27, 95% C.I. = 0.003-0.537; p = 0.047). The lack of heterogeneity suggests that although the study by Leinberry incorporated patients who may have had more severe CTS than those in the other studies,[342] its results were not derived from a different population than the results of other studies. It was therefore statistically valid to combine this study with the others for

meta-analysis. The effect sizes of the individual studies as well as the overall effect size, and their 95% confidence intervals are depicted graphically in Figure 33. Although the difference between groups is statistically significant, there is still considerable (80.6%) overlap between the global outcome scores of the two groups, as can be seen in Figure 34.

One difficulty in interpreting this meta-analysis comes from the large rate of patient attrition. Of the 494 cases treated in these studies, results were not reported for 99. Two of these had died, and an additional 16 could be accounted for by assuming that treatment had failed for them. This leaves a total of 81 (16.4%) patients unaccounted for. The existence of a large number of treated patients whose outcomes are not known may undermine the confidence with which these results are interpreted.

For three of the studies in this meta-analysis, more than one effect size could be calculated depending on the assumptions made about the data. In all cases, we chose the most conservative assumption. However, because of the distribution of patients between groups, the most conservative assumption did not always lead to the smallest possible effect size. In the study by Foulkes, there were 11 patients missing from the neurolysis group and only two from the no neurolysis group. Assuming that treatment had failed for all of these patients leads to a larger effect size (favoring no neurolysis) than either applying the anti-conservative assumption that treatment had succeeded for these patients or not attempting to account for missing patients at all. Thus, application of this assumption may have lead to an erroneous result. The effect of making conservative or anticonservative assumptions, or of not attempting to account for missing patients by recalculating data is summarized in Table 73.

As can be seen in Table 73, consistently applying either the conservative or the anti-conservative assumptions to the data leads to a statistically significant effect. Anti-conservative in this instance means assuming that treatment was successful for all missing patients, and using the larger of the two effect sizes calculable from the data of Blair. The fact that the results significantly favor no neurolysis regardless of whether conservative or anticonservative assumptions are applied strengthens our confidence in the results of our analysis.

When the data from the studies by Foulkes and Lowry were not recalculated to account for missing patients, the meta-analytic summary statistic was statistically significant only when the larger effect size from the study by Blair was used. This later meta-analysis, however, was only marginally nonsignificant ($p = 0.052$), and could be overturned by future studies. This result, however, does not establish that there is a benefit derived from performing neurolysis. To the contrary, if the true effect size is nonsignificant, this indicates that there is no effect of neurolysis on global outcome. The lack of a statistically significant effect of neurolysis does not arise because we included non-randomized and non-blinded studies in our meta-analysis. Removal of such studies again yielded a non-significant meta-analytic summary statistic ($d = 0.18$, 95% CI –0.7-0.42, $p=0.154$.

The results of our conservative meta-analysis suggest that in a typical case of carpal tunnel syndrome, there is no benefit from performing neurolysis along with surgical release of the carpal tunnel. When statistical assumptions are consistently applied while performing meta-analysis, results suggest that patients report superior global effect of surgery when neurolysis is not performed. The results of this meta-analysis become statistically nonsignificant when analysis is restricted to the results of blinded RCTs. Removal of studies, however, reduces the statistical power of the meta-analysis, and it may be this loss of power, rather than any bias in the non-blinded studies that causes the analysis to become non-significant. That there is no marked bias in these studies is suggested by the lack of heterogeneity, which, in turn, indicates that all eight studies in the meta-analysis measure the same population parameter. There is insufficient evidence to reach an evidence-based conclusion about whether neurolysis is of benefit in atypical cases, such as when there is marked scarring or neural adhesion.

Table 71. Effect of neurolysis on global outcome

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Leinberry, 1997 [342]		Number of hands with no symptoms	Not significantly different, test not reported
	Open Release 25	12 Months: 15	
	Release and Neurolysis 25	12 Months: 14	
	(Hands)		
Blair, 1996 [428]		Patients stating they would have surgery again	Not reported
	Open Release 27	26	
	Release and Neurolysis 48	46	
	(Hands)	Patient perceptions about relief of symptoms	
	Open Release 27	Permanent total: 13 Permanent partial: 12 Temporary total: 2	
	Release and Neurolysis 48	Permanent total: 31 Permanent partial:15 Temporary total: 2	
		Patient satisfaction	
	Open Release 27	Happy/very happy: 19 Satisfied, with reservations: 8 Disappointed/ very disappointed: 0	
	Release and Neurolysis 48	Happy/very happy: 35 Satisfied, with reservations: 9 Disappointed/ very disappointed: 4	

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Foulkes, 1994 [376]		Improvement at 29 Months	Not reported
	Open Release 8	Normal 2 Improved 6 Unimproved 0	
	Release and Neurolysis 15	Normal 5 Improved 9 Unimproved 1	
	Recalculated: Open Release 10[a]	Recalculated: Normal 2 Improved 6 Unimproved 2	Not reported
	Release and Neurolysis 26 (Hands)	Normal 5 Improved 9 Unimproved 12	
		Symptom severity score	
	Open Release 8	Preop: 2.5; 29 Months: 0.4 Recalculated to account for patient attrition:	
	Open Release 10	Preop: 2.5; 29 Months: 0.82	
	Release and Neurolysis 15	Preop 2.9; 29 Months: 0.3 Recalculated to account for patient attrition:	
	Release and Neurolysis 26 (Hands)	Preop: 2.9; 29 Months: 1.4	
Mackinnon 1991 [407]		Symptom rating at 12 months.	Not reported
	Open Release 32	Relief of all or most symptoms 28 Unimproved 4 Worse 0	
	Release and neurolysis 31 (Hands)	Relief of all or most symptoms 25 Unimproved 5 Worse 1	

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Lowry, 1988 [429]		3 Months	Not reported
	Open Release 23	Excellent 7 Good 8 Fair 6 Poor 2	
	Release and Neurolysis 24	Excellent 4 Good 12 Fair 7 Poor 1	
		Recalculated[b]:	
	Open Release 25	Excellent 7 Good 8 Fair 6 Poor 4	
	Release and Neurolysis 25	Excellent 4 Good 12 Fair 7 Poor 2	
Gelberman,1987 [415]; Rhodes, 1985 [451]		Number of patients with complete resolution of signs and symptoms	Significantly different ($p < 0.05$, chi square)
	Open Release: 29	Complete resolution: 18 Mean followup time: 16 Months	
	Release and Neurolysis 32	Complete resolution: 10 Mean followup time: 18 Months	

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Holmgren-Larsson, et al. 1985 [433] Holmgren, 1987 [416]	48 Patients; Number in each group not reported. Open Release Release and Neurolysis Open Release 20 Release and Neurolysis 23	Percent of patients reporting themselves symptom-free at 6 months 89% 89% 3-4 Years: Totally restituted: 12 Improved: 4 Dead: 1 Did not respond: 3 Totally restituted: 18 Improved: 3 Dead: 1 Did not respond: 1	Not reported
Freshwater, 1978 [426]	Open Release 12 Release and Neurolysis 14	Number of patients with no symptoms at 2 years 11 12	Not significantly different by chi square test conducted by ECRI, p = 0.64

[a]: Two hands were lost to followup in the open release group and eleven in the neurolysis group. These hands were conservatively assumed to be unimproved. The significant loss to followup, as well as the fact that loss was not evenly distributed between groups, may render these data unreliable. This recalculation does not account for the additional 13 patients (14 hands) who were lost to followup for whom the group assignment was not reported.

[b]: Recalculated to account for patient attrition using the conservative assumption that treatment had failed for the two patients missing from the open release group and the one patient missing from the release and neurolysis group.

Table 72. Results of conservative meta-analysis of global outcome among patients treated with neurolysis for carpal tunnel syndrome

Author	Year	N	Effect Size	95% CI	p-value	Standardized Residual	Outlier by Std Residual?
Leinberry, [342]	1997	50	0.089	-0.53-0.78	0.778	-0.64	No
Blair, [428]	1996	75	0.067	-1.28-1.42	0.923	-0.30	No
Foulkes, [376]	1994	36	0.432	-0.30-1.17	0.250	0.46	No
Mackinnon, [407]	1991	63	0.282	-0.48-1.04	0.465	0.03	No
Lowry, [429]	1988	50	0.140	-0.41-0.70	0.615	-0.52	No
Gelberman, [415]	1987	61	0.697	0.11-1.28	0.019	1.61	No
Holmgren, [416]	1987	41	-0.741	-2.04-0.56	0.263	-1.56	No
Freshwater, [426]	1978	26	0.324	-1.08-1.72	0.650	0.08	No
			Fixed effects model:				
			Overall Effect Size	95% CI	p-value of E.S.	Q	p-value of Q
			0.27	0.003-0.537	0.047	5.20	0.636

Figure 33. Results of meta-analysis of the effect of neurolysis on global outcome

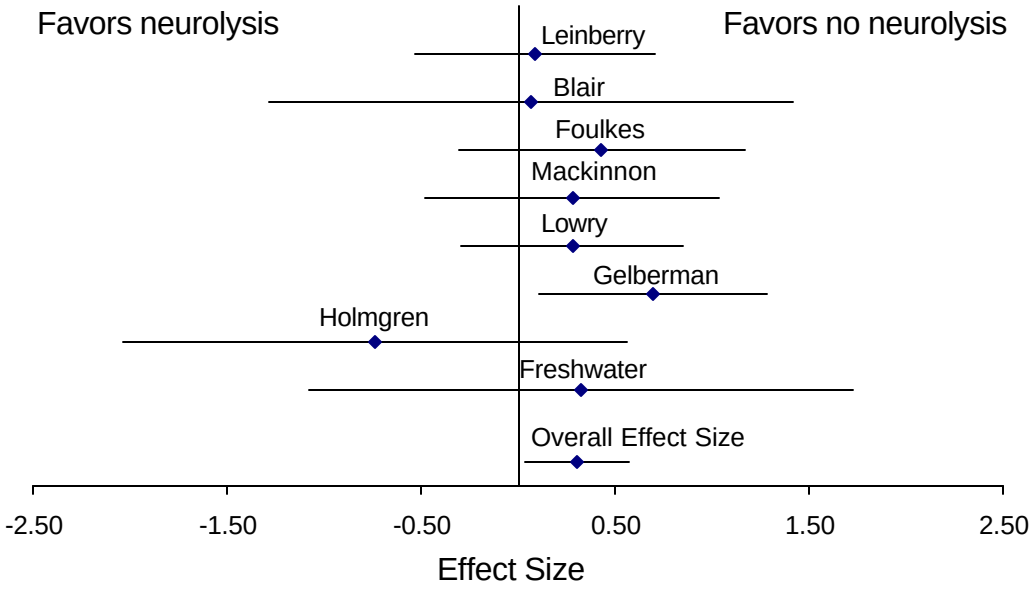


Figure 34. Overlap between effects of neurolysis and no neurolysis

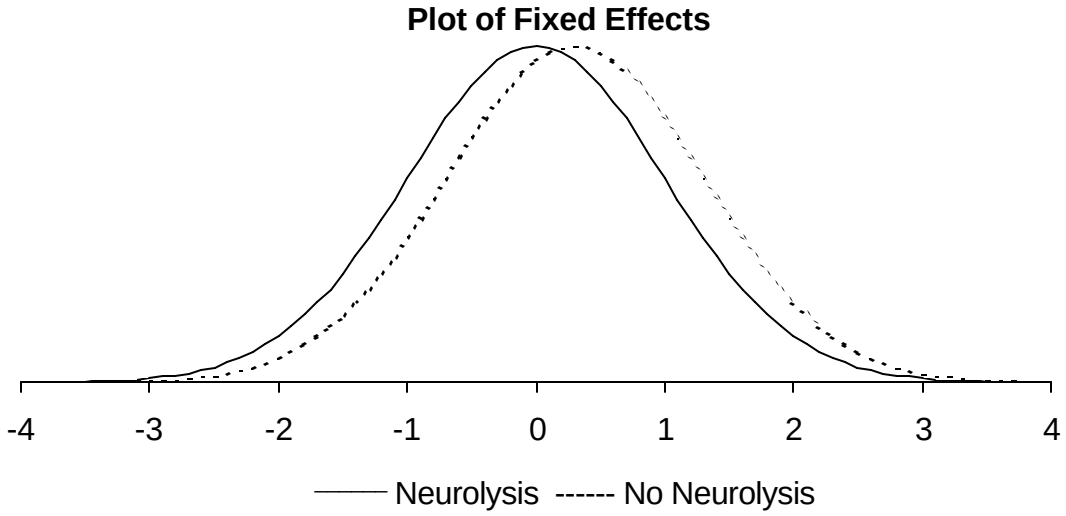


Table 73. Effect sizes of individual studies according to the assumptions used to calculate them

Study	Assumption used to calculate Hedges' d		
	Conservative	No Recalculation	Anti-conservative
Blair [428]	0.067 (-1.28-1.42)	N/A[a]	0.94 (-0.70-2.57)
Foulkes [376]	0.43 (-0.30-1.17)	0.30 (-1.53-2.13)	0.11 (-1.69-1.92)
Lowry [429]	0.14 (-0.41-0.70)	0.28 (-0.30-0.85)	0.37 (-0.19-0.93)
Overall Effect Size	0.27 (0.003-0.537)	0.29 (0.01-0.97)[b] 0.28 (-0.01-0.57)[c]	0.31 (0.03-0.59)

[a]: N/A; Not applicable. Data from this study were not recalculated.
[b]: If the anticonservative effect size from the study by Blair is used.
[c]: If the conservative effect size from the study by Blair is used.

Table 74. Effects of assumptions about individual studies on the overall effect size

Study			Is the overall effect size significantly different from zero?
Blair	Foulkes	Lowry	
Conservative	Conservative	Conservative	Yes
Conservative	No Recalculation	No Recalculation	No
Conservative	Anti-conservative	Anti-conservative	No
Anti-conservative	Conservative	Conservative	Yes
Anti-conservative	No Recalculation	No Recalculation	Yes
Anti-conservative	Anti-conservative	Anti-conservative	Yes

Return to work

Two controlled trials, one of which was randomized, reported some information describing return to work. Both included patients who received bilateral procedures, and one had high (36%) attrition. Results are presented in Table 75 and summarized in Table 76. Neither study reported the number of patients who were working or on sick leave prior to treatment, so the number of patients returning to work could not be determined. As can be seen in Table 76 and Figure 35, both studies favor release without neurolysis, with the difference achieving statistical significance in one study. Because of incomplete reporting, no meta-analysis or power analysis was possible.

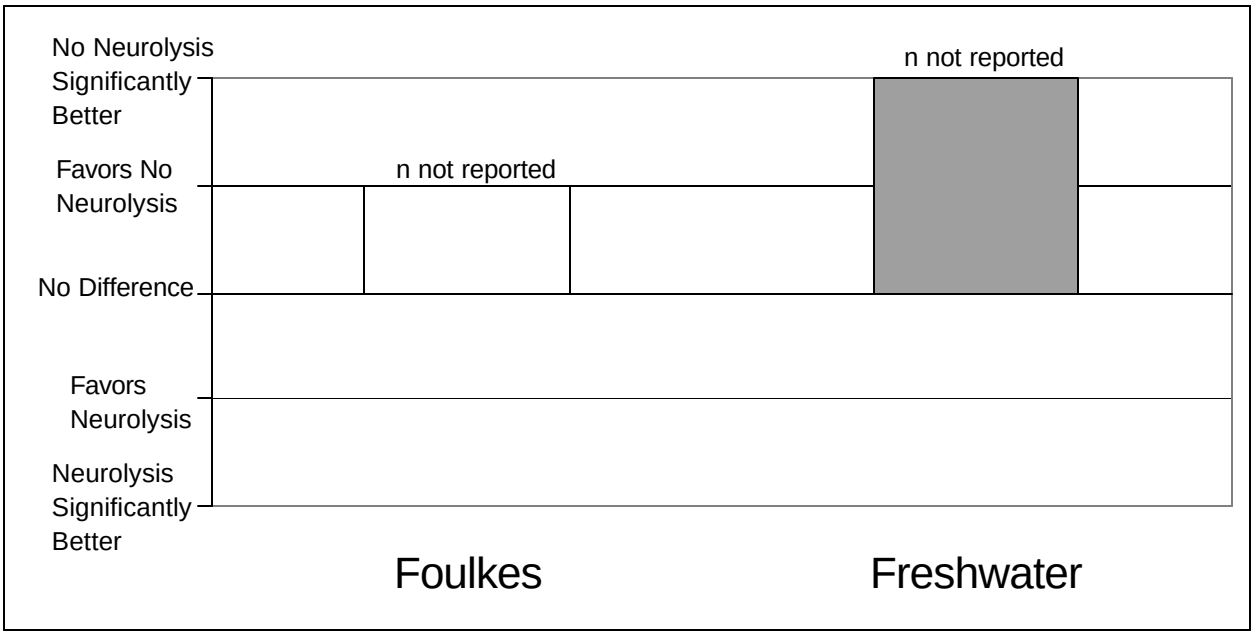
Table 75. Effect of neurolysis on return to work

Study	Number of Patients	Time to Return to Work	Statistical Significance of Difference Between Groups
Foulkes, 1994 [376]	Open Release Release and Neurolysis N not reported	Median 53 Days (Range 1-180) Median 59 Days (Range 14-120)	Not significantly different, statistical test not reported.
Freshwater, 1978 [426]	N not reported	Stated only that patients receiving open release without neurolysis returned to work more quickly than those who received neurolysis.	This difference was statistically significant by the Mann-Whitney U test ($p < 0.01$).

Table 76. Summary of the effect of neurolysis on return to work

Study	Which Procedure Had Faster Return to Work?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)	Effect Size (95% Confidence Interval)
Foulkes, 1994 [376]	No neurolysis	No	Not calculable	Not calculable
Freshwater, 1978 [426]	No neurolysis	Yes	Not calculable	Not calculable

Figure 35. Summary of the effect of neurolysis on return to work



An open bar indicates an RCT, while a striped bar indicates a CT.

Return to Activities of Daily Living

No studies reported this outcome.

Pain

Three controlled trials, two of which were randomized, compared pain in patients who received surgery with and without neurolysis. Results are presented in Table 77. The study by Freshwater and Arons found no statistically significant differences between groups in incidence of night pain and tenderness.[426] Too few patients (6, or 23%) had wrist pain prior to treatment for any statistical analysis of differences in pain between groups to be made. The study by Blair shows a trend toward superior results from neurolysis, but the difference between groups is not significant (chi square test conducted by ECRI, $p = 0.106$). Given the 36% loss to followup in the study, as discussed above, its results are not conclusive. If only the more successful candidates returned for followup, this would bias the results. Holmgren-Larssen et al.[433] found that the patients treated with neurolysis had a resurgence in pain at 6-month followup, while the patients with no neurolysis did not. The statistical significance of this trend cannot be determined, however, because they did not report the number of patients in each group.

These results are summarized in Table 78 and Figure 36. Calculable effect sizes are presented in Figure 37. The available data are of insufficient quality and quantity to allow one to reach n evidence-based conclusion about whether there is a difference in symptomatic pain resulting from performing or not performing neurolysis.

Table 77. Effect of neurolysis on carpal tunnel pain

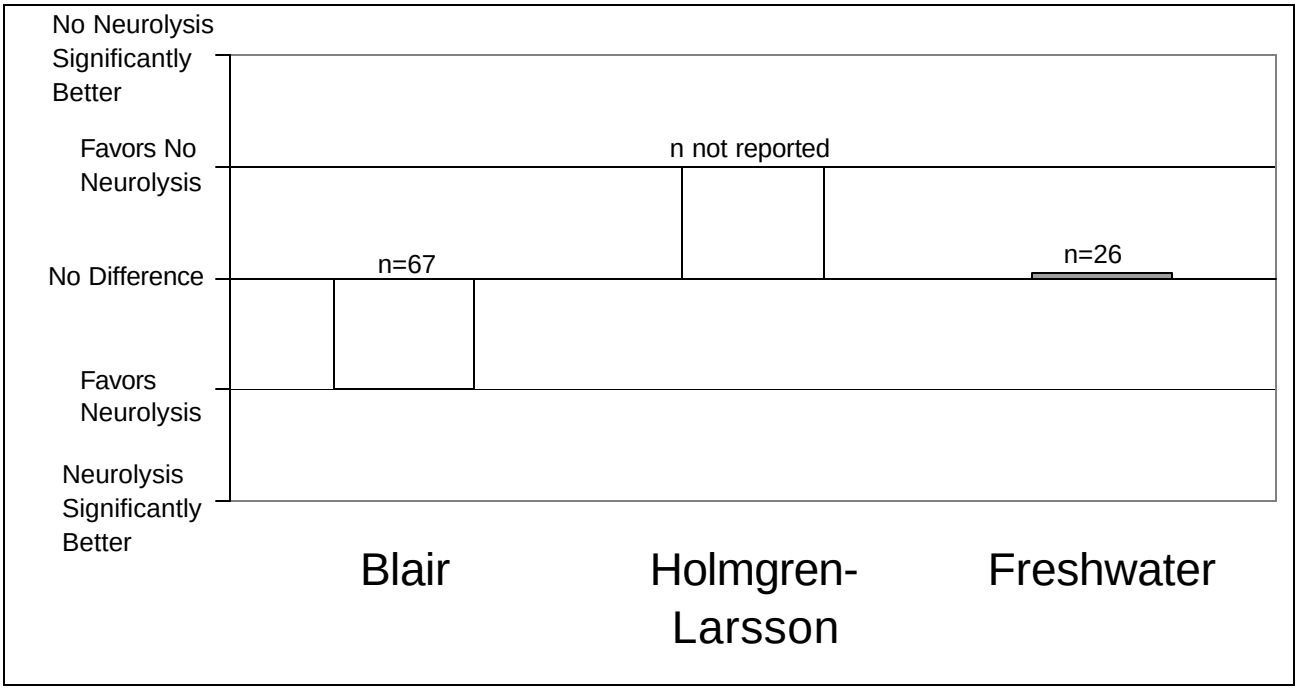
Study	Number of Hands	Pain	Statistical Significance of Difference Between Groups
Blair, 1996 [428]	Open Release 27 Release and Neurolysis 48 (Hands)	Preop: 25 had pain Unimproved: 0 Improved: 8 (32%) No Pain: 17 (68%) Preop: 42 had pain Unimproved: 1 (2.4%) Improved: 5 (12%) No Pain: 36 (86%)	Not significantly different by chi square test conducted by ECRI, p = 0.11
Holmgren-Larsson, 1985 [433]	48 Hands total; number in each group not reported. Open release Preop. 3-4 Weeks 6 Months Release and neurolysis Preop. 3-4 Weeks 6 Months	Percent of patients reporting pain 78 0 0 85 4 13	Not reported
Freshwater, 1978 [426]	 Open Release 12 Release and Neurolysis 14 Open Release 12 Release and Neurolysis 14	Patients with wrist pain: Preop: 2; Postop: 1 Preop 4; Postop: 1 Patients with night-waking pain and tenderness: Preop: 12; Postop: 0 Preop: 14; Postop: 0	Not significantly different by chi square test conducted by ECRI, p = 0.91 Not significantly different by chi square test conducted by ECRI, p = 0.97

Table 78. Summary of the effect of neurolysis on pain

Study	Which Procedure led to less pain?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Blair, 1996 [428]	Neurolysis	No	28%	-0.57 (-1.23-0.10)
Holmgren-Larsson, 1985 [433]	No Neurolysis	No	Not calculable	Not calculable
Freshwater, 1978 [426]	No difference	No	Not calculable	0.08 (-2.12-2.28)

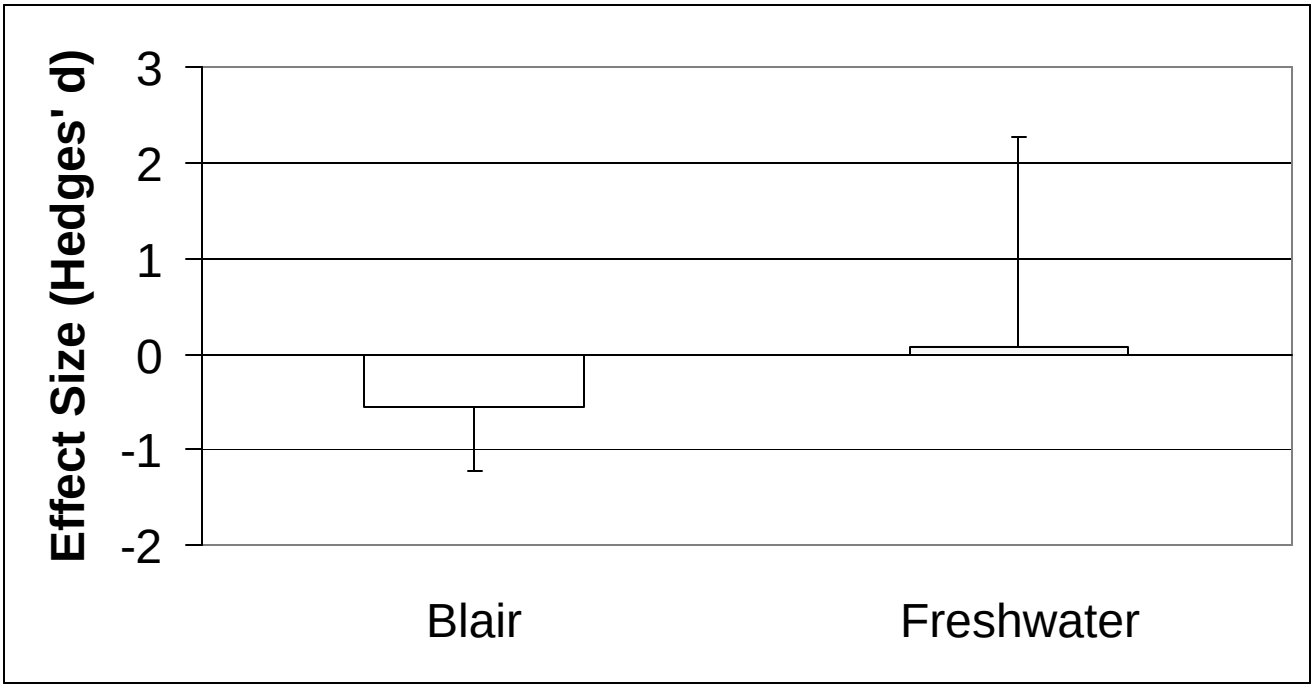
a: Calculated by ECRI

Figure 36. Summary of effect of neurolysis on pain



An open bar indicates an RCT, a striped bar indicates a CT.

Figure 37. Size of effect (Hedges' d) of neurolysis on pain



Function

Two randomized controlled trials of carpal tunnel release with or without neurolysis reported measures of function. Both included patients treated for bilateral CTS, and both had high (36%-50%) rates of attrition. Their results can be found in Table 79. Foulkes et al. asked patients to rate their hand function on a scale of 0-100, while Blair et al. reported the number of patients having difficulty in three specific activities. As can be seen in Table 80 and Figure 38, neither study found a statistically significant difference between groups, and no clear trends can be observed favoring one group or the other. Differences between groups are small, and, in the case of Blair, would have to be large (at least 44%) before the study would have the statistical power to find them significant.

Table 79. Effect of neurolysis on hand function

Study	Number of Patients	Function	Statistical Significance of Difference Between Groups
Blair et al., 1996 [428]		Patients having difficulty:	There were no significant differences between groups before or after treatment (test not reported)
		Screwing Lids:	
	Open Release 27	Preop: 25 (92.5%) 24 Months: 11 (40.7%)	
	Release and Neurolysis 48	Preop: 41 (85.4%) 24 Months: 15 (31.3%)	
		Picking up small objects:	
	Open Release 27	Preop: 18 (66.7%) 24 Months: 10 (37.0%)	
	Release and Neurolysis 48	Preop: 27 (56.3%) 24 Months: 9 (18.8%)	
		Lifting:	
	Open Release 27	Preop: 15 (55.6%) 24 Months: 7 (25.9%)	
	Release and Neurolysis 48	Preop: 25 (52.1%) 24 Months: 9 (18.8%)	
	(Hands)		
Foulkes et al., 1994 [376]		Function rating (0-100)	Not reported
	Open Release 8	Preop: 41 29 Months: 89	
	10	Recalculated[a]: 79.4	
	Release and Neurolysis 15	Preop: 34 29 Months: 88	
	26	Recalculated: 65.2	

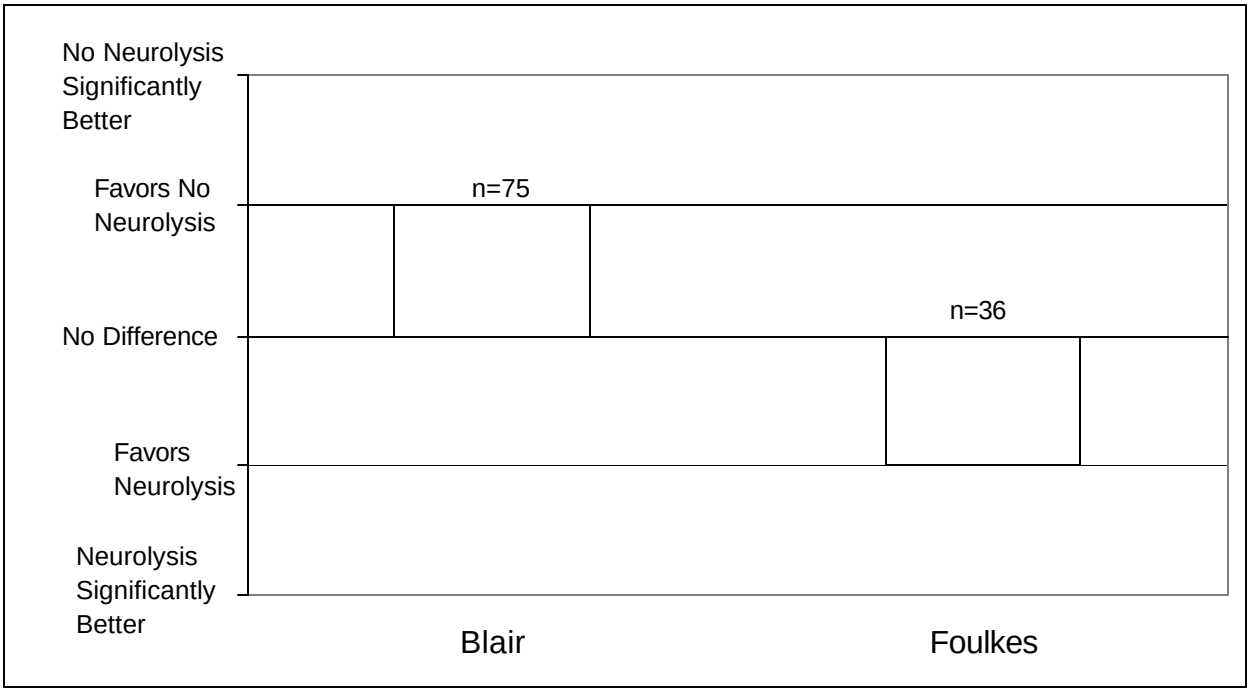
[a]: Recalculated by ECRI according to intent to treat principles by making the conservative assumption that the two patients lost to followup in the open release group had function ratings of 41 at 29 months, and the 11 lost to followup in the neurolysis group had function ratings of 34.

Table 80. Summary of effect of neurolysis on hand function

Study	Which Procedure led to superior function?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)
Blair, 1996 [428]	Neurolysis	No	Screwing Lids: 62% Picking up objects: 57% Lifting: 44%	Not calculable
Foulkes, 1994 [376]	Open release	Not reported	Not calculable	Not calculable

a: Calculated by ECRI

Figure 38. Summary of effect of neurolysis on hand function



Quality of Life

No studies reported on this outcome.

Harms

Only two randomized controlled trials reported on complications and adverse effects among patients receiving neurolysis. One of these had 50% attrition.[376] These trials are listed below in Table 81. One controlled trial and one retrospective trial reported that there were no complications.[415,426] There are insufficient data to allow one to reach an evidence-based conclusion.

Table 81. Complications in controlled trials of neurolysis for patients with carpal tunnel syndrome

Study	Group n	Complication	Number of patients reporting
Foulkes, 1994 [376]	No Neurolysis 8 Hands	Infection	0
	Neurolysis 15 Hands	Infection	2
Lowry, 1988 [429]	No Neurolysis 23	Persistent incisional pain Hand swelling Causalgia	3 0 1
	Neurolysis 24	Persistent incisional pain Hand swelling Causalgia	4 1 0

Conclusion

The available evidence suggest there is little or no benefit from performing neurolysis along with surgical release of the carpal tunnel. Meta-analysis of global outcomes demonstrates a benefit from not performing neurolysis that was not apparent from examination of the individual studies. Available return to work data also shows a trend toward an advantage of not performing neurolysis. There are insufficient data to allow one to reach an evidence-based conclusion, on the effect of neurolysis on pain or function. The possibility remains that neurolysis may be helpful is special cases, such as in the presence of marked scarring or neural adhesion, but no available evidence specifically documents the benefits and harms of neurolysis among such patients.

What are the relative benefits and harms of steroid injection into the carpal tunnel for persons with carpal tunnel syndrome?

Four prospective, randomized controlled trials describing 261 patients reported on the effect of steroid injections into the carpal tunnel.

Internal Validity

Three studies of steroid injections were double-blinded,[36,452,453] and one was unblinded.[427] Three studies assessed only one hand per patient, while Girlanda et al. assessed 53 hands in 32 patients.[36] This study therefore violated the statistical principle of independence between subjects. All four studies had no attrition and full compliance. Data on study internal validity may be found in Table 82.

Generalizability

None of the studies reported patient comorbidities, except when some comorbidities were excluded, as indicated by a zero in Table 83. Dammers, et al. excluded patients with mild disease.[452] Results in this study may therefore be different from results in others. None of the studies provided information about patient employment characteristics.

Table 82. Internal validity of studies of steroid injection for carpal tunnel syndrome

Study	Number of patients	Percent of patients with bilateral CTS	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
O'Gradaigh, 2000 [454]	123	0%	Single	Not reported	RCT	No	0	Yes	100
Dammers, 1999 [452]	60	0%	Single	No	RCT	Double	0	Yes	100
Girlanda, 1993 [36]	32	65.6%	Single	Not reported	RCT	Double	0	Yes	100
Ozdogan, 1984 [453]	37	0%	Single	Not reported	RCT	Double	0	Yes	100

Table 83. Generalizability of studies of steroid injection for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
O'Gradaigh, 2000 [454]	123	NR	NR	NR	NR	NR	0	NR	NR	NR	NR	No	No
Dammers, 1999 [452]	60	52	83.3	29	NR	NR	NR	NR	NR	NR	NR	No	Yes
Girlanda, 1993 [36]	32	45.5	81.3	53.5 (1-240)	0	0	NR	0	0	NR	0	No	No
Ozdogan, 1984 [453]	37	47.0	100	45.6	0	0	0	NR	NR	NR	0	No	No

Global outcome

One study compared steroid injection with no treatment,[454] two compared steroid injection with placebo (saline or lidocaine),[36,452] and one compared carpal tunnel injection with intramuscular injection.[453] Two therefore controlled for a possible placebo effect, while one is considered a comparison of treatments, as intramuscular steroid injection may exert an effect.

The results of the four trials may be found in Table 84. Because effect sizes could only be calculated for three studies, we did not perform a meta-analysis. After treatment, global outcomes were significantly higher in all treated groups (as compared to untreated) in the study by O'Gradaigh et al., but were not significantly different from each other at 6 weeks or 6 months (chi square tests conducted by ECRI). The difference from untreated remained statistically significant after applying the Bonfferoni correction for multiple statistical tests (critical p = 0.004).

Similarly, Dammers found that treated groups were significantly different from placebo groups at both time points reported,[452] while Girlanda reported global scores favoring steroid injection over placebo, but did not report on the statistical significance of this difference. The results of the four trials are summarized in Table 85 and Figure 39.

Both studies that reported longer followup times (>6 months) found that the effect of steroid injection declined over time. The period of relief that can be expected by the average patient cannot be determined from the available data.

The differences in effect sizes between studies may be explained by the differences in the groups to which steroid injection into the carpal tunnel is being compared. The largest effect sizes, ranging from 1.62 to 2.11, are found in the study by O'Gradaigh, who compared steroid injection to no treatment. The next largest (1.40-1.44) are in the study by Dammers, who compared steroid injection to placebo injection. If the placebo exerted a placebo effect, the difference between groups, and thus the effect size, would be smaller than that found in a study comparing treated and untreated groups. The smallest effect sizes (0.25-0.28) are found in the study by Ozdogan, who compaired steroid injection into the carpal tunnel with another active treatment, intramuscular steroid injection. Ozdogan thus tests not whether steroid injection into the carpal tunnel is effective, but whether it exerts an effect superior to that of intramuscular injection.

Table 84. Effect of steroid injection on global outcome

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
O'Gradaigh, 2000 [454]		Patients showing improvement of symptoms	Treatments were superior to controls at either time point by chi square test, p <0.05
		6 Weeks:	Treatments were not significantly different from each other at either time point by chi square test, p >0.05.
	No Injection 20	1 (5.0%)	
	20 mg Triamcinolone 18	13 (72.2%)	
	25 mg Hydrocortisone 32	21 (65.6%)	
	100 mg Hydrocortisone 53	34 (64.1%)	
		6 Months:	
	No Injection 20	0 (0%)	
	20 mg Triamcinolone 18	8 (44.4%)	
	25 mg Hydrocortisone 32	14 (43.8%)	
	100 mg Hydrocortisone 53	17 (32.1%)	
Dammers, 1999 [452]		Patients with No symptoms or minor symptoms	Treatments were significantly different at both time points (p = 0.000011 and 0.0002 respectively, chi square test conducted by ECRI)
		1 Month	
	Placebo (10 mg Lignocaine) 30	6 (20.0%)	
	10 mg Lignocaine and 40 mg Methylprednisone 30	23 (76.7%)	
		12 Months	
	Placebo (10 mg Lignocaine) 30	2 (6.7%)	
	10 mg Lignocaine and 40 mg Methylprednisone 30	15 (50.0%)	
Girlanda, et al., 1993 [36]		Mean symptom score (0-10)	Not reported
		Pretreatment:	
	Placebo (Saline) 26	9	
	15 mg Methylprednisone 27	8	
		1 Week	
	Placebo (Saline) 26	7	

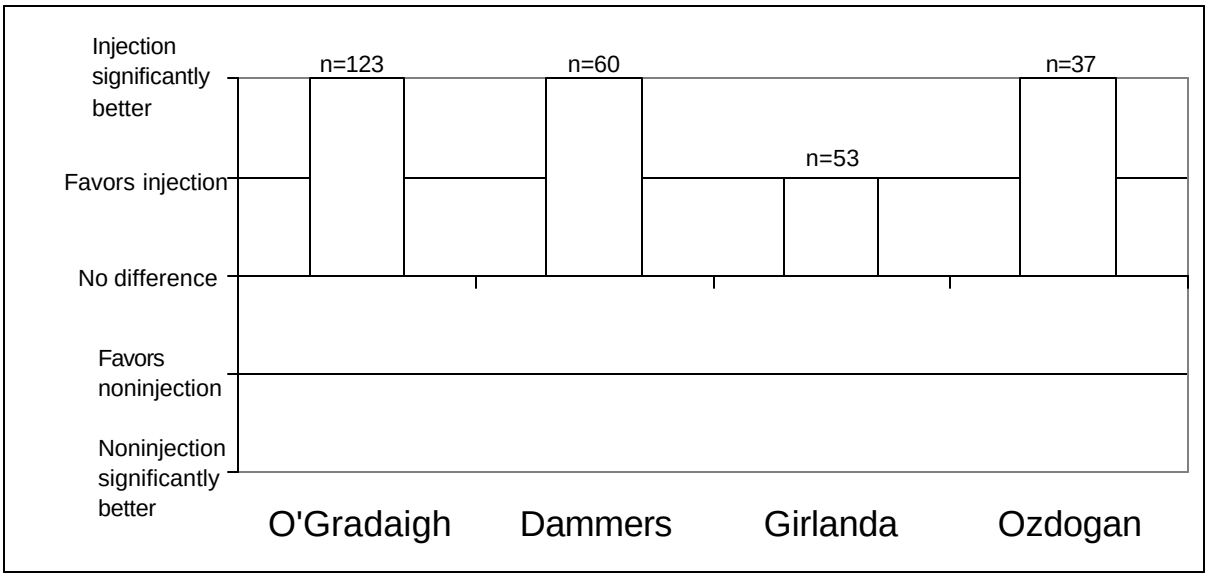
Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
	15 mg Methylprednisone 27 Placebo (Saline) 26 15 mg Methylprednisone 27	3 2 Months 8 1.5	
Ozdogan and Yazici, 1984 [453]	1.5mg Betamethasone in the deltoid muscle 19 1.5mg Betamethasone in the carpal tunnel 18 1.5mg Betamethasone in the deltoid muscle 19 1.5mg Betamethasone in the carpal tunnel 18 1.5mg Betamethasone in the deltoid muscle 19 1.5mg Betamethasone in the carpal tunnel 18	Pretreatment:: Severe 13 Moderate 4 Minimal 2 No Symptoms 0 Severe 11 Moderate 6 Minimal 1 No Symptoms 0 1 Week: Severe 5 Moderate 2 Minimal 8 No Symptoms 4 Severe 2 Moderate 3 Minimal 8 No Symptoms 5 1 Month: Severe 8 Moderate 8 Minimal 2 No Symptoms 1 Severe 6 Moderate 3 Minimal 0 No Symptoms 9	Groups were not significantly different, p = 0.83, chi square test conducted by ECRI Groups were not significantly different, p = 0.25, chi square test conducted by ECRI. Groups were significantly different, p = 0.009, chi square test conducted by ECRI

Table 85. Summary of effect of steroid injection on global outcome

Study	Which Procedure led to Superior Global Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
O'Gradaigh, 2000 [454]	Injection	Yes	20 mg Triamcinolone 22% 25 mg Hydrocortisone 18% 100 mg Hydrocortisone 17%	20 mg Triamcinolone 6 Weeks: 2.11 (0.86 – 3.35) 6 Months: 1.89 (0.27 – 3.52) 25 mg Hydrocortisone 6 Weeks: 1.95 (0.77 - 3.13) 6 Months: 1.88 (0.29 – 3.48) 100 mg Hydrocortisone 6 Weeks: 1.92 (0.77 – 3.07) 6 Months: 1.62 (0.05 – 3.20)
Dammers, 1999 [452]	Injection	Yes	16%	1 Month: 1.40 (0.720-02.08) 12 Months: 1.44 (0.55 – 2.32)
Girlanda, 1993 [36]	Injection	Not reported	Not calculable	Not calculable
Ozdogan, 1984 [453]	Injection	At 1 month only	Not calculable	1 Week: 0.25 (-0.39 – 0.90) 1 Month: 0.28 (-0.37 – 0.40)

[a]: Calculated by ECRI

Figure 39. Summary of effect of injection on global outcome



Return to Work

No studies reported this outcome.

Return to Activities of Daily Living

No studies reported this outcome.

Pain

No studies reported this outcome.

Function

No studies reported this outcome.

Quality of Life

No studies reported this outcome.

Harms

No side effects or complications were described by any of the reports. This does not necessarily indicate that there were no such occurrences. Only Dammers et al. specifically stated that there were no side effects.[452]

Conclusions

The results of these four studies indicate that injection of steroid into the carpal tunnel yields superior global outcomes than no treatment or placebo. Although the short-term (1 week) effect of carpal tunnel injection was not superior to intramuscular injection in the trial by Ozdogan and Yazici, the effects of injection may last longer.[453] Carpal tunnel injection was significantly better than intramuscular injection at a longer (1 month) followup time. Because no further time points were reported, we are unable to determine whether this difference persists beyond this time.

There are no data available that indicate whether any type of steroid may be superior to any other, or whether any particular dose is optimum. Although it is clear that the effects of steroid injection wear off after time, there is no information indicating the expected duration of relief for the average patient, or whether any patients can expect to experience permanent relief.

What are the relative benefits and harms of oral medications for persons with carpal tunnel syndrome?

Oral medications, including steroids, nonsteroidal anti-inflammatory drugs (NSAIDs) and diuretics have been used to treat carpal tunnel syndrome.

Internal Validity

Two prospective, double-blinded randomized controlled trials describing 109 patients reported the effects of oral medications on carpal tunnel syndrome.[35,455] Study characteristics affecting internal validity are listed in Table 86.

All results were reported per patient, rather than per hand. Therefore, there was no violation of the statistical assumption of independence. Both reports described only patients who completed the treatment. There was a 20% attrition before final followup in the study by Chang, including 7 patients who underwent carpal tunnel surgery during the course of the study. The study by Herskovitz reported a 16.7% attrition rate, including two patients from the prednisone group and one from the placebo group. This attrition may have resulted in an increase in the apparent effectiveness of the drugs, as patients who are unsatisfied with their treatment may have been more likely to drop out of the study. The seven patients described by Chang et al. who underwent surgery were clearly unsatisfied with the results of their medication. Neither trial provided a measure of patient compliance. Therefore it is unknown whether or how often the patients took their medication.

Generalizability

Patients were middle-aged (mean 46.3 years) and predominantly female (58%-80%). Both excluded patients with mild and severe CTS. Herskovitz included patients with diabetes and arthritis, while these patients were excluded from the study by Chang. This exclusion limits both the generalizability of the study and the extent to which the results of the two studies can be compared and combined. Patient characteristics from the two studies are presented in Table 87. Neither study described patient employment characteristics.

One trial compared oral prednisone with placebo,[455] while the other compared prednisolone, tenoxicam, trichlormethiazide and placebo.[35] These drugs and dosages are described in Table 88. The two studies tested different drugs. However, both report the effects of an anti-inflammatory steroid, and these results are to some extent comparable.

Table 86. Internal validity of studies of oral medication for carpal tunnel syndrome

Study	Number of patients	Percent of patients with bilateral CTS	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Chang, 1998 [35]	91	0%	Single	Not reported	RCT	Double	18	No	NR
Herskovitz, 1995 [455]	18	0%	Single	Not reported	RCT	Double	3	No	NR

Table 87. Generalizability of studies of oral medication for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Chang, 1998 [35]	91	45.7	58.2	NR	0	0	NR	NR	0	0	NR	Yes	Yes
Herskovitz, 1995 [455]	18	49.6	80.0	20.6	6.6	6.6	NR	0	0	NR	NR	Yes	Yes

Table 88. Oral drugs used to treat carpal tunnel syndrome in controlled studies

Drug	Dose	Description
Prednisone	20mg/day for 1 week, then 10mg/day for 1 week	An anti-inflammatory steroid
Prednisolone	20mg/day for 2 weeks, then 10mg/day for 2 weeks	An anti-inflammatory steroid
Tenoxicam	20mg/day for 4 weeks	A nonsteroidal anti-inflammatory drug (NSAID)
Trichlormethiazide	2mg/day for 4 weeks	A diuretic, used to reduce swelling and lower carpal tunnel pressure

Results

Global outcome

Both studies reported global symptom scores. This was the mean of five symptom severity ratings on a scale of zero to ten. The symptoms rated were pain, numbness, paresthesia, weakness/clumsiness and nocturnal awakening. These data are summarized in Table 89. As can be seen in Table 90 and Figure 40, both reports found statistically significant decreases in symptom scores among patients treated with steroids compared to placebo controls. However, Herskovitz et al. reported that symptoms returned after the cessation of treatment. In neither study did symptom scores approach zero, indicating that although there was some relief, symptoms were still present. Chang et al. reported a 64% mean decrease in global symptom scores, while Herskovitz et al reported a 68% decrease. Neither paper indicated whether the patients were satisfied with their level of symptom relief.

When the data were recalculated to account for patient attrition, the steroid groups in both studies still showed a greater than 50% reduction in global symptom scores. However, because we are unable to accurately estimate the standard deviations around the recalculated means, we are unable to determine whether the difference remains statistically significant. The number of patients reporting symptom relief in the report by Herskovitz is not statistically significantly different between groups once we attempted to compensate for patient attrition by assuming that patients for whom there was no data did not improve.

In the study by Chang, neither the diuretic nor the NSAID caused statistically significant symptom relief compared to placebo control. However, a single small trial with high loss to followup is not sufficient proof that these agents have no effect. Moreover, only a single dosage of each drug was tested. There are no published data on the effectiveness of these agents at other dosages. The power of the study by Chang was sufficient to detect medium-sized (20-30%) differences between groups. The differences between placebo and steroid were greater than this, while the differences between the other groups and placebo were too small to be statistically significant with the available power.

The study by Herskovitz had fewer patients than the study by Chang. Although the statistical power of this study to detect differences in global symptom score could not be calculated, it was likely lower than that of Chang. The study by Herskovitz had the power to detect only a large (49%) difference between number of improved patients in each group. Because of this low power and high attrition, we are unable to determine whether oral steroids lead to a statistically significant improvement in global outcome.

Table 89. Effect of oral medications on global outcome of carpal tunnel syndrome

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Chang, et al., 1998 [35]		Mean global symptom score[a]	
	Placebo 16	Baseline: 22.9±5.9 2 Weeks: 21.6±6.4 4 Weeks: 20.8±6.6	Symptom reduction among patients receiving steroid was significantly greater at 2 weeks than among patients in the other three groups (F = 7.37, p = 0.0002) Symptom reduction among patients receiving steroid was significantly greater at 4 weeks than among patients in the other three groups (F = 10.7, p = 0.0001) NSAID and diuretic groups were not significantly different from placebo at either time point.
	Diuretic 16	Baseline: 26.0±3.8 2 Weeks: 22.3±5.5 4 Weeks: 21.6±6.3	
	NSAID 18	Baseline: 29.7±8.4 2 Weeks: 24.7±8.6 4 Weeks: 24.0±9.7	
	Steroid 23 (Prednisolone)	Baseline: 27.9±6.9 2 Weeks: 15.0±6.8 4 Weeks: 10.0±7.5	
	Recalculated[b]	Recalculated[b]	
	Placebo 23	Baseline: 22.9 2 Weeks: 22.0 4 Weeks: 21.4	
	Steroid 26	Baseline: 27.9 2 Weeks: 16.5 4 Weeks: 12.1	
Herskovitz, et al., 1995 [455]		Mean global symptom score[a]	
	Placebo 9	Baseline: 23 2 Weeks: 19 4 Weeks: 17 8 Weeks: 16.5	Groups were significantly different only at 2 weeks (p <0.05, t-test)

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
	Steroid 6 (Prednisone)	Baseline: 25 2 Weeks: 8 4 Weeks: 11 8 Weeks: 20	
	Recalculated[b]	Recalculated[b]	
	Placebo 10	Baseline: 23 2 Weeks: 19.4 4 Weeks: 17.6 8 Weeks: 17.2	
	Steroid 8	Baseline: 25 2 Weeks: 12.3 4 Weeks: 14.5 8 Weeks: 21.3	
		Number of patients reporting improvement in symptoms:	Numbers were the same for all time points, and were significantly different between groups (p = 0.02, test not reported)
	Placebo 9	3	Improvement rates were no longer statistically significant if the two patients from the steroid group and one from the placebo group who were not reported on were assumed not to have improved, p = 0.058 by chi square test conducted by ECRI.
	Steroid 6 (Prednisone)	6	

a: The sum of severity ratings (scale 0-10) for 5 symptoms: pain, numbness, paresthesia, weakness/clumsines s, and nocturnal wakening

b: Recalculated to account for patient attrition using the conservative assumption that patients for whom no data was provided had scores equal to the mean baseline score for that group.

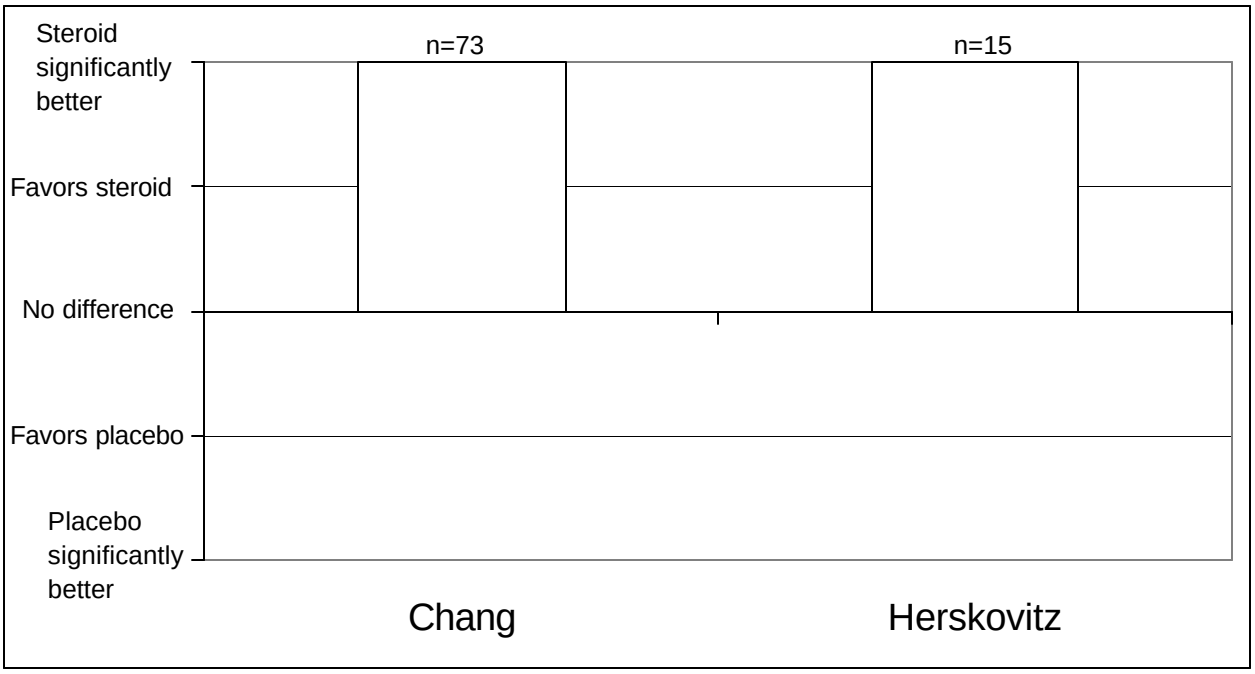
Table 90. Summary of effect of oral medications on global outcome of carpal tunnel syndrome

Study	Which Medication led to Superior Global Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Chang, 1998 [35]	Steroid	Yes	Diuretic 2 Weeks: 20.0% 4 Weeks: 22.4% NSAID 2 Weeks: 24.6% 4 Weeks: 27.9% Steroid 2 Weeks: 20.2% 4 Weeks: 22.4%	Diuretic 2 Weeks: -0.11 (-0.81 – 0.58) 4 Weeks: -0.12 (-0.81 – 0.57) NSAID 2 Weeks: -0.40 (-1.08 – 0.28) 4 Weeks: -0.37 (-1.05 – 0.31) Steroid 2 Weeks: 0.97 (0.30 – 1.65) 4 Weeks: 1.48 (0.76 – 2.20)
Herskovitz, 1995 [455]	Steroid	Yes	Global Symptom Score Not calculable Number of Patients Improved 49%	Global Symptom Score 2 Weeks: 1.08 (-0.03 – 2.18)[b] Number of Patients Improved 1.65 (-0.09 – 3.39)

a: Calculated by ECRI

b: Estimated by ECRI based on the conservative assumption that p = 0.049.

Figure 40. Summary of effect of oral steroids on global outcome



Return to Work

Neither study reported this outcome.

Return to Activities of Daily Living

Neither study reported this outcome.

Pain

Because the study by Chang did not report this outcome, only the effect of oral steroids can be considered. Herskovitz et al. reported that improvement in pain scores was significantly greater in the steroid group than the control ($p = 0.07$, 0.03 and 0.008 at 2, 4, and 8 weeks, respectively by t-test). Because the raw were not reported, no analysis is possible. Although the differences may be statistically significant, without information regarding their magnitude (effect size), we are unable to determine whether they are clinically significant. Further, the results of a single small trial are insufficient evidence for conclusions to be drawn.

Function

Neither study reported this outcome.

Quality of Life

Neither study reported this outcome.

Harms

Chang et al. reported the number of patients experiencing nausea and epigastric pain, while Herskovitz et al. reported the number experiencing any perceived effect. These results are presented in Table 91. In both studies, numbers of patients reporting side effects were not significantly different between treated groups and placebo groups by chi square test conducted by ECRI ($p > 0.3$). However, there are too few studies to allow one to reach a firm evidence-based conclusion about the side effects experienced by patients with carpal tunnel syndrome who are given oral medications.

Table 91. Side effects of oral medications for carpal tunnel syndrome

Study	Group	Complication	Number of patients experiencing complication
Chang, et al., 1998 [35]	Placebo 16	Nausea Epigastric pain	1 2
	Diuretic 16	Nausea Epigastric pain	0 2
	NSAID 18	Nausea Epigastric pain	3 3
	Steroid 23 (Prednisolone)	Nausea Epigastric pain	3 2
Herskovitz, et al., 1995 [455]	Placebo 9	Nausea/abdominal discomfort, constipation, insomnia, headache, dysuria, and burning nostrils	3
	Prednisone 6	Nausea/abdominal discomfort, constipation, dysgeusia, mild hypoglycemia	3

Conclusions

Two double-blinded randomized controlled trials suggest that oral steroids may lead to a reduction in symptoms of CTS. A single published randomized controlled trial indicates that oral tenoxicam and trichlormethiazide do not reduce the symptoms of CTS under the dosing regimens described. The effects of oral steroids are short-lived and may not be sufficient for patient satisfaction. There are no published controlled trials describing the effects of higher doses or longer treatment regimens.

What are the relative benefits and harms of oral and locally injected corticosteroids for persons with carpal tunnel syndrome?

A single randomized, double-blinded trial of 60 patients compared oral steroids with a single injection of steroid into the carpal tunnel. Patients in the steroid injection group received a single injection of 15mg methylprednisolone acetate directly into the carpal tunel and instructed to take placebo pills daily for 10 days. The oral steroid group received an injection of saline into the carpal tunnel, and took 25 mg of prednisolone daily for 10 days.

Internal Validity

Factors affecting internal validity are listed in Table 92. Although 14 patients had bilateral CTS, all results are reported per patient, rather than per effected hand. Therefore, there is no violation of the statistical assumption of independence. Whether patients with bilateral CTS received injections into both wrists was not reported. The effect of bilateral CTS on a patient's global symptom score (the only outcome measure reported) is not known. Patients with bilateral CTS may rate themselves as having more severe CTS than patients with only one arm affected. Bilateral patients were evenly distributed between groups by chi square test conducted by ECRI ($p = 0.54$). There was no patient attrition. Therefore, there was no violation of the intent-to-treat principle. However, the rate at which patients complied with instructions and took their oral medications was not reported.

Generalizability

Patient age and sex was consistent with the overall population of CTS patients as described in the introduction under Epidemiology. However, this study excluded patients with comorbidities, those with severe disease, and those with mild disease. These exclusions may limit the generalizability of the results of this study. Patient characteristics affecting generalizability are listed in Table 93.

Table 92. Internal validity of the study comparing oral and injected steroids

Study	Number of patients	Percent bilateral patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Wong, 2001 [456]	60	23.3%	Single	Not Reported	RCT	Double	0	Yes	NR

Table 93. Generalizability of the study comparing oral and injected steroids for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Wong, 2001 [456]	60	49	88.3%	NR	0	0	0	0	0	0	0	Yes	Yes

Results

Global Outcome

The outcome measure was global symptom score, the sum of ratings (0 to 10) of pain, numbness, paresthesia, weakness/clumsiness and nocturnal awakening. These scores are given in Table 94, and the results are summarized in Table 95. This outcome was statistically significantly different between groups at 8 weeks and 12 weeks. The difference between groups at two weeks was smaller than the study had the power to detect.

Table 94. Relative effect of steroid injection and oral steroids on global outcome of CTS

Study	Number of Patients	Global Symptom Score	Statistical Significance of Difference Between Groups
Wong, 2001 [456]	Injection 30		Groups were significantly different at 8 weeks and 12 weeks by t-test conducted by ECRI.
	Pretreatment	25.00±6.41	
	2 Weeks	13.57±7.47	
	8 Weeks	13.67±8.27	
	12 Weeks	14.30±8.42	
	Oral 30		
	Pretreatment	25.73±8.31	p = 0.705
	2 Weeks	17.77±9.98	p = 0.070
	8 Weeks	20.83±8.73	p = 0.0019
	12 Weeks	21.40±9.64	p = 0.0036

Table 95. Summary of the relative effect of steroid injection and oral steroids on global outcome of CTS

Study	Which Procedure led to Superior Global Outcome?	Was the Difference Statiscally Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Wong, 2001 [456]	2 Weeks: Injection	No	21%	0.47 (-0.09-1.03)
	8 Weeks: Injection	Yes	21%	0.831. (0.25-1.41)
	12 Weeks: Injection	Yes	22%	0.77 (0.20-1.35)

a: Calculated by ECRI

Return to Work

This study did not report this outcome.

Return to Activities of Daily Living

This study did not report this outcome.

Pain

This study did not report this outcome.

Function

This study did not report this outcome.

Quality of Life

This study did not report this outcome.

Harms

Harms reported among the two groups are given in Table 96. Steroid and placebo injection led to injection pain in two patients each. All other side effects were reported to have been experienced by the oral steroid group only. The difference in occurrence of side effects between groups was statistically significant by chi square test conducted by ECRI ($p = 0.0195$).

Table 96. Reported harms of injected and oral steroids

Study	Group	Complication	Number of patients experiencing complication
Wong, 2001 [456]	Injected 30	Injection pain	2
		Increased appetite	0
		Bloating	0
		Insomnia	0
	Oral 30	Injection pain	2
		Increased appetite	3
		Bloating	2
		Insomnia	2

Conclusions

Although only a single study, this study had high internal validity, providing evidence that, under the conditions of the experiment, steroid injection leads to greater reduction of symptoms with fewer side effects than oral steroid. The experiment is short-term (12 weeks) and does not address the issue of whether the effect of injection remains effective at longer time points. Further, it does not address whether continued treatment with oral steroids leads to further benefits or harms to the patient.

What are the relative benefits and harms of physical therapy for persons with carpal tunnel syndrome?

Two randomized controlled trials describing 121 patients reported on the effects of various forms of physical therapy. Tal-Akabi and Rushton compared groups receiving nerve mobilization, groups receiving bone mobilization and a no-treatment control group.[457] Provinciali et al. compared a program of physical therapy including strengthening exercises, massage, gliding exercises and sensory re-training to instruction in a program of home-based strengthening exercises.[427]

Internal Validity

The study by Provinciali was rater-blinded, while the other was unblinded. Trial characteristics affecting internal validity are listed in Table 97. Neither study had any reported attrition, and neither reported on patient compliance.

Generalizeability

In both studies, patients were predominantly middle-aged (mean 54.8 years) and female (67%-82%), as reported in Table 98. This is consistent with the overall population with CTS as described in the introduction under Epidemiology. Tal-Akabi excluded patients with comorbidities, while Provincialli did not report comorbidities. Both studies excluded patients with mild disease. This may limit generalizability, as patients with mild disease are more likely to receive noninvasive treatments such as physical therapy than patients with severe disease, who may be candidates for surgery. Neither study reported patient employment characteristics.

Table 97. Internal validity of studies of physical therapy for carpal tunnel syndrome

Study	Number of patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Provinciali, 2000 [427]	100	Single	Not reported	RCT	Rater	0	Yes	NR
Tal-Akabi, 2000 [457]	21	Not Reported	Not reported	RCT	No	0	Yes	NR

Table 98. Generalizability of studies of physical therapy for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Provincialli, 2000 [427]	100	56.45 (24-86)	82.0	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes
Tal-Akabi, 2000 [457]	21	47.1 (29-85)	66.6	27.6 (12-36)	0	0	0	0	0	0	NR	No	Yes

Results

Global Outcome

Global outcome was assessed in the study by Tal-Akabi and Rushton as the number of patients who did or did not go on to receive surgery after treatment. All patients had been drawn from a waiting list for surgery, which may eliminate factors such as economic status that might have influenced the patients' willingness to undergo surgery. Results are presented in Table 99, and summarized in Table 100. Outcomes of the two treated groups were not significantly different from each other ($p = 0.51$ by chi square test conducted by ECRI), but both the neurodynamic and carpal bone mobilization groups had significantly fewer patients going on to surgery than control ($p = 0.03$ and 0.008, respectively). Although differences between the treated groups and the control group were large enough to be statistically significant, the study lacks the statistical power required to demonstrate significant differences between-treatment groups. With only seven patients per group, a statistically significant effect can be detected only when there is at least a 50% difference between groups.

Table 99. Global outcome of physical therapy for carpal tunnel syndrome

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Tal-Akabi and Rushton, 2000 [457]		Global Score (Number of patients going on to receive surgery)	The two treated groups were not significantly different from each other (p = 0.51 by chi square test conducted by ECRI); both were significantly different from control (p = 0.03 and 0.008, respectively).
	Neurodynamic mobilization 7	2	
	Carpal Bone mobilization 7	1	
	No treatment (Control) 7	6	

Table 100. Summary of Global outcome of physical therapy for carpal tunnel syndrome

Study	Which Procedure led to Superior Global Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Tal-Akabi, 2000 [457]	Carpal bone mobilization	Yes	50%	Neurodynamic mobilization 1.40 (-0.08 – 2.87) Carpal bone mobilization 1.85 (0.20 – 3.50) Difference between-treatment groups 0.45 (-1.42-1.93)

[a]: Calculated by ECRI

Return to work

A single study reported time to return to work. Provincialli et al. reported that patients receiving physical therapy returned to work earlier than patients assigned to home exercise.[427] As can be seen in Table 101, the difference was statistically significant, but the number of patients for whom this measurement was taken was not reported. Further, it is unclear exactly what was measured. These numbers are described both as time to return to daily activities and time to return to work. These ambiguities render it difficult to draw conclusions from these data.

Table 101. Time to return to work after physical therapy for carpal tunnel syndrome

Study	Number of Patients	Days until Return to Activities of Daily Living	Statistical Significance of Difference Between Groups
Provincialli et al., 2000 [427]	Physical Therapy Home Exercise Number of patients is unknown because patients receiving workers' compensation were excluded. The number of such patients was not reported.	32.16±10.72 42.55±13.39	Difference was statistically significant by ANOVA ($p < 0.006$)

Return to Activities of Daily Living

This outcome was not reported by either study.

Pain

Both studies reported pain scores. Tal-Akabi and Rushton also reported pain relief scores. These data are given in Table 102. Provincialli et al. found no statistically significant difference between the program of physical therapy and home exercise instructions. Tal-Akabi and Rushton found that one treatment, carpal bone mobilization, but not the other treatment, neurodynamic modulation, led to pain scores statistically significantly lower than those in the control group ($p = 0.003$ and 0.35 respectively). The two treatment groups were not significantly different from each other ($p = 0.18$). The study lacked the statistical power to detect the difference between these groups. Only large between-group differences (>50%) could be detected in this study, as can be seen in Table 103. While the differences between carpal bone mobilization and control are large enough to be detected, other between-group differences are not. The fact that carpal bone mobilization led to a statistically significant effect while neurodynamic mobilization did not suggests, but does not prove, that carpal bone manipulation is the superior treatment for pain. Further study is necessary to test the differences between these therapies.

Although pain ratings in the VAS group were not significantly different from control after treatment, differences between pain relief scores were statistically significant. It is unclear which is the superior measure of pain.

Table 102. Effects of nerve and bone mobilization on pain from carpal tunnel syndrome

Study	Number of Patients	Pain	Statistical Significance of Difference Between Groups
Provinciali, 2000 [427]	Physical Therapy 50 Pretreatment 1 Month 2 Months Home Exercise 50 Pretreatment 1 Month 2 Months	Sum of patients' pain ratings (scale not reported) 149 55 50 145 54 50	Groups were not significantly different by chi square test (p >0.001; p-level required for significance adjusted by Provinciali using the Bonferroni correction related to 40 comparisons)
Tal-Akabi, 2000 [457]	Neurodynamic mobilization 7 Carpal Bone mobilization 7 No treatment (Control) 7 Neurodynamic mobilization 7 Carpal Bone mobilization 7 No treatment	Pain (VAS, 0-10) Baseline 2.42±1.51 3 Weeks 1.57±1.4 Baseline 2.29±0.95 3 Weeks 0.71±0.76 Baseline 2.0±1.29 3 Weeks 2.14±0.69 Pain Relief Rating 3.14±1.35 3.71±0.95 0±0	After treatment, the carpal bone mobilization group was significantly different from control by t-test conducted by ECRI (p = 0.003), but the neurodynamic mobilization group was not significantly different from control (p = 0.35) or from carpal bone mobilization (p = 0.18) Not significantly different between the two treated groups (p = 0.38), but both the neurodynamic mobilization group and the carpal bone mobilization group were significantly different from control (p = 0.00005 and 0.0000002, respectively)

Study	Number of Patients	Pain	Statistical Significance of Difference Between Groups
	(Control) 7		

Table 103. Summary of effects of nerve and bone mobilization on pain from carpal tunnel syndrome

Study	Which Procedure led to Less Pain?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Provinciali, 2000 [427]	No difference	No	Not calculable	Not calculable
Tal-Akabi, 2000 [457]	Carpal bone mobilization	Yes	Neurodynamic mobilization: 60% Carpal bone mobilization: 54%	VAS Neurodynamic mobilization 0.48 (-0.62 – 1.58) Carpal bone mobilization 1.84 (0.59 – 3.10) Pain Relief Rating Neurodynamic mobilization 3.08 (1.53 – 4.63) Carpal bone mobilization 5.17 (2.99 – 7.35)

[a]: Calculated by ECRI

Function

In the study by Provincialli, function was measured using a nine-hole peg test. Function scores were not significantly different between groups at any time point.[427] In the study by Tal-Akabi and Rushton, functional scores were based on the impairment rating of the patient's most impaired activity.[457] Thus, a lower score indicates superior function. These scores were not significantly different before treatment. Results are presented in Table 104. After treatment, functional scores in the carpal bone mobilization group were significantly lower than those of the control group ($p = 0.01$), while those of the neurodynamic mobilization group were not ($p = 0.09$). The two treatment groups were not significantly different from each other ($p = 0.57$). As presented in Table 105, the study only had the power to detect large (>50%) differences between groups. Only the difference between carpal bone mobilization and control was large enough to be found statistically significant.

Table 104. Effect of physical therapy on function

Study	Number of Patients	Function	Statistical Significance of Difference Between Groups
Provinciali et al. 2000, [427]	Physical Therapy 50	Time (units not stated) to complete nine-hole peg test	Groups were not significantly different by t-test (p >0.001; p-level required for significance adjusted by Provinciali using the Bonnferoni correction related to 40 comparisons
	Pretreatment	22.35±5.14	
	12 Days	23.8[a]	
	1 Month	20.5	
	2 Months	19.5	
	Home Exercise 50		
	Pretreatment	22.38±3.23	
	12 Days	20.5	
	1 Month	20.5	
	2 Months	19	
Tal-Akabi and Rushton, 2000 [457]	Neurodynamic mobilization 7	Function Score (Range 0-4) Baseline 2.0±1.41 3 Weeks 1.14±1.35	After treatment, carpal bone mobilization group was significantly different from control group (p = 0.01) neurodynamic mobilization group was not (p = 0.09). The two treatment groups were not significantly different from each other (p = 0.57). t-tests conducted by ECRI.
	Carpal Bone mobilization 7	Baseline 2.0±1.41 3 Weeks 0.71±0.76	
	No treatment (Control) 7	Baseline 2.42±1.27 3 Weeks 2.42±1.27	

[a]: Estimated by ECRI from a published chart

Table 105. Summary of the effect of physical therapy on function

Study	Which Procedure led to Superior Function?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Provinciali, 2000 [427]	No difference	No	Not calculable	Not calculable
Tal-Akabi, 2000 [457]	Carpal bone mobilization	Yes	Neurodynamic mobilization 63% Carpal bone mobilization 50%	Neurodynamic mobilization 0.91 (-0.21 – 2.19) Carpal bone mobilization 1.53 (0.34 – 2.72)

[a]: Calculated by ECRI

Quality of Life

This outcome was not reported by either study.

Harms

No harms were reported by either study.

Conclusions

Manual therapy may have some use in the treatment of carpal tunnel syndrome. A single study suggests that carpal bone mobilization provides pain relief, improves function, and delays or eliminates the need for surgery among patients with carpal tunnel syndrome.[457] Results from neurodynamic mobilization show a similar trend, but because of a lack of statistical power one cannot conclude that this trend is real. For the same reason, differences in effectiveness between these two treatment groups cannot be determined. The study was not placebo-controlled and was not blinded. The observed effects may have been influenced by a placebo effect or rater bias.

A larger, more statistically powerful study found no difference between the effects of a physical therapy program and home exercise instructions on pain or function. However, patients receiving physical therapy returned to work faster than those instructed to exercise at home.

Although these studies indicate a trend toward physical therapy having an effect on carpal tunnel syndrome, they are too small and inconclusive for one to reach a firm evidence-based conclusion.

What are the relative benefits and harms of ultrasound for persons with carpal tunnel syndrome?

One patient-blinded randomized controlled trial describing 18 patients reported on the effects of ultrasound.[33] This study compared two different levels of intensity of ultrasound to placebo.

Internal Validity

Factors affecting the internal validity of this study are listed in Table 106. The data are reported in terms of the number of hands, rather than number of patients, and among the 18 patients, 30 hands were treated. This violates statistical assumptions of independence.

Generalizability

As can be seen in Table 107, the 18 patients were middle-aged (range 37-66), and all were female. Patients with comorbidities were excluded, as were patients with very mild or severe CTS. These exclusions may limit the generalizability of the trial's results, especially given the fact that only a single trial has been published.

Table 106. Internal validity of the study of ultrasound for carpal tunnel syndrome

Study	Number of patients	Percent bilateral patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Oztas, 1998[33]	18	66.7%	Single	No	RCT	Patient	0	Yes	NR

Table 107. Generalizability of the study of ultrasound for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Oztas, 1998 [33]	18	51.6 (37-66)	100	84 (6-240)	0	0	0	0	0	0	0	Yes	Yes

Results

Because this is a single trial describing only two outcomes, we discuss the results together. Return to work, return to ADLs, function, quality of life and harms were not described. The results of the trial are presented in Table 108 and summarized in Table 109. There were no differences between groups. Moreover, the sham-treated group showed a statistically significant effect of treatment for both pain and global outcome.[33] This may indicate that some patients were incorrectly diagnosed, that patients were receiving additional treatments that were exerting an effect, or they were experiencing a placebo effect.

Pain scores, but not global outcome ratings, were lower in the group treated with 1.5 W/cm^2 ultrasound than in the control group. However, the difference was not statistically significant. The study had the statistical power to detect only large (49-52%) differences between groups. It is unknown whether a more powerful study would have found the difference between groups to be statistically significant.

Interpretation of these results is further complicated by the fact that VAS scores were higher in the placebo-treated group prior to treatment than in either of the treated groups. This may indicate that the randomization procedure in this study was ineffective. The decrease in both VAS and global symptom score after treatment was also greater among placebo-treated hands than among hands receiving ultrasound. This may have been simply because the higher initial scores allowed greater room for improvement, or the improvement may have been the result of regression to the mean.

Table 108. Effects of ultrasound on carpal tunnel syndrome

Study	Number of Hands[a]	Outcome	Statistical Significance of Difference Between Groups
Oztas, et al., 1998 [33]		Pain (VAS, 0-10)	
	1.5 W/cm² 10	Baseline 6.10±2.50 Posttreatment[b] 2.90±1.69	All posttreatment scores were significantly different from baseline ($p < 0.05$, t-test). There were no significant differences between groups ($p > 0.05$, 1-way ANOVA).
	0.8 W/cm² 10	Baseline 7.10±2.38 Posttreatment 3.60±1.90	
	0 W/cm² (Placebo) 10	Baseline 7.90±1.80 Posttreatment 4.00±2.40	
		Global Outcome (Mean of a categorical symptom rating, 0-3 scale)	
	1.5 W/cm² 10	Baseline 2.30±0.68 Posttreatment 1.40±0.52	
	0.8 W/cm² 10	Baseline 2.60±0.70 Posttreatment 1.70±0.82	
	0 W/cm² (Placebo) 10	Baseline 2.60±0.69 Posttreatment 1.40±0.97	

[a]: Eighteen patients with a total of 30 affected hands were treated.
[b]: Followup time was five days after two weeks of treatment

Table 109. Summary of effects of ultrasound on carpal tunnel syndrome

Study	Which Procedure led to Superior Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Oztas, 1998 [33]	No differences	No	Pain 49% Global Outcome 52%	Pain 1.5 W/cm² 0.51 (-0.38 – 1.40) 0.8 W/cm² 0.18 (-0.70 – 1.06) Global Outcome 1.5 W/cm² 0 (-0.88 – 0.88) 0.8 W/cm² -0.32 (-1.20 – 0.56)

[a]: Calculated by ECRI

Conclusions

Only one study meeting inclusion criteria addresses the use of ultrasound for carpal tunnel syndrome. Because of this, and because its design and analysis difficulties, one cannot reach a firm evidence-based conclusion.

What are the relative benefits and harms of full-time and nighttime-only splint use for persons with carpal tunnel syndrome?

A single unblinded randomized trial of 21 patients compared the effects of nighttime-only and full-time splint use.[34]

Internal Validity

Study characteristics related to internal validity are presented in Table 110. This study reported a 20% loss to followup. Of those patients who returned for followup, there was considerable noncompliance. Only 85% of the nighttime-only group reported complete or nearly complete nighttime splint use. Twenty-three percent of this group also reported some daytime use, despite instructions to wear the splint only at night. Complete or nearly-complete daytime use was reported by only 27% of patients instructed to wear the splints full-time. Nearly 43% of the patients had bilateral CTS, and results were reported per hand rather than per patient. This, combined with the loss to followup and noncompliance issues, raises serious doubts as to the reliability of the results of this study.

Generalizability

Patients were middle age (mean 60 years) and predominantly male. This distinguishes them from the majority of CTS patients, who are usually female. Patient characteristics are listed in Table 111. No information about comorbidities or employment characteristics was reported, except that 57.1% of patients were employed (Table 112).

Table 110. Internal validity of the study of full-time and nighttime-only splint use for carpal tunnel syndrome

Study	Number of patients	Percent of bilateral patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Walker, 2000 [34]	21	42.9%	Single	Not reported	RCT	No	4	No	14

Table 111. Generalizability of the study of full-time and nighttime-only splint use for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Walker, 2000 [34]	21	60	3.0	28.5	NR	NR	NR	NR	NR	NR	NR	No	Yes

Table 112. Patient employment characteristics in the study of full-time and nighttime-only splint use for carpal tunnel syndrome

Study	Number of patients	% Patients employed	% Patients receiving workers' compensation	% Patients retired	% Patients Homemakers	Reported occupations
Walker, 2000 [34]	21	57.1	Not reported	Not reported	Not reported	Not reported

Results

Because there is only a single study reporting two outcomes, we discuss the results together. No results were described for return to work, return to ADLs, pain, quality of life or harms. Reported results can be found in Table 113. There were no statistically significant differences between groups in global outcome or functional ability, as can be seen in Table 114. However, the study lacked the statistical power to detect small differences between groups. Only medium (28%-33%) or larger differences would have been statistically significant.

Table 113. Results of comparison between full-time and part-time splint wear for carpal tunnel syndrome

Study	Number of Hands	Outcome	Statistical Significance of Difference Between Groups
Walker et al., 2000 [34]		Global outcome (Symptom severity)	Change from pre to post was not significantly different between groups by t-test. p-values were not reported.
	Nighttime-only 13		
	Pretest	2.89±0.96	
	Posttest	2.30±0.93	
	Full-time 11		
	Pretest	2.79±0.69	
	Posttest	2.09±0.62	
		Functional (Levine) score	Change from pre to post was not significantly different between groups by t-test. p-values were not reported.
	Nighttime-only 13		
	Pretest	2.75±1.01	
	Posttest	2.14±0.87	
	Full-time 11		
	Pretest	2.27±1.03	
	Posttest	1.93±0.77	

Table 114. Summary of comparison between full-time and part-time splint wear for carpal tunnel syndrome

Study	Which Procedure led to Superior Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Walker et al., 2000 [34]	Full-time use	No	Global outcome 29% Functional (Levine) score 33%	Global outcome 0.25 (-0.55 – 1.06) Functional (Levine) score 0.25 (-0.56 – 1.05)

a: Calculated by ECRI

Conclusions

Splint use was addressed only by a single trial that had design difficulties. Because of this, one cannot reach an evidence-based conclusion about splint use.

What are the relative benefits and harms of open carpal tunnel release with ligament reconstruction for persons with carpal tunnel syndrome?

One non-blinded, retrospective controlled trial reported on the effects of ligament lengthening or reconstruction.[48]

Internal Validity

The study did not include patients with bilateral CTS, meaning that there were no violations of the assumption of statistical independence. There was no attrition. Therefore intent-to-treat principles were followed. Study characteristics related to internal validity are listed in Table 115.

Generalizability

Patients were predominantly female and the reported range of ages (24-88 years) is broadly similar to that of the overall CTS population. The trial did not describe patient comorbidities or employment characteristics.[48] Patient characteristics are presented in Table 116.

Table 115. Internal validity of studies of open carpal tunnel release with and without ligament reconstruction

Study	Number of patients	Percent of bilateral patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?
Karlsson, 1997 [48]	74	0%	Single	Not reported	Retro	No	0	Yes

Table 116. Generalizability of studies of open carpal tunnel release with and without ligament reconstruction

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Karlsson, 1997 [48]	74	NR; (24-88)	59.6	[Median) 6 (1-60)	NR	NR	NR	NR	NR	NR	NR	No	No

Results

Time to return to work among patients treated with open release or ligament reconstruction is reported in Table 117. No other patient-oriented outcomes were reported.

Patients who received ligament reconstruction were statistically significantly slower to return to work than those who received open release without ligament reconstruction. The effect size was statistically significantly different from zero (d = 0.65, 95% C.I. = 0.15 – 1.15).

Table 117. Effect of ligament reconstruction on time to return to work

Study	Number of Patients	Weeks until Return to Work	Statistical Significance of Difference Between Groups
Karlsson et al., 1997 [48]	Open release 50 Release and reconstruction 24	4.5 (Range 1-12) 6.0 (Range 3-24)	Groups were significantly different ($p < 0.01$, t-test.).

Conclusions

The results of one study suggest that suboptimal outcomes are obtained when patients receive ligament reconstruction. However, this trial was neither randomized nor blinded, so one cannot draw firm evidence-based conclusions from it.

What are the relative benefits and harms of open carpal tunnel release with early or late mobilization for persons with carpal tunnel syndrome?

Three prospective, randomized controlled trials describing 171 patients compared early and late mobilization (removal of cast or splint) after open carpal tunnel release.

Internal Validity

None of these trials were blinded. Study characteristics related to internal validity are presented in Table 118. Only one study had patient attrition, and two reported results of bilateral patients as per hand rather than per patient. One study had a high (92.7%) rate of compliance, while the other two did not report compliance.

Generalizability

Patient characteristics are reported in Table 119. The studies by Finsen and Bury included predominantly female, middle-aged patients, while Cook did not report these characteristics. The studies differed in their inclusion/exclusion criteria, with Bury et al excluding patients with mild carpal tunnel syndrome,[458] Cook et al. excluding both the most mild and the most severe cases,[432] and Finsen et al. not excluding according to severity.[319] Finsen and Cook excluded patients with comorbidities, while Bury included patients with other nerve impingement conditions. These differences may make it less valid to compare or combine the results of these studies.

Employment characteristics were under-reported in all three studies, as can be seen in Table 120.

Table 118. Internal validity of studies of splinting after carpal tunnel release

Study	Number of patients	Percent bilateral patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Finsen, 1999 [319]	74	10.8%	Single	Not reported	RCT	No	0	Yes	92.7
Bury, 1995 [364]	47	7.5%	Single	Not reported	RCT	No	7	No	NR
Cook, 1995 [432]	50	0%	Single	Not reported	RCT	No	0	Yes	NA

Table 119. Generalizability of studies of splinting after carpal tunnel release

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Finsen, 1999 [319]	74	54.7 (21-86)	81.1	NR	0	0	0	0	0	0	0	No	No
Bury, 1995 [364]	47	41.4 (19-79)	83.0	13 (5-36)	NR	NR	NR	7	NR	NR	NR	No	Yes
Cook, 1995 [432]	50	NR	NR	NR	0	NR	0	NR	0	0	0	Yes	Yes

Table 120. Patient employment characteristics in studies of splinting after carpal tunnel release

Study	Number of patients	% Patients employed	% Patients receiving workers' compensation	% Patients retired	% Patients Homemakers	Reported occupations
Finsen, 1999 [319]	74	63.5	Not reported	Not reported	Not reported	Not reported
Bury, 1995 [364]	47	Not reported	Not reported	Not reported	Not reported	Not reported
Cook, 1995 [432]	50	Not reported	16.0	Not reported	Not reported	Not reported

Results

Global Outcome

Effects of splinting after surgery on global outcome can be seen in Table 121. In the study by Bury et al., the number of patients said to be cured does not equal the number said to be symptom-free.[364] The reason for this discrepancy is not clear. Results are summarized in Table 122 and Figure 41. Both Bury and Cook found that superior global outcomes were obtained in the absence of splinting, with the difference statistically significant only in the study by Cook.

Table 121. Effect of splinting after surgery on global outcome

Study	Number of Patients	Global Outcome	Statistical Significance of Difference Between Groups
Bury et al., 1995 [364]		Global score (Scale not reported)	Not reported
	No splint 17	8.0	
	2 week splint 26	8.1	
		Number of patients symptom-free	Not significantly different by chi square test conducted by ECRI, p = 0.85.
	No splint 17	9	
	2 week splint 26	13	
		Categorical rating	Not significantly different by chi square test conducted by ECRI, p = 0.68.
	No splint 17	Cured: 8 Improved: 9 Unchanged: 0 Worse: 0	Not significantly different when data is collapsed into a dichotomous outcome (number cured or improved) by chi square test conducted by ECRI, p = 0.15
	2 week splint 26	Cured: 12 Improved: 11 Unchanged: 1 Worse: 2	
Cook et al., 1995 [432]		14 Days:	
	No splint 25	Excellent 9 Good 9 Fair 7	Significantly different by chi square test conducted by ECRI, p = 0.018.
	2 week splint 25	Excellent 1 Good 14 Fair 10	
		1 Month:	
	No splint 25	Excellent 12 Good 10 Fair 3	Significantly different by Chi square test conducted by ECRI, p = 0.007.
	2 week splint 25	Excellent 2 Good 18 Fair 5	

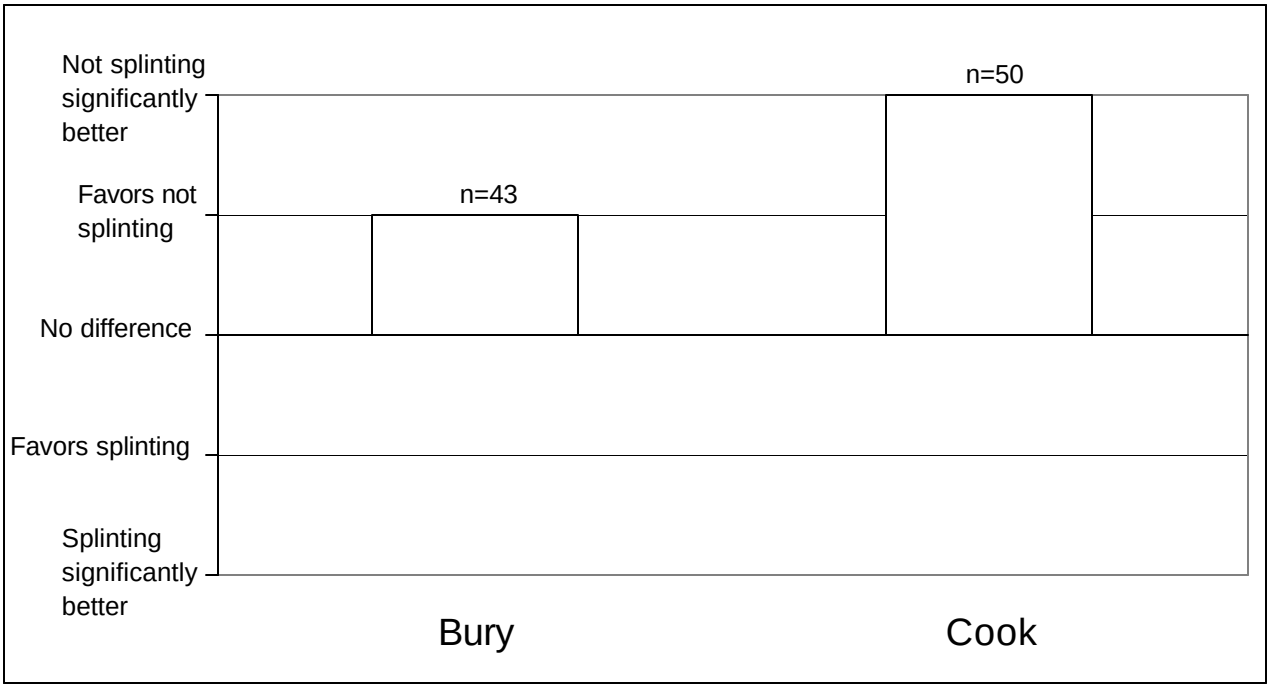
Table 122. Summary of effect of splinting after surgery on global outcome

Study	Which Procedure led to Superior Global Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Bury, 1995 [364]	No Splint	No	Number symptom-free 28% Categorical rating[b] 29%	Number symptom-free 0.06 (-0.61 – 0.72) Categorical rating[b] 0.89 (-0.78-2.56)
Cook, 1995 [432]	No Splint	Yes	Not calculable	14 Days 0.38 (-0.18-0.94) 1 Month 0.86 (0.28-1.44)

a: Calculated by ECRI

b: Calculated by ECRI by collapsing the categorical rating into a dichotomous one: number cured or improved.

Figure 41. Effect of splinting after surgery on global outcome



Return to work

All three trials reported on return to work. These results are presented in Table 123. As can be seen in Table 124 and Figure 42, two studies show a trend toward favoring no splint, with the difference becoming statistically significant in the study by Cook. In contrast, the study by Finsen shows no difference between groups.

Table 123. Effect of splinting after surgery on return to work

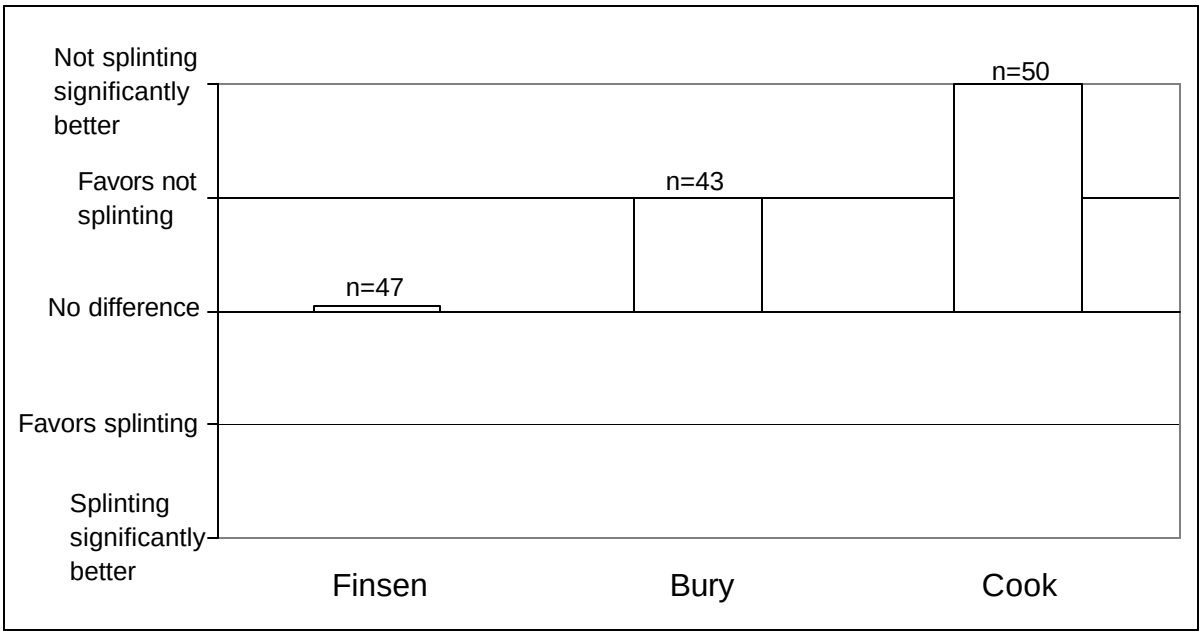
Study	Number of Patients	Return to work	Statistical Significance of Difference Between Groups
Finsen, 1999 [319]		Median time to return to work	Not reported
	No splint 28	6 Weeks (95% CI 5-6 Weeks)	
	4 week splint 19	6 Weeks (95% CI 4-7 Weeks)	
Bury, 1995 [364]		Number[a] of patients who had not returned to work at last followup (Mean 5.7 Months)	Not significantly different by chi-square test conducted by ECRI, p = 0.23
	No splint 17	2	
	2 week splint 26	7	
Cook, 1995 [432]		Time to return to work	Significantly different by t-test (Light duty p = 0.01; Full duty p = 0.005)
	No splint 25	Light duty: 15 Days Full duty: 17 Days	
	2 week splint 25	Light duty: 24 Days Full duty: 27 Days	

a: Calculated by ECRI from a published percentage

Table 124. Summary of effect of splinting after surgery on return to work

Study	Which Procedure led to Superior Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Finsen, 1999 [319]	No difference	No	Not calculable	Not calculable
Bury, 1995 [364]	No Splint	No	24%	0.55 (-0.39 – 1.49)
Cook, 1995 [432]	No Splint	Yes	Not calculable	Light duty: 0.75 (0.17 – 1.32) Full duty: 0.82 (0.24-1.40)

Figure 42. Effect of splinting after carpal tunnel surgery on return to work



Return to Activities of Daily Living

One study of 50 patients reported on time to return to activities of daily living. The results are presented in Table 125. These results show a statistically significant advantage to not splinting.[432] The effect size is significantly different from zero (d = 1.06, 95%C.I. 0.47 – 1.65).

Table 125. Effect of splinting after surgery on time to return to activities of daily living

Study	Number of Patients	Return to Activities of Daily Living	Statistical Significance of Difference Between Groups
Cook, 1995 [432]	No splint 25 2 week splint 25	Time to return to activities of daily living 6 Days 12 Days	Significantly different by t-test, p = 0.0004.

Pain

Two studies reported on pain. The results are presented in Table 126. Finsen et al. found no statistically significant differences between groups.[319] Cook et al. found statistically significant differences between groups at 2 weeks and 4 weeks. These differences were stated to be no longer significant at 3 and 6 months, but no data were reported. In this study, it is unclear whether the pain described after treatment is pain from carpal tunnel syndrome, pain resulting from surgery, or both. As can be seen in Table 127 and Figure 43, the results of the two studies show opposite trends, and as noted above, it is unclear whether the patients in these two studies are comparable.

Table 126. Effect of splinting after surgery on pain

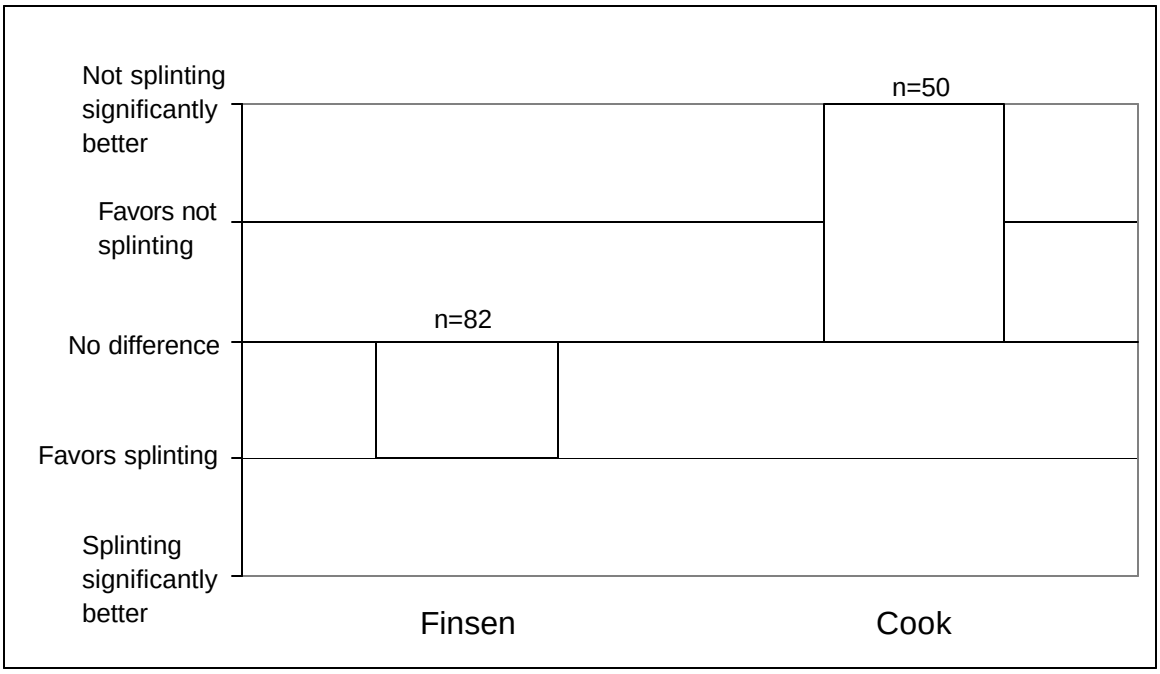
Study	Number of Patients	Pain	Statistical Significance of Difference Between Groups
Finsen, et al., 1999 [319]	No splint 45 Preop 2 Weeks 6 Months 4 week splint 37 Preop 2 Weeks 6 Months	Median VAS (0-100) 56 (Range 46-65) 6 (Range 4-17) 3 (Range 2-8) 51 (Range 38-57) 5 (Range 2-11) 2 (Range 0-4)	Not significantly different (p >0.05; test not reported)
Cook et al., 1995 [432]	No splint 25 14 Days 1 Month 2 week splint 25 14 Days 1 Month	Verbal Scale (1-10) 0.9 0.5 2.4 1.5	Significantly different at both time points (p = 0.001 and 0.01 respectively by t-test)

Table 127. Summary of effect of splinting after surgery on pain

Study	Which Procedure led to Superior Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Finsen, et al., 1999 [319]	Splinting	No	Not calculable	Not calculable
Cook et al., 1995 [432]	No Splint	Yes	Not calculable	14 Days: 0.98 (0.39 – 1.56) 1 Month: 0.75 (0.17 – 1.32)

a: Calculated by ECRI

Figure 43. Summary of effect of splinting after surgery on pain



Harms

All three studies reported harms, but as listed in Table 128, none reported the same harms. Although all reported harms occurred in the unsplinted group, both the numbers of patients and the numbers of harms are too small to demonstrate significant differences between groups. No evidence-based conclusions can be drawn as to whether splinting after surgery prevents complications.

Table 128. Reported harms in studies of splinting after carpal tunnel surgery

Study	Patients per group	Complication	Number reporting
Finsen, 1999 [319]	No splint 45	Superficial Hematoma Wound discharge	1 1
	2 Week splint 36	Superficial Hematoma Wound discharge	0 0
Bury, 1995 [364]	No splint 17	Persistent symptoms requiring reoperation	1
	2 week splint 26	Persistent symptoms requiring reoperation	0
Cook, 1995 [432]	No splint 25	Reported that there were no wound complications or bowstringing tendons	0
	2 week splint 25		

Conclusions

The three studies examining whether there was an advantage to splinting after carpal tunnel surgery have yielded fairly consistent results within each study. Cook, et al found a statistically significant advantage to not splinting for reduced pain, faster return to work and daily activities, and superior global outcome.[432] Bury also found that not splinting led to better global outcome and faster return to work, but neither of these effects was statistically significant.[364] This study lacked the statistical power to detect small (<20%) differences between groups. In contrast, Finsen et al. found a small and statistically nonsignificant trend advantage for the effect of splinting on pain, while times to return to work were the same for both groups. The reasons for the differences between studies is not readily apparent from an examination of the study or patient characteristics. There may be conditions under which splints offer an advantage and conditions under which they do not. Further studies are necessary before a conclusion may be reached.

What are the relative benefits and harms of vitamin B therapy for persons with carpal tunnel syndrome?

One trial of 17 patients examining the effect of vitamin B_6 therapy on carpal tunnel syndrome met exclusion criteria.[459]

Internal Validity

This was a small (n = 15) randomized controlled trial. There was 13% attrition, and compliance was not reported. Study characteristics affecting internal validity are listed in Table 129.

Generalizability

This study did not report patient characteristics except that patients with mild disease were excluded, so no discussion of its generalizability is possible.

Table 129. Internal validity of studies of vitamin B therapy for carpal tunnel syndrome

Study	Number of patients	Number of centers	Funded by a for-profit stakeholder?	Study design	Blinding	Total Patient Attrition (all patient groups)	Intent to treat analysis?	% Compliance
Stransky, 1989 [459]	15	Single	Not reported	RCT	Double	2	No	NR

Table 130. Generalizability of studies of vitamin B therapy for carpal tunnel syndrome

Study	Number of patients	Mean age and range	% Female	Mean Duration (Months) of condition and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Excluded severe disease?	Excluded mild disease?
Stransky, 1989 [459]	15	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	No	Yes

Results

This trial reported a single patient-oriented outcome (global outcome expressed as number of patients improved after treatment). A summary of the effect of vitamin B_6 therapy in this study is shown in Table 131. There was no statistically significant difference in percent of patients improved between-treatment groups. This study had few patients and very low power. Only large (46-48%) differences between groups were would have been statistically significant.

Table 131. Global outcome in patients treated with vitamin B therapy

Study	N (units)	Global outcome - number (%) patients improved	Statistical significance of difference between groups
Stransky et al. 1989 [459]	Vitamin B_6 6 Placebo 5 Untreated Control 4	3 (50) 4 (80) 3 (75)	Vitamin B_6 was not significantly different from placebo or control by chi-square test conducted by ECRI (p = 0.30 and 0.42, respectively)

Table 132. Summary of effect of vitamin B therapy on symptoms of carpal tunnel syndrome

Study	Which Treatment led to Superior Global Outcome?	Was the Difference Stastically Significant?	Power (Minimum percent difference detectable)[a]	Effect Size (95% Confidence Interval)[a]
Stransky et al. 1989 [459]	Placebo	No	Vitamine vs. Placebo 46% Vitamine vs. No treatment 48%	Vitamine vs. Placebo -0.55 (-1.86 – 0.75) Vitamine vs. No treatment -0.42 (-1.76 – 0.91)

[a]: Calculated by ECRI

Conclusions

Although the low power of the study prevents any solid conclusion from being drawn, the trend toward a greater percentage of improved patients in the placebo group does not support the therapeutic effectiveness of Vitamin B_6.

Question #4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with carpal tunnel syndrome?

In addressing this question, we consider whether published literature suggests that there are clinical findings that predict positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 133.

Table 133. Excluded studies

Author	Reason for exclusion
Walker (2000) [34]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Hasegawa (1999) [34]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Olney (1999) [323]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Rosen (1997) [343]	Stratified study that did not examine any correlations that were also examined by at least two other studies
LoMonaco (1996) [358]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Padua (1996) [358]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Wintman (1996) [362]	Stratified study with no clinical finding/outcome comparisons reported by at least three studies
Chang and Dellon (1993) [389]	Stratified study that did not examine any correlations that were also examined by at least two other studies

Evidence base

After these exclusions, there remained 12 studies with a total of 1723 patients.

Study quality

The evaluation of the quality of literature for this question differs from quality evaluations of studies of treatments. This is because, for the present question, the RCT is not necessarily the "gold standard". Case series data, if appropriately analyzed, can also yield valid information. Consequently, the method of data analysis plays a prominent role when considering the quality of the studies relevant to this question.

One valid way to analyze these data is to use multiple regression techniques. These techniques allow construction of a regression equation (or model) consisting of one or more predictor variables. The advantage of multiple regression is that the predictive ability of any given variable is adjusted for any other predictor variables in the equation.

Another valid way to analyze these data involves stratifying patients along some clinical variable. For example, in a stratified study one might compare the outcomes of patients with severe disease to those with mild disease. In a stratified study, the predictive ability of the variable of interest is not adjusted for any other predictor variables. Therefore, the magnitude of a variable's ability to predict future outcomes may be misestimated in stratified studies. For this reason, one can consider the results of stratified studies to be somewhat less reliable than those studies that employed regression techniques. However, an important advantage of stratified studies is that studies that have stratified patients into two groups have more statistical power than studies that used regression analysis.

Another aspect of study quality pertinent to the present question is whether the study was performed prospectively or retrospectively. Patients in retrospective studies may not be representative of the population of patients with carpal tunnel syndrome. This means that the generalizability of the results of retrospective studies is unknown. It also means that the patients in retrospective studies may be more homogeneous than the population of patients with carpal tunnel syndrome. If this were the case, then the magnitude of a clinical finding's ability to predict future outcome would be misestimated. In the extreme case, the artificial homogeneity of patients in a retrospective study could lead to "range restriction". This, in turn, could lead to the inability to detect important predictors of outcome. For these reasons, one can consider the results of prospective studies as stronger than those of retrospective studies.

Table 134 shows relevant quality characteristics of studies that met the inclusion criteria for this question.

Table 134. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Finsen and Russwurm (2001) [224]	Yes	Stratification
Shin (2000) [460]	No	Multiple logistic regression
Straub (1999) [305]	Yes	Stratification
Atroshi (1998) [461]	Yes	Multiple linear regression
Choi and Ahn (1998) [329]	No	Stratification
Katz (1998) [462]	Yes	Multiple logistic regression
Higgs (1997) [341]	No	Stratification
Glowacki (1996) [352]	No	Stratification
Jacobsen and Rahme (1996) [353]	Yes	Multiple regression[a]
Al-Qattan (1994) [375]	No	Stratification
Nathan (1993) [395]	Partly[b]	Multiple regression
Yu (1992) [403]	No	Stratification

aIndependent analysis of individual patient data conducted by ECRI
bPatients entering the study after a certain date were studied prospectively; patients who had treatment prior to that date were studies retrospectively.

Results

Table 135 shows the relationship of specific clinical findings to treatment outcomes in those studies that used regression to identify predictor variables. In the table, clinical variables are indicated by boldface type. There are five such studies with a total of 932 patients. Also presented in this table are non-clinical variables (e.g. age, gender) to show all of the variables used in each multiple regression.

No study that employed regression analysis reported statistically significant correlations between two-point discrimination or grip strength and any outcomes. However, three out of four studies that examined the "predictability" of electrodiagnostic tests reported statistically significant correlations between electrodiagnostic test results and various outcomes. Two of the studies that found a statistically significant relationship were prospective.

The outcomes predicted by electrodiagnostic test results in the three "significant" studies were odds of obtaining disability payment, patient satisfaction with surgery, and number of sick leave days. Odds of obtaining disability payment were higher in patients diagnosed with CTS (mild, moderate, or severe) compared to those with normal electrodiagnostic findings.[460] Another study found patient satisfaction with surgery was lower among patients with a better electrodiagnostic test (distal motor latency) before surgery.[461] Analysis of individual patient data from a third study revealed that number of sick leave days was higher among patients with a pre-surgical electrodiagnostic test indicating slight or intermediate CTS as opposed to pronounced CTS.[353] In the fourth

study, the relationship between electrodiagnostic test results and return to work was not statistically significant.[395] Electrodiagnostic test result was the only variable shown to predict treatment outcome in more than one of the studies that employed multiple regression.

We attempted to confirm the relationship between electrodiagnostic test results and patient outcomes by examining the results of studies that stratified according to the electrodiagnostic test results (Table 136). There were seven such studies, two of which were prospective. All studies evaluated surgical procedures. Six (85.7%) of the studies did not find a statistically significant relationship between electrodiagnostic test results and global outcomes. The remaining study (which was retrospective) found that patients with normal/near normal nerve deficit before treatment had a significantly better global outcome after treatment.

Table 135. Relationship between specific clinical findings and treatment outcomes among patients with Carpal Tunnel Syndrome (Multiple regression analysis)

Author	N	Treatment	Outcomes	Variables examined by at least two studies (significant correlation with outcome?)									Unique study variables
				Age	Gender	Treatment	Hand dominance	Insurance type	Employment status	**Two-point discrimination**[d]	**Electrodiagnostic test**	**Grip strength**	
Shin (2000) [460]	210	Conservative treatments Surgery[a]	Odds of obtaining employment disability	NS	NS	NS	–	–	–	–	Sig	–	Mechanism of injury (NS)
Atroshi (1998) [461]	140	Surgery[b]	Global outcome (patient dissatisfaction)	Sig	NS	–	NS	–	NS	NS	Sig	NS	Vibration exposure (sig), ADL score (NS), **thenar atrophy** (NS), **pinch strength** (NS), **tinel sign** (NS), **phalen sign** (NS)
Katz (1998) [462]	315	Surgery and conservative treatments (not described)	Work absence (18 months after treatment)	NS	NS	NS	–	NS[e]	NS	–	–	NS	Occupation (NS), baseline function (sig), function at 6 months (sig), hired attorney (sig), work absence at enrollment (NS), work absence at 6 months (sig), mental health status (NS), physical and clerical self-reported exposure scales
Jacobsen and Rahme (1996) [353]	29 (32 hands)	Surgery[c]	Number of sick days after surgery	NS	NS	NS	NS	–	–	NS	Sig	–	None
Nathan (1993) [395]	238	Surgery[a]	Return to work	NS	NS	–	NS	Sig	NS	–	NS	–	Laterality (NS), year of study (NS), referral source (NS), incision length (NS), occupational hand use (NS), **diabetes** (NS),

Author	N	Treatment	Outcomes	Variables examined by at least two studies (significant correlation with outcome?)									Unique study variables
				Age	Gender	Treatment	Hand dominance	Insurance type	Employment status	**Two-point discrimination**[d]	**Electrodiagnostic test**	**Grip strength**	
													rheumatoid arthritis (NS), number and density of hand therapy sessions/ week (NS)

aOpen release
bUnilateral endoscopic release
cOpen and endoscopic release
dVariables in boldface represent clinical findings
dIn a related publication, surgical patients alone were analyzed and insurance type significantly correlated with work absence 6 months post-surgery.[302]
NS – Not significant

Table 136. Stratified studies (global outcome)

Study	N	Treatment	Global outcome measure	Stratification variable
				Electrodiagnostic nerve deficit
Finsen and Russworm (2001) [224]	79	Surgery (open release)	VAS for pain and discomfort	NS
Straub (1999) [305]	100	Surgery (endoscopic release)	Satisfactory/unsatisfactory result	NS (but trend toward more success in abnormal sensory/ normal motor nerve conduction group)
Choi and Ahn (1998) [329]	154	Surgery (open release)	Patient satisfaction (poor, fair, good, or excellent)	NS
Higgs (1997)	93	Surgery (open release)	Improved/not improved	Sig (normal/near normal)
Glowacki (1996) [352]	167	Surgery (open release)	Symptoms resolved, improved, or same or worse	NS
Al-Qattan (1994) [375]	112	Surgery (open release)	Satisfactory/poor outcome	NS
Yu (1992) [403]	53	Surgery (open release)	Good/fair/poor result	NS

NS – Not signficant

Conclusions

Studies that searched for relationships between clinical findings and treatment outcomes did so by using multiple regression analysis or stratified patient groups. Among studies that used regression analysis, the only clinical finding variable shown by more than one study to significantly predict treatment outcomes was electrodiagnostic testing. This finding was statistically significant in three of the four studies that examined it. The outcomes predicted by these three studies were patient satisfaction with surgery, odds of obtaining disability payment, and number of sick days after surgery. Odds of obtaining disability payment were higher in patients diagnosed with CTS (mild, moderate, or severe) compared to those with normal electrodiagnostic findings. Another study found patient satisfaction with surgery was lower among patients with a better electrodiagnostic test results (distal motor latency) before surgery. Analysis of individual patient data from a third study revealed that number of sick leave days was higher among patients with a pre-surgical electrodiagnostic test indicating slight or intermediate CTS as opposed to pronounced CTS. The fourth study of electrodiagnostic tests found no statistically significant relationship between electrodiagnostic test results and return to work. This apparent lack of consistency of results could indicate that, although the relationship between electrodiagnostic tests and treatment outcomes is statistically significant, it may not be substantial. The possibility that this relationship is small is supported by the results of stratified studies that examined the relationship between electrodiagnostic test results and global outcomes. Six of seven studies did not find a statistically significant relationship.

Question #5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with carpal tunnel syndrome?

In addressing this question, we consider whether published literature suggests that duration of symptoms predicts positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different duration of symptoms.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 137.

Table 137. Excluded studies

Author	Reason for exclusion
Wintman (1996) [362]	Stratified study with no duration of symptoms/outcome comparisons reported by at least three studies

Evidence base

After this exclusion, there remained six studies with 984 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4. One prospective study and one retrospective study conducted a multiple regression analysis, while four studies performed stratifications
(Table 138). Only one of the four stratified studies was prospective in design.

Table 138. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Straub (1999) [305]	Yes	Stratification
Atroshi (1998) [461]	Yes	Multiple linear regression
Choi and Ahn (1998) [329]	No	Stratification
DeStefano (1997) [463]	No	Multivariable proportional hazards regression
Al-Qattan (1994) [375]	No	Stratification
Yu (1992) [403]	No	Stratification

Results

Table 139 shows the relationship between duration of symptoms and treatment outcomes in the only study that used regression to adjust for the effects of other predictor variables. All other variables used in this regression are also presented in the table. Atroshi et al. (1998) found that duration of symptoms was not a statistically significant predictor of patient dissatisfaction at three or six months following surgery.[461] The range of duration of symptoms was not reported in this study. DeStefano et al. (1997) found that duration of symptoms was a statistically significant predictor of symptom resolution among surgical patients (symptom duration <3 years correlated with greater likelihood of symptom resolution) but not among non-surgical patients.[463] They did not report the specific range of duration of symptoms, except that it ranged from <2 months to >3 years.

We searched further for a relationship between duration of symptoms and patient outcomes by examining the results of studies that stratified according to duration of symptoms (Table 140). There were four such studies, one of which was prospective. All studies evaluated the effects of surgical procedures, and all contained patients with a duration of symptoms ranging from weeks to years. Three out of four studies found no statistically significant relationship between duration of symptoms and global outcomes. The fourth study found a statistically significant correlation between shorter duration of symptoms and improved global outcome.

Table 139. Relationship between duration of symptoms and treatment outcomes among patients with Carpal Tunnel Syndrome.

Author	N	Treatment	Outcomes	Duration of symptoms – significance (duration associated with better outcome)	Other variables examined
Atroshi (1998) [461]	140	Surgery (unilateral endoscopic release)	Global outcome (patient dissatisfaction)	NS	Age (sig), sex (NS), hand dominance (NS), unemployment (NS), vibration exposure (sig), ADL score (NS), DML (sig), surgeon (NS), subjective weakness (NS), type of work (NS), type of symptoms (NS), Tinel sign (NS), Phalen's test results (NS), thenar atrophy (NS), two-point discrimination (NS), grip strength (NS), pinch strength (NS)
DeStefano (1997) [463]	425	Non-surgical (oral meds, oral steroids, steroid injections, splints) Surgical (carpal tunnel release)	Global outcome (symptom resolution)	NS (non-surgical patients) Sig (surgical patients, <3 years)	Age (NS), sex (NS), carpal tunnel syndrome category (NS), hand involved (NS), arthritis (NS), pregnancy (NS), injury (NS), diabetes or hypothyroidism (sig for surgical patients)

Table 140. Stratified studies (global outcome)

Study	N	Treatment	Global outcome measure	Duration of symptoms – significance (duration associated with better outcome)
Straub (1999) [305]	100	Surgery (endoscopic release)	Satisfactory/unsatisfactory result	NS
Choi and Ahn (1998) [329]	154	Surgery (open release)	Patient satisfaction (poor, fair, good, or excellent)	Sig (shorter duration, <3 months)
Al-Qattan (1994) [375]	112	Surgery (open release)	Satisfactory/poor outcome	NS
Yu (1992) [403]	53	Surgery (open release)	Good/fair/poor result	NS, but trend toward more success in ≥6 month group

NS – Not signficant

Conclusions

The majority of available evidence is less than optimal because it consists primarily of retrospective studies. The highest quality study (prospective with multiple regression analysis) suggested that there was no statistically significant correlation between duration of symptoms and global outcome after surgery. One prospective and two retrospective stratified studies found similar results. Two retrospective studies (one performing multiple regressions, one stratified) found a statistically significant relationship between shorter duration of symptoms and symptom resolution or patient satisfaction after surgery. The retrospective nature of these trials could have created bias that influenced these findings. An additional high quality prospective study is needed before firm conclusions can be reached.

Question #6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with carpal tunnel syndrome?

In addressing this question, we consider whether published literature suggests that there are demographic variables that predict positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment demographic characteristics.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 141.

Table 141. Excluded studies

Author	Reason for exclusion
Walker (2000) [34]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Braun (1999) [316]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Hasegawa (1999) [34]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Higgs (1997) [341]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Rosen (1997) [343]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Padua (1996) [358]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Wintman (1996) [362]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Nancollas (1995) [464]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Chang and Dellon (1993) [389]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies
Feinstein (1993) [390]	Data presentation did not allow determination of correlation
Hagberg (1991) [308]	Stratified study with no demographic variables/outcome comparisons reported by at least three studies

Evidence base

After these exclusions, there remained 22 studies with a total of 3616 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4 of our section on carpal tunnel syndrome. Table 142 shows the 22 included studies and the relevant study design and quality characteristics. Six studies used multiple regression and 16 used stratifications to identify correlations between demographic variables and treatment outcomes. Of the six studies utilizing regression, three were prospective, one was partially prospective, and two were retrospective. Of the 16 stratified studies, eight were prospective.

Table 142. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Shin (2000) [460]	No	Multiple logistic regression
Olney (1999) [323]	No	Stratification
Straub (1999) [305]	Yes	Stratification
Atroshi (1998) [461]	Yes	Multiple linear regression
Davies (1998) [330]	No	Stratification
Katz (1998) [462]	Yes	Multiple logistic regression
DeStefano (1997) [463]	No	Multivariable proportional hazards regression
Elmaraghy and Hurst (1996) [349]	Yes	Stratification
Glowacki (1996) [352]	No	Stratification
Jacobsen and Rahme (1996) [353]	Yes	Multiple regression
Lee and Jackson (1996) [355]	No	Stratification
Nagle (1996) [357]	Yes	Stratification
Strickland (1996) [361]	No	Stratification
Wintman (1996) [362]	Yes	Stratification
Hallock and Lutz (1995) [368]	Yes	Stratification
Mirza (1995) [371]	Unknown	Stratification
Al-Qattan (1994) [375]	No	Stratification
Roth (1994) [383]	Yes	Stratification
Nathan (1993) [395]	Partly[a]	Multiple regression
Palmer (1993) [397]	Yes	Stratification
Agee (1992) [46]	Yes	Stratification
Yu (1992) [403]	No	Stratification

WC – Workers' compensation

bPatients entering the study after a certain date were studied prospectively; patients who had treatment prior to that date were studies retrospectively

Results

Table 143 shows the relationship of specific demographic variables to treatment outcomes in those studies that used regression to identify predictor variables (demographic variables are shown in bold type). There are six such studies with a total of 1357 patients. Also presented in this table are non-demographic variables (e.g. grip strength) to show all of the variables used in each multiple regression.

Gender, employment status, and hand dominance did not correlate significantly with any treatment outcomes in any of these studies. Two studies found that insurance type (workers' compensation vs non-workers' compensation) correlated significantly with treatment outcomes (work absence and return to work) after surgical treatment.[302,395] One of these studies was a subgroup analysis derived from a larger study that analyzed surgical and non-surgical patients together.[462] When data from these patients were combined, the correlation between insurance type and treatment outcome was not statistically significant. Although one out of five studies found age to be significantly correlated with patient satisfaction,[461] the reported odds ratio was close to 1. Two studies evaluated diabetes as a potential predictor variable. One retrospective study found it to have a statistically significant relationship with symptom resolution, but only among surgical patients.[463] The other study (partly retrospective, partly prospective) found no statistically significant relationship between diabetes and return to work among surgical patients.[395]

Table 144 and Table 145 summarize the results of studies that conducted stratification and outcome comparisons (e.g. stratification by age, evaluated by patient satisfaction) that were reported by at least three studies. The only two outcomes reported by at least three studies were global outcome (Table 144) and return to work (Table 144), and the only stratifications reported by at least three studies were insurance type and job category. All of these studies evaluated the effectiveness of various surgical procedures.

Of the four stratified studies that attempted to correlate workers' compensation status with global outcomes, three found that non-workers' compensation patients had significantly better global outcomes after treatment.[330,352,375] These were the three largest studies that examined this relationship, but all were retrospective. The remaining study, which was prospective but slightly smaller, found a non-significant trend toward a better global outcome in the non-workers' compensation group.[305] Of three studies that attempted to correlate job category with global outcomes, two (one of which was prospective) found that patients with jobs that were not physically strenuous had significantly better global outcomes after treatment.[375,403] The remaining study found no statistically significant difference among job categories as measured by global outcome.[305]

Of studies that examined return to work as an outcome measure, 11 studies stratified patients by workers' compensation status, and 10 (six of which were prospective) found a significantly quicker return to work after treatment in the non-workers' compensation group. The remaining study showed a significantly quicker return to work among non-workers' compensation patients only in the subgroup of manual workers.[361]

Table 143. Relationship between demographic factors and treatment outcomes among patients with Carpal Tunnel Syndrome (multiple regression analysis)

Author	N	Treatment	Outcomes	Variables examined by at least two studies (significant correlation with outcome?)									Unique study variables
				Age[d]	Gender	Treatment	Hand dominance	Insurance type	Employment status	Two-point discrimination	Electrodiagnostic test	Grip strength	
Shin (2000) [460]	210	Conservative treatments Surgery[a]	Odds of obtaining employment disability	NS	NS	NS	–	–	–	–	Sig	–	Mechanism of injury (NS)
Atroshi (1998) [461]	140	Surgery[b]	Global outcome (patient dissatisfaction)	Sig	NS	–	NS	–	NS	NS	Sig	NS	**Vibration exposure** (sig), ADL score (NS), thenar atrophy (NS), pinch strength (NS), tinel sign (NS), phalen sign (NS)
Katz (1998) [462] [302]	315	Surgery and conservative treatments (not described)	Work absence (18 months after treatment)	NS	NS	NS	–	NS (all patients)[e] Sig (surgery patients)	NS	NS	–	NS	**Occupation** (NS), **baseline function** (sig), function at 6 months (sig), **hired attorney** (sig), work absence at enrollment (NS), work absence at 6 months (sig), mental health status (NS), physical and clerical self-reported exposure scales
DeStefano (1997) [463]	425	Conservative treatments Surgery (carpal tunnel release)	Global outcome (symptom resolution)	NS	NS	Sig	NS	–	–	Sig (surgical patients only)	–	–	–

Author	N	Treatment	Outcomes	Variables examined by at least two studies (significant correlation with outcome?)									Unique study variables
				Age[d]	**Gender**	**Treatment**	**Hand dominance**	**Insurance type**	**Employment status**	Two-point discrimination	Electrodiagnostic test	Grip strength	
Jacobsen[e] and Rahme (1996) [353]	29 (32 hands)	Surgery[c]	Number of sick days after surgery	NS	NS	NS	NS	–	–	NS	Sig	–	None
Nathan (1993) [395]	238	Surgery[a]	Return to work	NS	NS	–	NS	Sig	NS	–	NS	–	**Laterality** (NS), **year of study** (NS), **referral source** (NS), **incision length** (NS), **occupational hand use** (NS), diabetes (NS), rheumatoid arthritis (NS), number and density of hand therapy sessions/ week (NS)

aOpen release
bUnilateral endoscopic release
cOpen and endoscopic release
dVariables in boldface represent demographic characteristics
eIn a related publication, surgical patients alone were analyzed and insurance type significantly correlated with work absence 6 months postsurgery.[302]
eMultiple regression performed independently by ECRI from individual patient data presented in this study
NS – Not significant

Table 144. Stratified studies (global outcome)

Study	N	Treatment	Global outcome measure	Stratification variable	
				Workers' compensation (WC) status	Job category
Straub (1999) [305]	100	Surgery (endoscopic release)	Satisfactory/unsatisfactory result	NS (but trend toward more success in non-WC group)	NS
Davies (1998) [330]	239	Surgery (endoscopic release)	Patient satisfaction/dissatisfaction	Sig (non-WC)	–
Glowacki (1996) [352]	167	Surgery (open release)	Symptoms resolved, improved, or same or worse	Sig (non-WC)	–
Al-Qattan (1994) [375]	112	Surgery (open release)	Satisfactory/poor outcome	Sig (non-WC)	Sig (not physically strenuous)
Yu (1992) [403]	53	Surgery (open release)	Good/fair/poor result	–	Sig (not physically strenuous)

NS – Not significant

Table 145. Stratified studies (return to work)

Study	N	Treatment	Stratification variable
			Workers' compensation (WC) status
Olney (1999) [323]	211	Surgery (open or endoscopic release)	Sig (non-WC and non-contested WC)
Davies (1998) [330]	239	Surgery (endoscopic release)	Sig (non-WC)
Elmaraghy and Hurst (1996) [349]	75	Surgery (endoscopic release)	Sig (non-WC)
Lee and Jackson (1996) [355]	237	Surgery (limited incision release using carposcope)	Sig (non-WC)
Nagle (1996) [357]	291	Surgery (endoscopic release)	Sig (non-WC)
Strickland (1996) [361]	62	Surgery (hypothenar fat pad flap for patients who received unsuccessful open release)	NS, except for manual labor subgroup (non-WC)
Hallock and Lutz (1995) [368]	96	Surgery (open or endoscopic release)	Sig (non-WC)
Mirza (1995) [371]	236	Surgery (endoscopic release)	Sig (non-WC)
Roth (1994) [383]	95	Surgery (endoscopic release)	Sig (non-WC)
Palmer (1993) [397]	163	Surgery (open or endoscopic release)	Sig (non-WC)

Study	N	Treatment	Stratification variable
			Workers' compensation (WC) status
Agee (1992) [46]	122	Surgery (open or endoscopic release)	Sig (non-WC)

NS – Not significant

Conclusions

The available evidence suggests that patients who are not receiving workers' compensation tend to return to work faster than those receiving such compensation. This is suggested by one of two "multiple regression" studies of this relationship and by a combination of 10 prospective and retrospective stratified studies. Some evidence also suggests that patients who are not receiving workers' compensation have better global outcomes, but this evidence is derived exclusively from retrospective studies. Therefore, these latter findings require confirmation. In any event, one cannot ascribe causal relationships to these correlations.

Available evidence suggests that there is no strong relationship between gender, employment status, or hand dominance and return to work or global outcomes. There is insufficient evidence to arrive at a firm evidence-based conclusion on the relationship between type of work, diabetes, or age and patient outcomes.

Question #7: What are the surgical and nonsurgical costs or charges for treatment of carpal tunnel syndrome?

According to the Medicare Provider Analysis and Review (MEDPAR) database, which covers hospital inpatient services, average total charges per patient for the DRG (diagnosis-related group) of carpal tunnel release are $8,185.24 (calculated by dividing total charges by number of discharges). This DRG includes open and endoscopic release. The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for endoscopic release of the transverse carpal ligament is $849.84 (cost of open release was not reported by this database). The reported median cost for application of a short arm static splint is $72.69.

Question #8: For persons who have had surgery for carpal tunnel syndrome, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

This question distinguishes symptom recurrence from continued symptoms after treatment. The latter may be caused by incomplete sectioning of the transverse carpal ligament, damage to the median nerve during the operation, initial misdiagnosis of carpal tunnel syndrome, or the presence of additional compressive nerve injuries.[465-467] Recurrence of carpal tunnel syndrome after initial relief of symptoms may be caused by compression of the medial nerve due to fibrosis, hematoma, neuroma, scarring, or re-injury.[465,466,468]

Techniques that have been recommended to prevent recurrence include changing work habits, use of ergonomic equipment, and other forms of occupational therapy.[469] Careful surgical technique to prevent excessive scarring,[468] and physical therapy to prevent formation of adhesions may also have some utility.[32,466] However, no controlled trials have been published that report on the efficacy or effectiveness of any technique for the prevention of recurrence of carpal tunnel syndrome. Controlled trials are necessary so that incidence of recurrence among patients for whom measures have been taken to prevent recurrence may be compared with recurrence among patients for whom no such measures have been taken, drawn from the same population. Controls enable one to distinguish treatment effects from effects due to population differences, changes in behavior, and/or medications (including over-the-counter drugs, and other, unknown factors that may influence recurrence rates. In the absence of controlled trials, no analysis may be performed and no evidence-based conclusions may be drawn.

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with carpal tunnel syndrome?

Instruments have been developed that allow patients to self-report their degree of functional impairment. Self-administered questionnaires require few personnel to adminster and are a low-cost way to collect information, especially of data for which the patient's self-report is the only possible source. However, such instruments tend to suffer from certain biases caused by basic human psychological tendencies. These biases are listed in Table 146. The effect of these biases on the results of assessment instruments can be reduced by careful instrument design, but never completely eliminated. Because these biases can distort the results of assessment instruments, each assessment instrument must be evaluated as to its usefulness and accuracy.

Evaluating the usefulness and accuracy of functional assessment instruments is difficult because there is no "gold standard" against which to compare the results. However, these instruments can be evaluated according to three key components: internal reliability, test-retest reliability, and validity of results. If there is a treatment available for the disorder causing the functional impairment, instruments are also evaluated as to their ability to respond to changes in function caused by treatment.[470]

Internal reliability, or internal consistency, refers to the degree to which scores on subsections of the test correlate with scores from other subsections. For example, if a subject has significant functional impairment in the use of the hands, it is likely that the subject will score as impaired on questions about both work activities and home activities.

Test-retest reliability means that the score of a test depends solely on the impairments of the individual taking the test, not on factors such as the time of day the test is administered, or who is administering the test. Test-retest reliability is usually measured by having the subject take the test several times under different conditions.

Evaluating the validity of an assessment instrument can be difficult. Content validity, which refers to whether the test questions reflect the functions required to perform the task(s) in question, is largely a theoretical concept and cannot be directly measured.[89] Concurrent validity refers to the way a test's scores correlate with other measurements of what the test is purported to assess.[89] However, findings on clinical examinations often do not correlate well with functional impairment and thus can be problematic when used to validate functional assessment instruments.[471-473] Predictive validity refers to a test's ability to reflect future performance, i.e., if a subject's scores predict little functional impairment and the subject soon returns to full work, the test may be said to have predictive validity.[89]

We define an instrument that can accurately assess functional limitations in an individual with carpal tunnel syndrome as one that has been shown to have: test-retest reliability, internal reliability, concurrent validity, predictive validity, and responds to treatment.

Table 146. Potential biases in assessment instruments[a]

Bias	Definition
Yea-saying	The tendency to always agree with yes-no questions.
End aversion	The tendency to use middle values rather than the end points of analog scales
Question framing	The tendency for the wording of a question to affect the response.
Motivation to seem better	Patients want to subconsciously please their health-care providers by responding to treatment and are embarrassed to complain about problems.
Motivation to seem worse	Can occur if patients will lose services or benefits if they improve.
Response shifts	The tendency of patients to modify their internal standards of evaluation so that their current level of functioning is seen as normal.
Memory failure	Difficulty in remembering past function may influence assessment of current function.
Leading the patient	The tendency of the questionnaire itself to change the way the patient assesses functioning.

a Adapted from Gotay 1996[474]

Evidence base

Eight studies met the inclusion criteria (see the section Inclusion Criteria). They are listed in Table 147. The functional assessment instruments evaluated by the studies that met the inclusion criteria are listed in Table 148.

Table 147. Trials of functional assessment instruments that met the inclusion criteria

Study	Instruments evaluated[a]	N subjects	Outcome measurements
Vaile 1999 [475]	NHP, SF-36, mSHAQ, V-VAS	27	Response to treatment
Alderson 1999 [315]	AMHFQ	26	Validity Test-retest reliability
Atroshi 1998 [326]	SF-36 and CTS-I	102	Test-test comparison Test-retest reliability Response to treatment
Pransky 1997 [476]	UEF	165	Validity Test-test comparison
Atroshi 1997 [477]	SF-36 and CTS-I	277	Validity
Katz 1994 [377]	Global score	104	Validity
Katz 1994 [303]	CTS-I and K-ADL	74	Response to treatment
Levine 1993 [393]	CTS-I	67	Validity Test-retest reliability Response to treatment

a The full names of the instruments and descriptions of the instruments are given in

.

Table 148. Instruments evaluated to measure functional limitations associated with carpal tunnel syndrome

Instrument	Abbreviation	First described by	Scoring system	Subjects covered	Extent of use[a]
Alderson-McGall Hand Function Questionnaire	AMHFQ	Alderson and McGall 1999[318]	Functional difficulty categories	Common tasks performed with the hands	Not widely used
Calculated Global Score	Global Score	Katz 1994[377]	VAS	Grip strength, numbness, pain, parethesia	Not widely used
Carpal Tunnel Syndrome Instrument	CTS-I	Levine 1993[393]	Functional difficulty categories/ symptom severity categories	Eight ADL, and severity of symptoms	Widely used
Katz Activities of Daily Living	K-ADL	Katz 1994[303]	Functional difficulty categories	Ten ADL	Not widely used
Medical Outcomes Study 36-Item Short-Form Health Survey	SF-36	Ware 1992[478]	Categories	Impact of health on physical activities, social activities, activities of daily living, pain, psychological distress, emotional health, and energy	Extensively used
Modified Stanford Health Assessment Questionnaire	mSHAQ	[479]	Categories	ADL	Widely used
Nottingham Health Profile	NHP	Hunt 1985[480]	Categories	Pain, energy, emotional reactions, sleep problems, social isolation, physical mobility, employment, hobbies, sex life, personal relationships, and holiday	Widely used
Upper Extremity Function Scale	UEF	Pransky 1997[476]	Functional difficulty categories	Eight ADL	Not widely used
Vaile Visual Analog Scales	V-VAS	Vaile 1999[475]	VAS	Impact of CTS on well being, discomfort, activities	Not widely used

[a]Extent of use was determined by searching Medline for manuscripts that used the assessment instrument. Not widely used = 3 or fewer studies. Widely used= four to ten studies. Extensively used= more than ten studies.

Study quality

Internal validity

Studies evaluating instruments need not include a separate control group, because each patient acts as his/her own control. The patient's score on the assessment instrument can be directly compared to the patient's score on the parameter against which the test is being measured. All of the studies included in this section are single-arm prospective cohort studies. Factors relating to the quality of the studies are shown in Table 149. Five of the eight studies administered and scored the instruments with evaluators who were blinded to the identity, history, and other test scores of the patients. Studies that did not use blinded evaluators may have been subject to bias.

Table 149. Details of study design

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Vaile 1999 [475]	27	2	NR	Cohort	Yes	No	0	Yes	NA
Alderson 1999 [315]	26	1	NR	Cohort	Yes	Rater	34	No	NA
Atroshi 1998 [326]	102	1	No	Cohort	Yes	Rater	0	Yes	NA
Pransky 1997 [476]	165	1	No	Cohort	Yes	No	44.8	No	NA
Atroshi 1997 [477]	277	3	No	Cohort	Yes	No	23.4	No	NA
Katz 1994 [377]	104	4	No	Cohort	Yes	Rater	0	Yes	NA
Katz 1994 [303]	74	4	NR	Cohort	Yes	Rater	NR	No	NA
Levine 1993 [393]	67	2	No	Cohort	Yes	Rater	0	No	NA

Generalizability

It is important for studies that evaluate assessment instruments to enroll patients who are representative of the population of interest. Information about patients enrolled in the studies addressing this question are shown in Table 150. All eight studies recruited populations that appear to be "typical" of patients presenting with carpal tunnel syndrome as has been established by epidemiology studies (See the Introduction). The patient groups are predominantly female and middle aged. Few of the studies reported on the presence of co-morbid conditions that may have contributed to functional limitations. The occupations and employment status of the patients are shown in Table 151. The two studies by Katz recuited patients from the same large randomized controlled trial, a trial that was comparing different methods of surgically treating carpal tunnel syndrome.

Table 150. Study generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of conditon mean and range months	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditons	% Patients with peripheral neruopathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Vaile 1999 [475]	27	57 (29-84)	81.4	NR	NR	55.5	NR	NR	NR	NR	NR	No	No
Alderson 1999 [315]	26	44.4 (22-79)	70.5	(3-48)	NR	0	NR	NR	NR	NR	NR	No	No
Atroshi 1998 [326]	102	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pransky 1997 [476]	165	46 (19-65)	67	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Atroshi 1997 [477]	277	46.6 (13-91)	77.8	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Katz 1994 [377]	104	55 (25-87)	70	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Katz 1994 [303]	74	55 (25-87)	70	NR	NR	0	NR	0	0	0	NR	No	No
Levine 1993 [393]	67	57 (19-88)	75	18 (3-58)	NR	NR	NR	NR	NR	NR	NR	NR	No

Table 151. Generalizability: employment status and occupations

Study	Number of patients	% Patients employed	% Patients on Workers Compensation	% Patients retired	% Patients homemakers	Reported Occupations
Vaile 1999 [475]	27	NR	0	NR	NR	NR
Alderson 1999 [315]	26	NR	35	NR	5.6%	Business-17.6% Sciences-5.9% Health-11.8% Education-5.9% Recreation-5.9% Sales-11.8% Trades and Transport-5.9% Industry-5.9% Manufacturing-23.5%
Atroshi 1998 [326]	102	NR	NR	NR	NR	NR
Pransky 1997 [476]	165	89	10	NR	NR	NR
Atroshi 1997 [477]	277	NR	28.8	NR	NR	NR
Katz 1994 [377]	104	NR	8	NR	NR	NR
Katz 1994 [303]	74	NR	8	NR	NR	NR
Levine 1993 [393]	67	NR	13	NR	NR	NR

Results

Test-retest reliability

Two studies have reported that two tests, the CTS-I and the AMFHQ, give similar results when administered twice to the same subject. The correlation coefficients describing the test-retest reliability are shown in Table 152.

Table 152. Results of test-retest reliability tests

Study	Number of patients	Tests evaluated	Time between test administrations	Type of statistical comparison being made	Was the instrument reliable?
Alderson 1999 [315]	26	AMFHQ	NR	Intraclass correlation coefficient Reported to be consistent	Yes
Atroshi 1998 [326]	22	CTS-I	24 hours	Correlation coefficient r = 0.71	Yes
Levine 1993 [393]	67	CTS-I	24 hours	Pearson's correlation coefficient r = 0.93	Yes

Internal reliability

None of the studies reported on this aspect of instrument evaluation.

Response to treatment

Four studies have reported the ability of six different assessment instruments to respond to changes in subjects treated for carpal tunnel syndrome. For the purposes of answering this question, studies that analyzed the test scores of patients who were successfully treated separately from those patients who failed treatment are superior. If the test scores of patients who failed treatment are included with those who were successfully treated, the results will be biased towards finding that the assessment instrument cannot detect a response to treatment. None of the studies separately analyzed data from successfully treated patients and data from unsuccessfully treated patients. The studies by Vaile 1999 and Katz 1995 included only patients who had been successfully treated. The results of the response to treatment evaluations are summarized in Table 153.

Because there are three or fewer studies evaluating each test, we did not perform a meta-analysis. We scored an instrument as being responsive to treatment if there was a statistically significant difference in the effect sizes determined from the pre-treatment and post-treatment scores. By this criterion, the mSHAQ and NHP were not responsive to treatment, while the V-VAS and the K-ADL were responsive to treatment. Three studies evaluated the CTS-I; all three found the instrument to be responsive to treatment. Two studies reported that the SF-36 was not responsive to treatment.

In summary, the more general instruments were not found to be responsive to treatment for carpal tunnel syndrome (NHP, SF-36, mSHAQ). Instruments designed to evaluate carpal tunnel syndrome were found to respond to treatment for carpal tunnel syndrome (CTS-I, K-ADL, V-VAS).

Table 153. Results of response to treatment tests

Study	Number of patients	Test evaluated	Treatment	Time of testing months	Effect size hedges' d (95% CI)[a]	Was the instrument responsive to treatment?
Vaile 1999 [475]	27	mSHAQ	Injection of corticosteroids	0 1	0.31 (-0.23 to 0.85)	No
		SF-36	Injection of corticosteroids	0 1	-0.29 (-0.82 to 0.24)	No
		NHP	Injection of corticosteroids	0 1	0.38 (-0.16 to 0.91)	No
		V-VAS	Injection of corticosteroids	0 1	1.58 (0.97 to 2.19)	Yes
Atroshi 1998 [326]	102	CTS-I	Carpal tunnel release surgery	0 3	0.78 (0.50 to 1.07)	Yes
	48	SF-36	Carpal tunnel release surgery	0 3	-0.052 (-0.45 to 0.35)	No
Katz 1994 [303]	43	CTS-I	Carpal tunnel release surgery	0 3	1.08 (0.63 to 1.53)	Yes
	55	K-ADL	Carpal tunnel release surgery	0 3	1.32 (0.91 to 1.73)	Yes
Levine 1993 [393]	38	CTS-I	Carpal tunnel release surgery	0 14 mean	0.97 (0.50 to 1.45)	Yes

a calculated by ECRI

Validity

The validity tests performed on the instruments evaluated are summarized in Table 154. The validity tests can be separated into two groups: those measuring predicitive validity, and those measuring concurrent validity.

Predictive validity

Atroshi 1997 compared the test scores of those receiving Workers' Compensation to the scores of those not receiving Workers' Compensation. Atroshi 1997 found no statistically significant differences between the two groups in their scores on either the SF-36 or the CTS-I. Workers' Compensation is paid to only those with injuries so severe that they cannot work. Thus, the results of this study suggest that either the SF-36 and the CTS-I are not valid tests for functional limitations, or that Workers' Compensation is not a valid measure of the severity of functional limitations. Due to a lack of reported data, we were unable to verify that the study by Atroshi 1997 had sufficient statistical power to be able to detect a statistical significance between the two groups if one had existed.

Pransky 1997 compared test scores on the UEF of those working and those not working. However, instead of calculating the correlation between the individual scores and work status, Pransky 1997 compared the mean scores of the two groups of patients. There was a statistically significant difference between the means of the two groups for both a mixed population of upper extremity disorders and a population with carpal tunnel syndrome. Comparing the means suggests that the UEF can discriminate between subjects who are working and not working, but provides little information as to whether an individual score on the test can be used to predict an individual's ability to work.

Katz 1994 tested individuals shortly after surgery for carpal tunnel syndrome and found a statistically significant correlation between the Global Score and time to return to work for those treated with open tunnel release surgery, but not for those treated with endoscopic tunnel release surgery. This finding can be explained by the fact that one of the measurements that contributes to the Global Score is the amount of pain the individual experiences at the site of surgery. Thus it is likely that the Global Score is not a particularly valid measurement of functional limitations related to the WRUEDs.

In summary, none of the instruments have been reported to have predictive validity as measured by the ability to work. None of the instruments were evaluated as to predictive validity as measured by the ability to perform activities of daily living.

Concurrent validity

The clinical examination results used to validate the instruments consist of measurements of hand grip strength, and measurements of hand sensory function or nerve conduction speed. One study per test has reported a weak correlation (see Table 154 for the values of the correlation coefficients) between scores on the AMHFQ, the UEF, and the CTS-I and hand grip strength. This suggests that all three tests may have concurrent validity as measured by hand grip strength.

Alderson 1999 reported no statistically significant correlation between scores on the AMHFQ and measurements of hand sensory capability. Levine 1993 reported a weak correlation between hand sensory capability and scores on the CTS-I. Pransky 1997 and Levine 1993 reported no statistically significant correlation between nerve conduction speed tests and scores on the UEF and CTS-I. These results indicate that the instruments cannot be used to predict sensory/nerve function.

In summary, the AMHFQ, the UEF, and the CTS-I may all be concurrently valid as measured by hand grip strength, but not of hand sensory ability.

Table 154. Results of validity tests

Study	Number of patients	Test evaluated	Type of statistical comparison being made	Validated against	Was the instrument valid by this measurement?
Alderson 1999 [315]	26	AMHFQ	Pearson's correlation coefficient	pinch strength r = 0.295	Yes, but the r value is low
				grip strength r = 0.3867	Yes, but the r value is low
				two-point discrimination r = -0.127	No
Atroshi 1997 [477]	102	SF-36	ANOVA	On workers comp. vs. not on workers comp. p = 0.5	No
		CTS-I	ANOVA	On workers comp. vs. not on workers comp p = 0.07	No
Pransky 1997 [476]	165	UEF	Difference between two means with t-test	working vs. not working p <0.001	Yes
				normal Phalen's test vs. abnormal Phalen's test p <0.05	Yes
			Pearson's correlation coefficient	nerve conduction speed test p >0.05	No
				pinch strength p <0.001	Yes
				grip strength p <0.001	Yes
Katz 1994 [377]	104	Global score	Pearson's correlation coefficient	time to return to work- treated with open release surgery r = 0.67	Yes
				time to return to work- treated with endoscopic release surgery r = 0.2	Yes, but the r value is low
Levine 1993 [393]	67	CTS-I	Spearmann's correlation coefficient	Semmes-Weinstein monofilament testing r = 0.24	Yes, but the r value is low
				two-point discrimination test r = 0.42	Yes
				pinch strength r = 0.60	Yes
				grip strength r = 0.50	Yes
				median nerve sensory conduction velocity r = 0.12	No

Test-test comparisons

One study compared the scores of the same patients on different tests (Table 155). Atroshi 1998 compared the CTS-I and the SF-36 tests on patients with carpal tunnel syndrome. Before treatment of the carpal tunnel syndrome, the test scores correlated fairly well, but the correlation dropped after treatment. This change may be attributed to the finding, discussed previously, that the CTS-I instrument is responsive to treatment while the SF-36 is not.

Table 155. Results of test-test comparisons

Study	Tests being compared	Type of statistical comparison being made	Value of comparison r	Were the tests consistent?
Atroshi 1998 [326]	CTS-I and SF-36, pre-treatment	Spearmann's correlation coefficient	0.62	Yes
	CTS-I and SF-36, post-treatment	Spearmann's correlation coefficient	0.56	Yes

Conclusion

Eight studies evaluated the ability of nine different instruments as ways to measure functional limitations of patients with carpal tunnel syndrome. Of the available instruments, only two were evaluated by more than one trial. The two instruments that were evaluated by three and four trials, respectively, were the SF-36 and the Levine CTS-I.

It can be tentatively concluded that the SF-36 is not a useful instrument for assessing functional limitations in individuals with carpal tunnel syndrome. The SF-36 was reported to not be responsive to treatment and to not be able to predict ability to work.

It can be tentatively concluded that the Levine CTS-I may be a useful instrument for assessing functional limitations in individuals with carpal tunnel syndrome. This instrument was reported to be responsive to treatment, and to have concurrent validity as measured by grip and pinch strength. However, the Levine CTS-I was not evaluated by the studies included in the answer to this question for internal reliability, or prediction of the ability to perform activities of daily living. In addition, the Levine CTS-I has been reported by one study to not be able to predict ability to work.

It is difficult to reach an evidence-based conclusion as to the usefulness of the other instruments evaluated in this report due to the limited evidence base.

Question #10: What are the functional limitations for an individual with carpal tunnel syndrome before treatment?

This question inquires about the functional limitations of an individual before they have received conservative or surgical treatment for carpal tunnel syndrome. In addressing it, our objective is to catalogue these limitations, and not to address the effectiveness of these treatments. We address the effectiveness of conservative and surgical treatments in Question 3.

The available literature governs our approach to the present question. Hence, we address functional status rather than functional limitations, because no published studies specifically addressed the latter. In addition, the only available data operationally defines functional status in terms of scores on certain written tests. Hence, we also address functional status in these terms. The validity and reliability of these written tests is discussed in Question 9. Study inclusion criteria are described under Methods (section).

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 156.

Table 156. Excluded studies

Author	Reason for exclusion
Sefcovic (2000) [481]	Some patients had prior treatment (including surgery), some did not, but all were analyzed together.
Davis (1998) [438]	Used CTOA-I scale that has not been validated against accepted functional scales for carpal tunnel syndrome

There were also nine studies wherein functional status was reported for patients prior to receiving surgical treatment.[44,311,313,326,428,476,482-484] These patients generally had received prior conservative treatment that had been ineffective at relieving symptoms (or had not provided enough relief). Because patients who eventually receive surgery may have more severe pre-treatment symptoms than non-surgical patients, these nine studies do not address the question and are not considered further.

Evidence Base

Two studies (with a total of 51 patients) remained that addressed this question after the above exclusions.

Internal validity

Aspects of study quality that are most relevant to the present question are shown in Table 157. Because we are cataloging functional status rather than using it to compare treatments, randomization and the use of control groups are not of paramount importance here. Therefore, Table 157 does not depict these aspects of study design. However, the following variables are particularly important: attrition rates, whether the trial was prospective, and whether the raters of functional status (in this case the patients) were blinded to the treatment the patient received.

One study reported no patient attrition, the other reported an attrition rate of 19 percent. This latter study did not perform an intent-to-treat analysis.[34] Both studies were prospective, but neither employed blinding. Because it is difficult to blind patients to the treatment received, we are considering unblinded studies to be of acceptable quality for this question.

Table 157. Internal validity

Author	Number of patients	Number of centers	Funded by a for-profit agency?	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Walker (2000) [34]	21	1	No	Yes	No	19.0	No	92
Vaile (1999) [485]	30	2	NR	Yes	No	0	Yes	NR

NR – Not reported

Generalizability

Selected patient characteristics are presented in Table 158. Both studies reported mean patient age and percentage of female patients. For the remaining categories, one study reported combidities,[485] and neither study reported duration of symptoms or selection of patients based on severity of disease. In one study (Walker et al., 2000), the percent of female patients was much lower than that found in a typical population of carpal tunnel patients. This study examined a population of Veteran's Administration patients, of which men comprise an overwhelming majority.[34] Although Vaile et al. (1999) did not report a mean age, the range suggests that the mean age is probably consistent with epidemiologic studies (see Introduction section, carpal tunnel syndrome, subheading epidemiology, as well as Question two for CTS).

Only one study reported any information relating to patient employment or occupation. Vaile et al. (1999) reported that there were no patients receiving workers' compensation (Table 159).[485] Because there were only two studies, and they incompletely presented information on occupation-related variables, one cannot determine how generalizable these studies are to the greater population of patients with carpal tunnel syndrome.

Table 158. Patient characteristics

Author	Number of patients	Mean age (range)	% female	Duration of condition mean and range (months)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Walker (2000) [34]	21	60 (44-81)	4.8	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Vaile (1999) [485]	30	(29-84)	81.5	NR	NR	55.6	NR	7.4	NR	NR	NR	NR	NR

NR – Not reported

Table 159. Patient occupation

Author	Number of patients	% Patients employed	% Patients on Workers Compensation	% Patients retired	% Patients homemakers	Reported Occupations
Walker (2000) [34]	21	NR	NR	NR	NR	NR
Vaile (1999) [485]	30	NR	0	NR	NR	NR

NR – Not reported

Results

Table 160 shows the reported functional status of patients with carpal tunnel syndrome who had no prior treatment. Since each study used a different scale to measure functional status, the scores are not directly comparable. The two studies suggested that untreated patients on average score in the middle range (the 30-65% level) of functional status scales, suggesting mild to moderate difficulty with functional activities.[34,485]

Table 160. Studies with patients who had no prior treatment

Study	N	Future treatment	Scale	Range of scale	Overall mean pre-treatment functional status score	% of maximum score
Walker (2000) [34]	21	Non-surgical (splints)	CTS-I	1-5	Splint (night only): 2.75 (1.01) Splint (full-time): 2.27 (1.03)	43.8 31.8
Vaile (1999) [485]	30	Non-surgical (steroid injections)	Vaile VAS	0-100	64.2 (24.0)	64.2

CTS-I – Carpal Tunnel Syndrome Instrument
VAS – Visual Analog Scale

Conclusions

There is some evidence to suggest that most untreated patients with carpal tunnel syndrome have mild to moderate functional difficulties before treatment. However, this evidence is derived from only two studies comprised of a total of 51 patients. This is too few patients and too few studies to allow one to reach a firm evidence-based conclusion.

Question #11: What are the functional limitations of an individual with carpal tunnel syndrome after treatment?

This question inquires about the functional limitations of an individual after they have received conservative or surgical treatment for carpal tunnel syndrome. Our objective is as described in Question 10 for carpal tunnel syndrome. As also discussed in Question 10, our approach is governed by the available literature. We refer the reader to that question for additional details.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. Table 161 shows these latter studies and the reason we did not consider them for this question.

Table 161. Excluded studies

Author	Reason for exclusion
Provinciali (2000) [427]	Used Jebsen-Taylor test to measure functional limitation. The test is not validated for carpal tunnel syndrome
Atroshi (1999) [486]	Study group overlaps with Atroshi et al.[326]
Bessette (1998) [487]	Used SF-36 scale that is not accurate for carpal tunnel syndrome (see Question 9 for carpal tunnel syndrome)
Davis (1998) [438]	Used CTOA-I scale that has not been validated against accepted functional scales for carpal tunnel syndrome
Katz (1998) [462]	Study group contains an unspecified number of the same patients evaluated in Katz et al.[482]
Atroshi (1997) [483]	Lack of information about treatment status of the study group
Katz (1996) [488]	Study group contains an unspecified number of the same patients evaluated in Katz et al.[482]
Katz (1994) [303]	Biased post-hoc selection of patients for analysis

Evidence base

Twelve studies (with a total of 1567 patients) that addressed this question remained after the above exclusions.

Internal Validity

Aspects of study quality that are most relevant to the present question are shown in Table 162. Because we are cataloging functional status rather than using it to compare treatment, randomization and the use of control groups are not of paramount importance here. Therefore, Table 162 does not depict these aspects of study design. However, the

following variables are particularly important: attrition rates, whether the trial was prospective, and whether the raters of functional status (in this case the patients) were blinded to the treatment the patient received.

None of the studies that reported attrition performed an intent-to-treat analysis. Four studies reported an attrition rate that exceeded 20 percent. This is sufficient attrition to cast doubt on the internal validity of the studies. Nine of 12 studies were prospective. In another study, some, but not all, patients were prospectively enrolled. No studies employed blinding of patients to the treatment they received. Because it is difficult to blind patients to the treatment received (especially surgical treatments), we are considering unblinded studies to be of acceptable quality for this question.

Table 162. Study quality

Author	Number of patients	Number of centers	Funded by a for-profit agency?	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Mondelli (2000) [311]	110	1	No	NR	No	15.5	No	NA
Porras (2000) [313]	85	1	NR	Yes	No	0	Yes	NA
Walker (2000) [34]	21	1	No	Yes	No	19.0	No	92
Vaile (1999) [485]	30	2	NR	Yes	No	0	Yes	NR
Atroshi (1998) [326]	111	1	No	Yes	No	8.1	No	NA
Katz (1998) [482]	429	26	No	Yes	No	21 (6 months) 28 (18 months) 31 (30 months)	No	NR
Atroshi (1997) [477]	277	1	No	NA	NA	24	No	NR
Pransky (1997) [476]	165	1	No	Yes	No	13 37 (18 months)	No	NR
Amadio (1996) [484]	22	1	No	Yes	No	0	Yes	NA
Blair (1996) [428]	86	1	No	Yes	Single (partly)	11.8	No	NA
Worseg (1996) [44]	126	1	No	Yes	No	0	Yes	NA
Levine (1993) [393]	105	1	No	Yes (partly)	No	Not clear	Yes	NR

NR – Not reported

Generalizability

Selected patient characteristics are presented in Table 163. Ten of 12 studies (83.3%) reported mean patient age and all studies reported percentage of female patients. The mean ages of patients in surgical studies (53.4 years) was similar to that reported in epidemiological studies (see Introduction section, subheading epidemiology) and the average obtained from the 124 surgical studies (50.5 years) that were evaluated for any question in this document (see Question 2). The percentage of female patients in surgical studies was generally similar to that observed when compared to all surgical studies. The

non-surgical study by Walker et al. (2000) reported a low percentage of females (4.8%) compared to the typical carpal tunnel population.[34] This study examined Veterans Administration patients, a population that is overwhelmingly male.

For the remaining categories, two studies reported duration of symptoms, zero to three studies reported specific comorbidities, and no studies reported selection of patients based on severity of disease.

Few studies reported information on patient employment or occupation (Table 164). Two of 12 studies (16.7%) reported percentage of patients employed, six of 12 (50%) reported percentage on workers' compensation, two of 12 (16.7%) reported specific patient occupations, and only one study (8.3%) reported percentage of patients retired or homemakers. There is not enough information in epidemiological studies to determine the relative generalizability of these studies regarding patient occupation. Likewise, there were too few studies in the larger group of 124 surgical studies that reported this type of information to determine generalizability.

Table 163. Patient characteristics

Author	Number of patients	Mean age (range)	% female	Duration of condition mean and range (months)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Mondelli (2000) [311]	110	56 (20-82)	86.0	NR	5.4	0	4.3	NR	1.1	NR	0	NR	NR
Porras (2000) [313]	85	52 (18-81)	90.6	39 (6-300)	NR	NR	NR	NR	NR	NR	NR	NR	NR
Walker (2000) [34]	21	60 (44-81)	4.8	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Vaile (1999) [485]	30	(29-84)	81.5	NR	NR	55.6	NR	7.4	NR	NR	NR	NR	NR
Atroshi (1998) [326]	111	52 (21-88)	65.7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Katz (1998) [482]	429	NR	74.2	NR	NR	NR	NR	NR	NR	0	NR	NR	NR
Atroshi (1997) [477]	277	WC: 41 (25-62) Non-WC: 49 (13-91)	77.8	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pransky (1997) [476]	165	46 (22-80)	67	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Amadio (1996) [484]	22	60 (33-80)	59.1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Author	Number of patients	Mean age (range)	% female	Duration of condition mean and range (months)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Blair (1996) [428]	86	49 (23-82)	82.7	NR	NR	NR	NR	NR	0	NR	NR	NR	NR
Worseg (1996) [44]	126	56 (35-90)	69.8	23.4	NR	NR	NR	NR	0	NR	NR	NR	NR
Levine (1993) [393]	105	58 (19-88)	74.3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

NR – Not reported

Table 164. Patient occupation

Author	Number of patients	% Patients employed	% Patients on Workers Compensation	% Patients retired	% Patients homemakers	Reported Occupations
Mondelli (2000) [311]	110	NR	NR	NR	NR	NR
Porras (2000) [313]	85	NR	NR	NR	NR	Homemaker, low functional demand, cleaners, keyboard workers, heavy work, assembly line
Walker (2000) [34]	21	NR	NR	NR	NR	NR
Vaile (1999) [485]	30	NR	0	NR	NR	NR
Atroshi (1998) [326]	111	NR	NR	NR	NR	NR
Katz (1998) [482]	429	NR	38.2	NR	NR	NR
Atroshi (1997) [477]	277	NR	28.8	NR	NR	NR
Pransky (1997) [476]	165	89	10	NR	NR	NR
Amadio (1996) [484]	22	63.6	0.9	NR	NR	NR
Blair (1996) [428]	86	NR	NR	NR	NR	NR
Worseg (1996) [44]	126	NR	NR	47.6	6.3	Retired, employee, worker, unemployed, homemaker, other
Levine (1993) [393]	105	NR	12.4	NR	NR	NR

NR – Not reported

Results

Table 165 shows the results of the two nonsurgical studies of post-treatment functional limitations in patients with carpal tunnel syndrome. Since these studies used different scales to measure functional status, their scores are not directly comparable. Both studies suggested that after nonsurgical treatment, patients score, on average, in the lower range (the 20-30% level) of functional status scales.[34,485] However, it is unclear whether the results of these two studies are generalizable to the larger patient population.

Table 165. Studies with patients who had no prior treatment

Study	N	Treatment	Scale	Range of scale	Overall mean post-treatment functional status score (± SD)	% of maximum score
Walker (2000) [34]	21	Non-surgical (splints)	CTS-I	1-5	Splint (night only): 2.14 (0.87) Splint (full-time): 1.93 (0.77)	28.5 23.3
Vaile (1999) [485]	30	Non-surgical (steroid injections)	Vaile VAS	0-100	23.8 (26.2)	23.8

CTS-I – Carpal Tunnel Syndrome Instrument
VAS – Visual Analog Scale

Table 166 shows the results of the two surgical studies that reported individual functional activity mean scores using the CTS-I scale. Lower scores on this scale indicate less functional limitation. Table 167 shows the number of patients for each level of the scale in the surgical study of Atroshi et al. (1998).[326]

Table 168 shows the results of a third surgical study, performed by Blair et al.[428] Although these latter authors did not use a specific scale, they did report the number of patients who had difficulty with specific functional activities. Both of these studies suggest that patients have relatively mild functional limitations following surgery, and the study by Blair et al. suggests that the majority of patients do not have any noticeable difficulty with certain functional activities after surgery.

Seven studies reported overall mean functional activity scores on the CTS-I scale prior to surgery (Table 169). Four out of seven studies did not describe the surgical procedure, so no evidence-based conclusions can be reached concerning functional limitations after specific surgical procedures. However, one can make some broad conclusions about functional limitations after surgical procedures as a group. These studies suggested that most patients report no-to-moderate difficulty with functional activities (mean 1.4-2.6 on CTS-I) after surgery. Although there were no statistically significant posttreatment differences between specific patient groups, in two studies there was a trend toward more difficulty with functional activities among patients receiving workers' compensation.

The utility of functional status scales would be enhanced if they could be shown to predict work-related outcomes. The relevance of the CTS-I scale in relating functional limitation to work-related outcomes was examined by the Maine Carpal Tunnel Study (Katz et al.).[462] Results of this study suggest that patients with functional difficulty at six months after treatment have greater odds of being absent from work at 18 months post-treatment (odds ratio 3.3, 95% CI 1.5-6.9, p = 0.002). This odds ratio, as determined by logistic regression was per one unit change on the CTS-I scale. However, the available data were insufficient to allow an estimation of the percentage of patients with a particular score who were absent from work.

Table 166. Studies with post-treatment functional limitation data for patients with carpal tunnel syndrome (individual functional activities – mean scores from CTS-I)

Study	N	Treatment	Range of scale	Writing	Holding a book	Buttoning clothes	Gripping the telephone	Opening jars	Performing household chores	Carrying a grocery bag	Bathing and dressing
Atroshi (1998) [326]	111	Endoscopic release	1-5	1.5	1.7	1.7	1.5	2.1	1.7	2.1	1.3
Worseg (1996) [44]	126	Endoscopic release	1-5	1.0 (0.2)[a]	1.0 (0.1)	1.0 (0.1)	1.0 (0.1)	1.6 (0.7)	1.4 (0.8)	1.4 (0.8)	1.2 (0.4)
		Open release		1.0 (0.2)	1.0 (0.2)	1.2 (0.4)	1.1 (0.2)	1.9 (0.8)	1.2 (0.4)	1.7 (0.8)	1.2 (0.4)

[a]Numbers in parentheses indicate standard deviations

Table 167. Studies with post-treatment functional limitation data for patients with carpal tunnel syndrome (individual functional activities – number of patients)

Study	N	Score	Number of patients in each CTS-I Functional Status category (%)							
			Writing	Holding a book	Buttoning clothes	Gripping the telephone	Opening jars	Performing household chores	Carrying a grocery bag	Bathing and dressing
Atroshi (1998) [326]	111	1	69 (70.4)	59 (60.2)	59 (59.6)	69 (72.6)	42 (42.4)	56 (56.6)	41 (42.3)	77 (77)
		2	17 (17.3)	21 (21.4)	19 (19.2)	12 (12.6)	26 (26.3)	21 (21.2)	25 (25.8)	18 (18)
		3	6 (6.1)	9 (9.2)	15 (15.2)	7 (7.4)	13 (13.1)	16 (16.2)	16 (16.5)	3 (3)
		4	6(6.1)	9 (9.2)	2 (2.0)	4 (4.2)	14 (14.1)	4 (4.0)	12 (12. 4)	2 (2)
		5	0 (0)	0 (0)	4 (4.0)	3 (3.2)	4 (4.0)	1 (1.0)	3 (3.1)	0 (0)

Table 168. Studies with post-treatment functional limitation data for patients with carpal tunnel syndrome (individual functional activities – number of patients)

Study	Treatment	Difficulty	Self-described difficulty in performing selected activities of daily living after carpal tunnel release (% of patients)		
			Screwing lids	Picking up small objects	Lifting
Blair (1996) [428]	Open release plus epineurotomy (n = 48)	Yes	15 (31.3)	9 (18.8)	9 (18.8)
		No	33 (68.8)	39 (81.3)	39 (81.3)
	Open release without epineurotomy (n = 27)	Yes	11 (40.7)	10 (37.0)	7 (25.9)
		No	16 (59.3)	17 (63.0)	20 (74.1)

Table 169. Studies with post-treatment functional limitation data for patients with carpal tunnel syndrome (mean function score on CTS-I)

Study	N	Treatment	Study Design	Range of scale	Followup time	Overall mean post-treatment functional status score (SD)	% of maximum score
Mondelli (2000) [311]	110	Surgical (open release)	Prospective case series	1-5	1 month	2.0 (0.7)	25
					6 months	1.5 (0.6)	12.5
Porras (2000) [313]	85	Surgical (open release)	Prospective case series	1-5	6 months	1.4 (range 1-4.2)	10
Atroshi (1998) [326]	111	Surgical (endoscopic release)	Prospective case series	1-5	3 months	1.7 (range 1.6-1.9)	17.5
Katz (1998) [482]	429	Surgical (n = 270, procedures not described) Non-surgical (n = 125) (34 patients who crossed over to surgery were not evaluated)	Prospective case series (stratified)	1-5	6 months	Surgical patients: >55 years: 1.7 (0.9) ≤55 years, WC non-recipient:: 1.6 (0.7) ≤55 years, WC recipient: 2.1 (0.9)	17.5 15 27.5
						Non-surgical patients: >55 years: 2.6 (0.8) ≤55 years, WC non-recipient:: 1.9 (0.9) ≤55 years, WC recipient: 2.2 (0.7)	40 22.5 30
					18 months	Surgical patients: >55 years: 1.6 (0.7) ≤55 years, WC non-recipient: 1.6 (0.7) ≤55 years, WC recipient: 2.2 (0.9)	15 15 30

Study	N	Treatment	Study Design	Range of scale	Followup time	Overall mean post-treatment functional status score (SD)	% of maximum score
						Non-surgical patients: >55 years: 2.3 (0.9) ≤55 years, WC non-recipient:: 2.0 (1.0) ≤55 years, WC recipient: 2.4 (0.7)	32.5 25 35
					30 months	Surgical patients: >55 years: 1.6 (0.9) ≤55 years, WC non-recipient: 1.6 (0.7) ≤55 years, WC recipient: 2.2 (1.0)	15 15 30
						Non-surgical patients: >55 years: 2.2 (0.8) ≤55 years, WC non-recipient:: 2.0 (0.9) ≤55 years, WC recipient: 2.2 (0.8)	30 25 30
Atroshi (1997) [477]	277	Surgical or non-surgical (or both) (procedures not described)	Cross-sectional study	1-5	6-20 months	WC patients: 2.5 (95% CI: 2.2-2.7) Non-WC patients: 2.2 (2.0-2.4)	37.5 30
Amadio (1996) [484]	22	Surgical (not described)	Prospective case series	1-5	3 months	1.77 (0.68)	19.3

Study	N	Treatment	Study Design	Range of scale	Followup time	Overall mean post-treatment functional status score (SD)	% of maximum score
Levine (1993) [393]	67	Surgical or non-surgical (not described)	Prospective case series	1-5	3 months	Prospective: 2.1 (1.1)	27.5
	38	Surgical (not described)	Retrospective case series		Median: 14 months	Retrospective: 2.0 (1.1)	25

WC – Workers' Compensation

Table 170. Studies with post-treatment functional limitation data for patients with carpal tunnel syndrome (summary function score on UEFS)

Study	N	Treatment	Study Design	Range of scale	Followup time	Overall summary post-treatment functional status score (SD)	% of maximum score
Pransky (1997) [476]	108	Surgical or non-surgical (not described)	Prospective case series	1-10	Mean: 18 months	25.4 (18.1)* Note: this study also had a case series of mixed upper extremity disorders (UEDs)	17.1

Conclusions

Although studies of non-surgical therapies suggested that most patients experience only mild difficulty with functional activities after treatment, it is unclear whether the results of these two studies are generalizable to the larger patient population. Studies with surgical outcomes suggested that most patients report no-to-moderate difficulty with functional activities (mean 1.4-2.6 on CTS-I) after surgery. Although there were no statistically significant differences between specific patient groups, in two studies there was a trend toward more difficulty with functional activities among workers' compensation patients. Decreased functional ability on the CTS-I scale shows a strong correlation with work absence. The available data are insufficient to determine a cutoff point on measuring scales above which patients are unable to work.

Chapter 3. Results (continued)

Cubital Tunnel Syndrome

Question #1: What are the appropriate methods and approaches for the early identification and diagnosis of cubital tunnel syndrome?

Evidence Base

Articles were included in this analysis if they reported data that could be used for evaluation of the test in diagnosing cubital tunnel syndrome, and they included ten or more patients.

Twenty-two articles met the initial inclusion criteria. Two (Table 171) were subsequently excluded because they contained no diagnostic data. The remaining 20 articles reported on a total of at least 557 cubital tunnel syndrome patients and at least 448 controls. These figures are approximate because Odusote et al. did not report the number of patients or controls in their study[489] and Eisen et al. did not report the number of controls in their 1974 article.[490] Three of the articles (15%) reported on multi-center trials; the rest were conducted at single centers. Half of the articles were from the United States, and half were from other countries.

Two articles (10%) reported only summary data for groups of patients (i.e., mean test results for cubital tunnel syndrome group and for control group). Four articles (20%) reported patient-level data either in tables or in charts from which counts of patients with positive and negative test results could be made. The remaining 14 articles reported those counts directly, but only nine articles (45% of total) reported sufficient information on both cubital tunnel syndrome patients and normal controls to permit both sensitivity and specificity to be determined. Details on data reporting levels and other characteristics of each study are found in Table 181 through Table 183.

Internal Validity of Results

Table 172 details aspects of study design and reporting that bear on the internal validity of the results: whether the published results truly reflect the diagnostic effectiveness of the test as used in the trial. The quality of reporting of these characteristics is summarized in Table 173. Only two articles reported that the person interpreting the test was blinded to patients' group assignment, and only one reported that the person performing the test was blinded. Blinding helps assure that test results were free of intentional or unintentional biases. The numbers of men and women in the cubital tunnel syndrome and control groups were not reported in 11 of the 20 articles (55%). Without reporting of these figures, one cannot be sure that the results of these studies were free of sex bias. Likewise, seven articles (35%) failed to report ages of patients and controls, even though some of the tests are known to be affected by age.

Generalizability of Results

Table 174 lists study characteristics that might affect the generalizability of results from the patient population in the study to the patient population. The quality of reporting of these characteristics is summarized in Table 175. Many studies did not report important patient characteristics such as sex and previous treatment. Without this information, one cannot determine whether diagnostic results were affected by these variables, or whether the results were representative of test performance in routine practice.

The overall quality of articles in this evidence base is low. Important variables that could affect the validity or generalizability of results from these studies were not reported. Though this lack of reporting is not evidence of bias in the studies, it limits the confidence one can have in any conclusions drawn from them.

A tabulation of patient selection and types of controls appears in Table 176. See Table 174 for the definition of these categories. Only three studies (15%) used objective criteria to define their cubital tunnel syndrome patient group, while eight (40%) diagnosed patients with unspecified methods. Eleven articles (55%) compared the cubital tunnel syndrome patients to healthy normal volunteers; this comparison may cause spectrum bias in the results because these control subjects may be less likely than patients referred for cubital tunnel syndrome testing to have other conditions that could cause false-positive test results.

The poor quality of the literature, particularly in reporting of study characteristics that demonstrate that study results are free of bias and generalizable to the diagnosis of cubital tunnel syndrome in routine practice, argues against trying to draw evidence-based conclusions from the results of a single study. If there is sufficient data on a particular test, meta-analytic techniques can be used to see if any of these variables affected study results.

Results

Table 177 tabulates reported tests (by type of test: there are different tests in each category) and patient selection categories in the 20 articles. There were no tests for which at least 10 articles reported sensitivity and specificity, not just for any one category of patient selection, but even for all categories combined. Therefore, we did not perform any meta-analyses of diagnostic tests for cubital tunnel syndrome.

The reported methods for defining cubital tunnel syndrome in the 20 included studies appear in Table 178. The most common criteria were symptoms (7 studies, 35%) and motor nerve conduction velocity across the elbow (6 studies, 30%). Seven studies (35%) used both clinical criteria and nerve conduction criteria, three studies (15%) used nerve conduction criteria only, and two studies (10%) used clinical criteria only. The table demonstrates the variability in authors' definitions of cubital tunnel syndrome. The lack of agreement on what constitutes cubital tunnel syndrome hinders assessing tests for diagnosing the condition.

Because there was little agreement in the clinical trial articles on appropriate diagnostic methods for cubital tunnel syndrome, we also examined review articles, to see if they identified any standard approaches to diagnosis. The four articles that reviewed cubital tunnel

diagnosis[57,97,491,492] listed typical symptoms of the condition, but did not recommend specific diagnostic strategies (i.e., which test to use first). They disagreed on the value of clinical signs like Tinel's sign. The only characteristic of cubital tunnel syndrome mentioned in all four articles was abnormal ulnar motor nerve conduction velocity at the elbow. Piligian[53] came closest to recommending a diagnostic strategy, suggesting that cubital tunnel syndrome be diagnosed using both symptoms (paresthesia of the fourth and fifth fingers and pain in the medial aspect of the elbow) and nerve conduction tests (reduced ulnar motor nerve conduction velocity at the elbow). There was not sufficient evidence in the reported clinical trials of these tests for us to meta-analyze their results and determine how effective they are.

Because ulnar motor nerve conduction velocity at the elbow was described as a characteristic of cubital tunnel syndrome in all four review articles we examined, and no tests for cubital tunnel syndrome met our *a priori* meta-analysis criteria, we abstracted sensitivity and specificity data from the three articles in which this was possible (the article by So et al.[173] was excluded because no specificity data was reported for the nerve conduction tests). The results reported in those three articles are presented in Table 179 and Figure 44. All three studies reported high specificity but low sensitivity.

Conclusions

All of the articles on diagnosis of cubital tunnel syndrome suffered from poor reporting of study methods and patient characteristics, so one cannot be assured that the results of any individual study were unaffected by bias. There were no diagnostic tests for cubital tunnel syndrome for which 10 or more articles reported sensitivity and specificity. Therefore, we could not perform meta-analyses to see if results were affected by differences in patient characteristics and study design. One test, ulnar motor nerve conduction velocity at the elbow, was mentioned by reviewers, and three studies reported high specificity and low sensitivity for this test. Due to the small number of studies, however, one cannot draw quantitative conclusions about the effectiveness of the test. There are insufficient data to permit evidence-based conclusions about the effectiveness of this or any other tests for cubital tunnel syndrome.

Table 171. Excluded Studies

Author	Reason for Exclusion
Okamoto, 2000 [493]	No diagnostic data
Rosenberg, 1995 [494]	No diagnostic data

Table 172. Study Design: Characteristics Affecting Internal Validity

Article	Funded by for-profit	Inclusion criteria	Exclusion criteria reported	Method of diagnosis	Patient selection	Comorbidity reported	Sex reported	Possible sex bias	Ages reported	Possible age bias	Duration of condition	Test operator blinded	Test reader blinded	Multiple readers	Method for multiple	Independent reference	Were patients given both
Montagna, 2000 [227]	NR	Yes	NR	NR	NR	NR	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	No	No
Ellemann, 1999 [495]	NR	Yes	Yes	NR	NR	Yes	Yes	NC	Yes	NC	NR	NR	NR	NR	NR	No	No
Merlevede, 1999 [496]	NR	Yes	NR	Yes	NR	Yes	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	No	No
Chiou, 1998 [497]	NR	Yes	NR	Yes	NR	NR	Yes	No	Yes	P	NR	NR	NR	2	NR	Yes	Yes
Dellon, 1997 [107]	Yes	Yes	Yes	Yes	NR	Yes	NR	GNR	NR	ANR	NR	NR	NR	NR	NR	Yes	Yes
Kaneko, 1997 [250]	NR	Yes	NR	Yes	NR	Yes	Yes	P	NR	ANR	NR	NR	NR	NR	NR	No	No
Britz, 1996 [498]	NR	Yes	NR	NR	Prospective	NR	Yes	GNR	Yes	ANR	NR	NR	Yes	NR	NR	No	No
Kingery, 1995 [499]	NR	Yes	Yes	Yes	NR	NR	NR	GNR	Yes	No	NR	NR	NR	NR	NR	No	No
Tassler, 1995 [115]	Yes	Yes	Yes	NR	Retrospective	Yes	NR	GNR	NR	ANR	NR	Yes	NR	NR	NR	Yes	Yes
Novak, 1994 [500]	No	Yes	Yes	Yes	NR	NR	Yes	No	Yes	P	NR	NR	NR	NR	NR	Yes	Yes
Uchida, 1993 [501]	NR	Yes	Yes	Yes	Retrospective	Yes	Yes	NC	Yes	NC	NR	NR	NR	NR	NR	No	No
Robinson, 1992 [502]	NR	Yes	Yes	Yes	Retrospective	NR	Yes	NC	NR	NC	Yes	NR	NR	NR	NR	No	No
So, 1989 [173]	NR	Yes	NR	Yes	NR	NR	NR	GNR	NR	ANR	NR	NR	Yes	NR	NR	Yes	No
Buehler, 1986 [503]	NR	Yes	Yes	Yes	NR	Yes	Yes	NC	NR	NC	NR	NR	NR	NR	NR	No	No
Kimura, 1984 [55]	NR	Yes	Yes	NR	NR	NR	Yes	No	Yes	No	NR	NR	NR	NR	NR	No	No
Tackmann, 1984 [54]	NR	Yes	NR	NR	NR	NR	NR	GNR	Yes	No	NR	NR	NR	NR	NR	No	No
Odusote, 1979 [489]	NR	Yes	Yes	NR	NR	Yes	NR	GNR	Yes	No	Yes	NR	NR	NR	NR	Yes	Yes
Ring, 1979 [504]	NR	Yes	NR	NR	Prospective	NR	Yes	C	Yes	P	NR	NR	NR	NR	NR	No	No
Eisen, 1977 [298]	NR	Yes	Yes	Yes	NR	NR	NR	GNR	Yes	P	NR	NR	NR	NR	NR	No	No

Article	Funded by for-profit	Inclusion criteria	Exclusion criteria reported	Method of diagnosis	Patient selection	Comorbidity reported	Sex reported	Possible sex bias	Ages reported	Possible age bias	Duration of condition	Test operator blinded	Test reader blinded	Multiple readers	Method for multiple	Independent reference	Were patients given both
Eisen, 1974 [490]	NR	Yes	Yes	Yes	Prospective	NR	Yes	GNR	Yes	No	NR	NR	NR	NR	NR	No	No

Key:
Possible sex bias: No—proportion women in epicondylitis group within 20% of proportion of women in control group; P—Patients were more likely to be female; C—Controls were more likely to be female; GNR—Genders not reported for both groups; NC—Study did not contain a separate control group
Possible age bias: No—mean age of epicondylitis group within 5 years of mean age of control group; P—Patients were older than controls; C—Controls were older than patients; ANR—Ages not reported for both groups; NC—Study did not contain a separate control group
Method for multiple test readers: Indep—Independent
NR—Not reported

Table 173. Summary of Characteristics Affecting Internal Validity

Study characteristic	Number of studies reporting	Details
Whether trial was funded by a for-profit institution	3 (15%)	For-profit funding: 2 (10%) No such funding: 1 (5%)
Patient inclusion criteria	20 (100%)	See Table 183
Patient exclusion criteria	12 (60%)	See Table 183
Method of diagnosis	12 (60%)	Clinical and NCS: 7 (35%) NCS only: 3 (15%) Clinical only: 2 (10%)
Was selection of patients prospective or retrospective?	6 (30%)	Prospective: 3 (15%) Retrospective: 3 (15%)
Were patient comorbidities reported?	8 (40%)	Various
Was the sex distribution of patients reported?	11 (55%)	[a]Percentage female: 31.6%
Was the percentage of females in the patient group within 20 percentage points of the control group?	5 (25%)	Yes: 4 (20%) No, patients were = 20% more female: 0 No, control group was =20% more female: 1 (5%)
Were patient ages reported?	12 (60%)	[a, b]Mean age: 46.6
Was the mean patient age within 5 years of the mean control age?	9 (45%)	Yes: 5 (25%) No, patients were = 5 years older: 4 (20%)
Was the duration of patients' condition reported?	1 (5%)	[a]Mean duration: 7.5 months
Was the test operator blinded?	1 (5%)	Yes: 1 (5%)
Was the test reader blinded?	2 (10%)	Yes: 2 (10%)
Were there multiple test readers?	1 (5%)	2 readers: 1 (5%)
What was the method for multiple test readers?	0	NA
Was the test compared to an independent reference standard?	6 (30%)	Yes: 6 (30%)
Were all patients given the test and the reference standard?	6 (30%)	Yes: 5 (25%) No: 1 (5%)

Key:
NA-not applicable
[a]Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)
[b]Calculation excludes study reporting median age [54] and study that failed to report the number of patients [489]

Table 174. Study Design: Characteristics Affecting Generalizability of Results

Article	Years in which trial was conducted	Number of centers	Country where trial was conducted	Inclusion criteria reported?	Exclusion criteria reported	Patient comorbidity reported?	Sex reported	Ages reported	Duration of condition reported	Did all patients have previous conservative treatment?	Did any patients have previous surgical treatment?	Source of patients adequately described and generalizable to broader clinical practice?	Potential selection bias for easy cases?	Potential selection bias for difficult cases?
Montagna, 2000 [227]	NR	Single	Italy	Yes	NR	No	NR	NR	NR	No	No	No	Yes	No
Ellemann, 1999 [495]	NR	Multiple (<5)	Denmark	Yes	Yes	Yes	Yes	Yes	NR	No	No	No	Yes	No
Merlevede, 1999 [496]	NR	Single	Belgium	Yes	NR	Yes	NR	NR	NR	No	No	No	Yes	Yes
Chiou, 1998 [497]	NR	Single	Taiwan	Yes	NR	No	Yes	Yes	NR	No	No	No	No	No
Dellon, 1997 [107]	1993	Single	USA	Yes	Yes	Yes	NR	NR	NR	No	No	No	Yes	No
Kaneko, 1997 [250]	NR	Single	Japan	Yes	NR	Yes	Yes	NR	NR	No	No	No	Yes	No
Britz, 1996 [498]	NR	Multiple (<5)	USA	Yes	NR	No	Yes	Yes	NR	No	Yes	No	No	No
Kingery, 1995 [499]	NR	Single	USA	Yes	Yes	No	NR	Yes	NR	No	No	No	No	Yes
Tassler, 1995 [115]	1993-1994	Single	USA	Yes	Yes	Yes	NR	NR	NR	No	No	No	Yes	No
Novak, 1994 [500]	NR	Single	USA	Yes	Yes	No	Yes	Yes	NR	No	No	No	No	No
Uchida, 1993 [501]	1985-1992	Single	Japan	Yes	Yes	Yes	Yes	Yes	NR	No	No	No	No	No
Robinson, 1992 [502]	1984-1988	Single	Israel	Yes	Yes	No	Yes	NR	Yes	No	No	No	Yes	No
So, 1989 [173]	NR	Single	USA	Yes	NR	No	NR	NR	NR	No	No	Yes	No	No
Buehler, 1986 [503]	NR	Single	USA	Yes	Yes	Yes	Yes	NR	NR	No	No	No	Yes	No
Kimura, 1984 [55]	NR	Single	USA	Yes	Yes	No	Yes	Yes	NR	No	No	No	No	No
Tackmann, 1984 [54]	NR	Single	Germany	Yes	NR	No	NR	Yes	NR	No	No	No	No	No
Odusote, 1979 [489]	NR	Single	USA	Yes	Yes	Yes	NR	Yes	Yes	No	No	No	Yes	Yes
Ring, 1979 [504]	NR	Multiple (<5)	Israel	Yes	NR	No	Yes	Yes	NR	No	No	No	No	No

Article	Years in which trial was conducted	Number of centers	Country where trial was conducted	Inclusion criteria reported?	Exclusion criteria reported	Patient comorbidity reported?	Sex reported	Ages reported	Duration of condition reported	Did all patients have previous conservative treatment?	Did any patients have previous surgical treatment?	Source of patients adequately described and generalizable to broader clinical practice?	Potential selection bias for easy cases?	Potential selection bias for difficult cases?
Eisen, 1977 [298]	NR	Single	Canada	Yes	Yes	No	NR	Yes	NR	No	No	No	No	Yes
Eisen, 1974 [490]	NR	Single	USA	Yes	Yes	No	Yes	Yes	NR	No	No	No	No	No

Key:
NR—not reported

Table 175. Summary of Characteristics Affecting Generalizability

Study characteristic	Number of studies reporting	Details
Years in which study was conducted	4 (20%)	1984-1988: 1 (5%) 1985-1992: 1 (5%) 1993: 1 (5%) 1993-1994: 1 (5%)
Number of centers in which trial was conducted	20 (100%)	Single: 17 (85%) Multiple (<5): 3 (15%)
Country(s) where trial was performed	20 (100%)	USA: 10 (50%) Other: 10 (50%)
Patient inclusion criteria	20 (100%)	See Table 183
Patient exclusion criteria	12 (60%)	See Table 183
Were patient comorbidities reported?	8 (40%)	Various
Was the sex distribution of patients reported?	11 (55%)	[a]Percentage female: 31.6%
Were patient ages reported?	12 (60%)	[a, b]Mean age: 46.6 years
Was the duration of patients' condition reported?	1 (5%)	[a]Mean duration: 7.5 months
Did all patients have previous conservative treatment?	0	NA
Did any patients have previous surgical treatment?	1 (5%)	Yes: 1 (5%)
Adequate reporting of study's source of patients	1 (5%)	Yes: 1 (5%)
Was there a potential selection bias for easy cases?	9 (45%)	Yes: 9 (45%)
Was there a potential selection bias for hard cases?	4 (20%)	Yes: 4 (20%)

Key:
NA-not applicable
[a]Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)
[b]Calculation excludes study reporting median age [54] and study that failed to report the number of patients [489]

Table 176. Patient and Control Group Selection in Cubital Tunnel Syndrome Diagnostic Articles

Control Selection	Patient selection					Total
	Complex objective standard	Simple nerve conduction	Symptoms/ presented	Unspecified diagnosis	Workers at risk	
Healthy control group and asymptomatic arms of patients	0	0	1	0	0	1
Healthy control group	1	2	4	3	1	11
Other control group	0	0	2	2	0	4
Asymptomatic arm as control	0	0	1	0	0	1
No controls	0	0	0	3	0	3
Total	1	2	8	8	1	20

Table 177. Cubital Tunnel Syndrome Tests and Patient Groups

Legend:

Numeric entries in each cell— Total number of articles, articles from which sensitivity and specificity can be calculated

Test type	Patient selection				
	Complex objective standard	Simple objective standard	Symptoms/ presented	Unspecified diagnosis	Workers at risk
Composite nerve conduction	1, 1	1, 1	7, 4	2, 1	1, 0
Imaging	0, 0	0, 0	2, 1	0, 0	0, 0
Nerve conduction	1, 1	1, 1	5, 2	3, 1	1, 0
Sensory	0, 0	0, 0	1, 1	3, 1	0, 0
Signs/Symptoms	0, 0	1, 1	2, 2	3, 0	1, 0
Other	0, 0	0, 0	4, 3	2, 2	0, 0

See **Table 3** CODING OF PATIENT INCLUSION —METHODS SECTION for the definition of these groups

Table 178. Definitions of Cubital Tunnel Syndrome Used in Reported Clinical Trials

Article	Clinical findings			Nerve conduction studies			Comments
	SYM	CLN	OTH CLN	MCV ELB	OTH MOT	SEN	
Montagna, 2000 [227]	?	?	?	?	?	?	NR
Ellemann, 1999 [495]	?	?	?	?	?	?	NR
Merlevede, 1999 [496]	☑	?	?	☑	☑	?	
Chiou, 1998 [497]	?	?	?	?	?	?	NCS (tests not reported)
Dellon, 1997 [107]	?	☑	☑	?	?	?	
Kaneko, 1997 [250]	?	?	?	☑	?	?	
Britz, 1996 [498]	?	?	?	?	?	?	NR
Kingery, 1995 [499]	☑	?	?	☑	☑	☑	
Tassler, 1995 [115]	?	?	?	?	?	?	NR
Novak, 1994 [500]	☑	?	?	☑	?	?	
Uchida, 1993 [501]	☑	☑	?	☑	?	?	
Robinson, 1992 [502]	?	☑	?	?	?	?	NCS (tests not reported)
So, 1989 [173]	☑	☑	☑	?	?	?	
Buehler, 1986 [503]	?	?	?	?	☑	☑	
Kimura, 1984 [55]	?	?	?	?	?	?	NR
Tackmann, 1984 [54]	?	?	?	?	?	?	NR
Odusote, 1979 [489]	?	?	?	?	?	?	NR
Ring, 1979 [504]	?	?	?	?	?	?	NR
Eisen, 1977 [298]	☑	?	☑	?	☑	☑	
Eisen, 1974 [490]	☑	?	?	☑	☑	☑	
Totals (20 articles)	7	4	3	6	5	4	

Key:
SYM - Were positive symptoms included in the author's method of diagnosis?
CLN - Was a positive clinical exam included in the author's method of diagnosis?
OTH CLN - Were other clinical findings included in the author's method of diagnosis?
MCV ELB - Was ulnar motor nerve conduction velocity across the elbow included in the author's method of diagnosis?
OTH MOT - Were other motor conduction studies included in the author's method of diagnosis?
SEN - Were sensory conduction studies included in the author's method of diagnosis?
NR - Method of diagnosis was not reported

Table 179. Clinical Trial Results: Ulnar Motor Nerve Conduction Velocity at the Elbow for Diagnosis of Cubital Tunnel Syndrome

Study	TP	FN	FP	TN	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)	Prevalence
[a]Odusote, 1979 [489]	72	181	10	229	28.5% 23.2% 34.4%	95.8% 92.4% 97.7%	87.8% 78.8% 93.3%	55.9% 50.9% 60.7%	51.4%
[b]Eisen, 1977 [298]	12	6	0	60	66.7% 43.3% 84.0%	100% 93.8% 100%	100% 75.0% 100%	90.9% 81.3% 95.8%	23.1%
[a, b]Kingery, 1995 [499]	16	34	2	68	32.0% 20.6% 46.1%	97.1% 90.0% 99.2%	88.9% 66.7% 97.0%	66.7% 56.9% 75.2%	41.7%

Insufficient data for meta-analysis

[a]Data reported on a per-arm basis, rather than per-patient.

[b]Counts for control group (false positive, true negative) estimated by ECRI from threshold reported by authors

Figure 44. Clinical Trial Results: Ulnar Motor Nerve Conduction Velocity at the Elbow for Diagnosis of Cubital Tunnel Syndrome

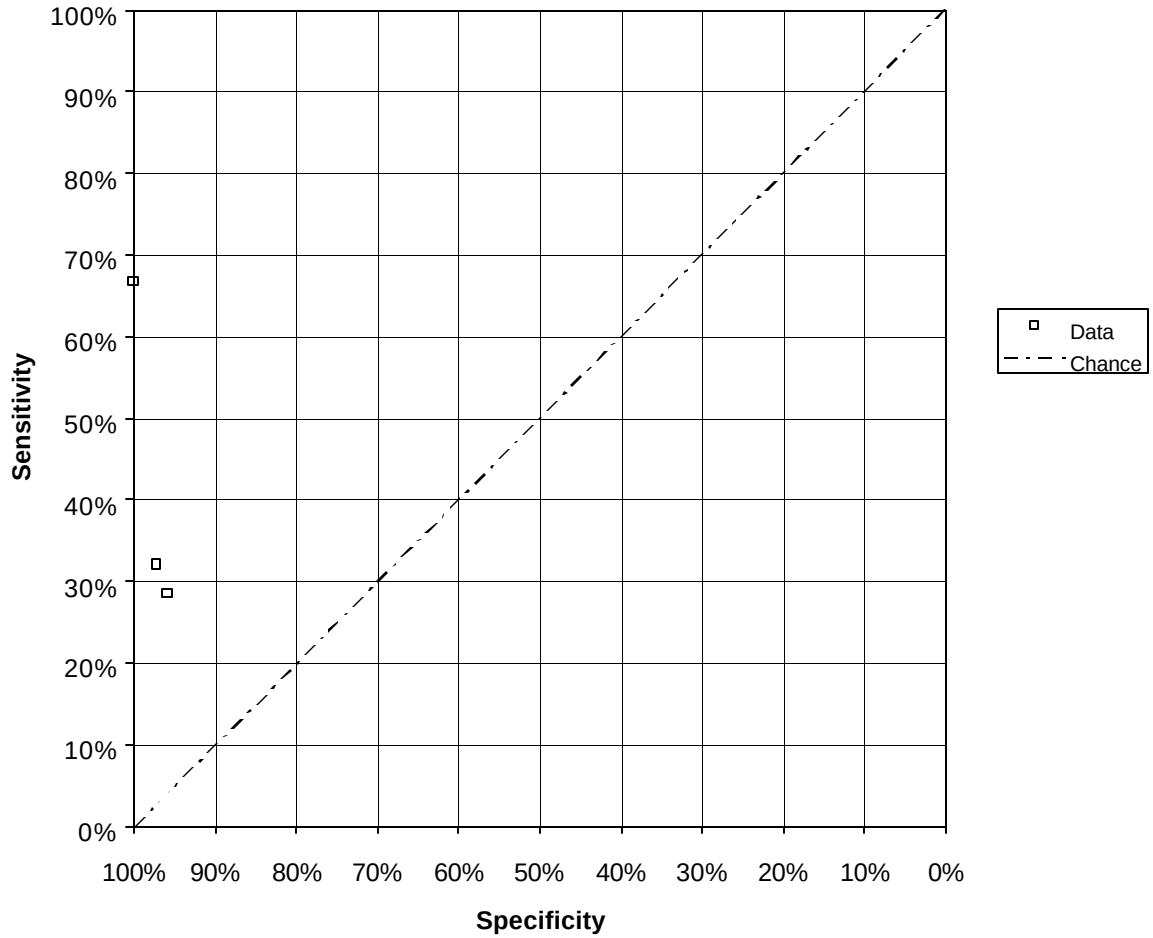


Table 180. Cubital Tunnel Syndrome–Test Types Reported

Article	Signs/ Symptoms	Sensory Tests	Nerve Conduction	Composite Nerve Conduction	Imaging	Other
Montagna, 2000 [227]	☐	☐	☐	☐	☐	☑
Ellemann, 1999 [495]	☐	☑	☐	☑	☐	☐
Merlevede, 1999 [496]	☐	☐	☑	☑	☐	☐
Chiou, 1998 [497]	☐	☐	☐	☐	☑	☐
Dellon, 1997 [107]	☑	☑	☐	☐	☐	☐
Kaneko, 1997 [250]	☐	☐	☑	☑	☐	☐
Britz, 1996 [498]	☑	☐	☐	☑	☑	☑
Kingery, 1995 [499]	☑	☐	☑	☑	☐	☑
Tassler, 1995 [115]	☐	☑	☐	☑	☐	☐
Novak, 1994 [500]	☑	☐	☐	☐	☐	☐
Uchida, 1993 [501]	☐	☐	☑	☐	☐	☐
Robinson, 1992 [502]	☑	☑	☐	☐	☐	☐
So, 1989 [173]	☐	☐	☑	☐	☐	☑
Buehler, 1986 [503]	☑	☐	☐	☐	☐	☐
Kimura, 1984 [55]	☐	☐	☑	☑	☐	☑
Tackmann, 1984 [54]	☐	☐	☑	☑	☐	☐
Odusote, 1979 [489]	☐	☐	☑	☑	☐	☑
Ring, 1979 [504]	☑	☐	☑	☑	☐	☐
Eisen, 1977 [298]	☐	☐	☑	☑	☐	☐
Eisen, 1974 [490]	☐	☐	☑	☑	☐	☐

Table 181. Cubital Tunnel Syndrome–Study Design

Article	Centers	Cubital tunnel groups	Cubital tunnel patients	Negative groups	Negative subjects	Prospective or retrospective design	Level of reporting	Could sensitivity and specificity be determined?
Montagna, 2000 [227]	Single	1	10	1	15	NR	Counts	Reported by authors
Ellemann, 1999 [495]	Multiple (<5)	1	39	0	0	NR	Patient level	Reported by authors (note: normed to contralateral hand)
Merlevede, 1999 [496]	Single	1	10	1	60	NR	Patient level	Calculated by ECRI
Chiou, 1998 [497]	Single	1	14	1	10	NR	Summary	No: only summary statistics reported
Dellon, 1997 [107]	Single	1	42	1	52	NR	Counts	Control data not reported
Kaneko, 1997 [250]	Single	1	10	1	46	NR	Summary	No: only summary statistics reported
Britz, 1996 [498]	Multiple (<5)	1	27	1	10	Prospective	Patient level	Reported by authors
Kingery, 1995 [499]	Single	1	42	1	40	NR	Counts	Reported by authors
Tassler, 1995 [115]	Single	1	13	1	14	Retrospective	Counts	Reported by authors
Novak, 1994 [500]	Single	1	32	1	33	NR	Counts	Reported by authors
Uchida, 1993 [501]	Single	1	60	0	0	Retrospective	Counts	No: no control group
Robinson, 1992 [502]	Single	1	22	0	0	Retrospective	Counts	No: no control group
So, 1989 [173]	Single	1	15	1	20	NR	Counts	Reported by authors
Buehler, 1986 [503]	Single	1	13	0	0	NR	Counts	No: no control group
Kimura, 1984 [55]	Single	1	44	1	25	NR	Counts	Control data not reported
Tackmann, 1984 [54]	Single	1	103	1	52	NR	Counts	Control data not reported
Odusote, 1979 [489]	Single	4	237	1	230	NR	Counts	Reported by authors
Ring, 1979 [504]	Multiple (<5)	1	32	1	50	Prospective	Counts	Control data not reported
Eisen, 1977 [298]	Single	1	18	1	60	NR	Patient level	Calculated by ECRI
Eisen, 1974 [490]	Single	1	30	1	48 limbs	Prospective	Counts	Control data not reported

Table 182. Cubital Tunnel Syndrome–Patient Groups

Article	Disorder type	Patient selection	Number of patients	Percent female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (mths)	Shortest duration	Longest duration	Patient co-morbidities reported?
Montagna, 2000 [227]	Carpal tunnel syndrome	Unspecified diagnosis	30	NR							No
Montagna, 2000 [227]	Cubital tunnel syndrome	Unspecified diagnosis	10	NR							No
Montagna, 2000 [227]	Normal	Healthy volunteers	15	NR							No
Ellemann, 1999 [495]	Cubital tunnel syndrome	Symptoms/ presented	39	54	46	21	72				Yes
Merlevede, 1999 [496]	Other	Other	24	NR							Yes
Merlevede, 1999 [496]	Normal	Healthy volunteers	60	63	33.6	13	61				Yes
Merlevede, 1999 [496]	Cubital tunnel syndrome	Simple nerve conduction	10	NR							Yes
Chiou, 1998 [497]	Cubital tunnel syndrome	Symptoms/ presented	14	43	50	21	80				No
Chiou, 1998 [497]	Normal	Healthy volunteers	10	50	45	30	60				No
Dellon, 1997 [107]	Normal	Other	52	62							Yes
Dellon, 1997 [107]	Carpal tunnel syndrome	Unspecified diagnosis	72	NR							Yes
Dellon, 1997 [107]	Cubital tunnel syndrome	Unspecified diagnosis	42	NR							Yes
Kaneko, 1997 [250]	Carpal tunnel syndrome	Unspecified diagnosis	15	87		40	54				Yes
Kaneko, 1997 [250]	Cubital tunnel syndrome	Unspecified diagnosis	10	20		45	56				Yes
Kaneko, 1997 [250]	Normal	Healthy volunteers	46	22		25	45				Yes
Kaneko, 1997 [250]	Combined WRUEDs	Unspecified diagnosis	10	50		40	62				Yes
Britz, 1996 [498]	Cubital tunnel syndrome	Symptoms/ presented	27	11	51	31	69				No
Britz, 1996 [498]	Normal	Healthy volunteers	10	NR							No

Article	Disorder type	Patient selection	Number of patients	Percent female	Mean age	Age of youngest	Age of oldest	Duration of condition before treat-ment (mths)	Shortest duration	Longest duration	Patient co-morbidities reported?
Kingery, 1995 [499]	Cubital tunnel syndrome	Symptoms/ presented	42	NR	51	32	72				No
Kingery, 1995 [499]	Other	Other	40	NR	47	28	76				No
Tassler, 1995 [115]	Carpal tunnel syndrome	Unspecified diagnosis	14	NR							Yes
Tassler, 1995 [115]	Cubital tunnel syndrome	Unspecified diagnosis	13	NR							Yes
Novak, 1994 [500]	Normal	Healthy volunteers	33	39	41	23	59				No
Novak, 1994 [500]	Cubital tunnel syndrome	Simple nerve conduction	32	41	46	24	81				No
Uchida, 1993 [501]	Cubital tunnel syndrome	Unspecified diagnosis	60	23	48.6	17	74				Yes
Robinson, 1992 [502]	Cubital tunnel syndrome	Unspecified diagnosis	22	55		18	65	7.5	16		No
So, 1989 [173]	Normal	Healthy volunteers	20	NR							No
So, 1989 [173]	Carpal tunnel syndrome	Unspecified diagnosis	22	NR							No
So, 1989 [173]	Cubital tunnel syndrome	Unspecified diagnosis	15	NR							No
Buehler, 1986 [503]	Cubital tunnel syndrome	Unspecified diagnosis	13	NR							Yes
Kimura, 1984 [55]	Normal	Healthy volunteers	25	40	40.8	20	66				No
Kimura, 1984 [55]	Cubital tunnel syndrome	Symptoms/ presented	44	32	41.6	18	64				No
Tackmann, 1984 [54]	Normal	Healthy volunteers	52	NR	a-39	20	69				No
Tackmann, 1984 [54]	Cubital tunnel syndrome	Symptoms/ presented	103	NR	a-43	12	76		0	72	No
Odusote, 1979 [489]	Other	Other	230	NR	48.8	17	88				Yes
Odusote, 1979 [489]	Cubital tunnel syndrome	Symptoms/ presented	NR	NR	56.1	21	83	34.4	1	636	Yes
Odusote, 1979 [489]	Cubital tunnel syndrome	Symptoms/ presented	NR	NR	49.8	30	78	9.6	0	108	Yes

Article	Disorder type	Patient selection	Number of patients	Percent female	Mean age	Age of youngest	Age of oldest	Duration of condition before treatment (mths)	Shortest duration	Longest duration	Patient co-morbidities reported?
Odusote, 1979 [489]	Cubital tunnel syndrome	Symptoms/ presented	NR	NR	49.2	16	70	11.2	0	108	Yes
Odusote, 1979 [489]	Cubital tunnel syndrome	Symptoms/ presented	NR	NR	45.6	22	77	16.4	0	120	Yes
Ring, 1979 [504]	Cubital tunnel syndrome	Workers at risk	32	6	40.6						No
Ring, 1979 [504]	Normal	Healthy volunteers	50	48	27.2						No
Eisen, 1977 [298]	Normal	Healthy volunteers	60	NR	41.5	11	74				No
Eisen, 1977 [298]	Carpal tunnel syndrome	Complex objective standard	30	NR	56.1	21	76				No
Eisen, 1977 [298]	Combined WRUEDs	Other	23	NR	50	7	68				No
Eisen, 1977 [298]	Cubital tunnel syndrome	Complex objective standard	18	NR	51.7	26	65				No
Eisen, 1974 [490]	Normal	Healthy volunteers	NR	NR	43.7	19	78				No
Eisen, 1974 [490]	Cubital tunnel syndrome	Symptoms/ presented	30	50	42.9	17	66				No

a—Study reported median age rather than mean age

Table 183. Cubital Tunnel Syndrome–Inclusion and Exclusion Criteria

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Montagna, 2000 [227]	Diagnosed with carpal tunnel or cubital tunnel.	None reported
Ellemann, 1999 [495]	Admitted for surgical treatment for symptoms consistent with sulcus compression in the ulnar nerve at the elbow: weakness of the small hand muscles innervated by the ulnar nerve, sensory disturbances, paresthesia, and tingling or pain in the ulnar, palmar side of the hand or little finger.	Exposure to vibration within the previous 24 hours, systemic illness, possible secondary neuropathies, polyneuropathy.
Merlevede, 1999 [496]	Cubital tunnel patients: Obvious ulnar neuropathy at the elbow. Motor or sensory deficit, and either 1) partial/complete motor conduction block across the elbow, or 2) MCV across the elbow <50 m/s. Other patients: Other neurological disorders but no symptoms of ulnar neuropathy.	None reported
Chiou, 1998 [497]	Complaints of aching pain and numbness over the medial elbow, ulnar side of the forearm, and ring and little fingers.	None reported
Dellon, 1997 [107]	Already diagnosed with either carpal tunnel or cubital tunnel. Diagnosis was based on the clinical history and physical examination, which included positive provocative testing, positive Tinel's sign at the wrist or elbow, abnormal tuning fork perception.	Cervical radiculopathy, diabetes, thoracic outlet syndrome, thyroid disease, collagen vascular disease, using narcotics or antidepressants.
Kaneko, 1997 [250]	Group 01: Coexisting entrapment neuropathy and cervical cord compression demonstrated by MRI. Group 02: Diagnosed with carpal tunnel. Group 03: Diagnosed with cubital tunnel. Group 04: Control group, no subjective symptoms or neurologic findings associated with peripheral or central lesions.	None reported
Britz, 1996 [498]	History and physical exam consistent with cubital tunnel syndrome. Symptoms included numbness and paresthesias of the ring and little fingers and weakness and clumsiness of the hand.	None reported
Kingery, 1995 [499]	Chronic paresthesias in the ulnar distribution	Carpal tunnel, brachial plexopathy, cervical radiculopathy, polyneuropathy.
Tassler, 1995 [115]	Symptomatic patients who had been diagnosed, had not been cured by nonoperative methods, and later received surgery for the condition.	Diabetes, alcoholism, other toxicity.
Novak, 1994 [500]	Patients diagnosed with cubital tunnel based on symptoms and nerve conduction tests. Symptoms included complaints of paresthesia and numbness in the ulnar nerve distribution. Nerve conduction criteria was conduction velocity across the elbow <50 m/s and a decrease of 15% at the elbow.	Previous surgery, or brachial plexus decompression.
Uchida, 1993 [501]	Signs and/or symptoms of high ulnar nerve palsy, and MCV across the elbow <48 m/s.	Radiculopathy, other signs and symptoms.
Robinson, 1992 [502]	Pre-operatively evaluated patients with cubital tunnel syndrome. Clinical diagnosis as well as positive nerve conduction for cubital tunnel based on a reduction to two-third of normal.	Intrinsic atrophy

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
So, 1989 [173]	Patients were selected from referrals to the lab. Carpal tunnel: Confident clinical diagnosis based on history of pain and paresthesias in the hand and fingers, and physical findings that localized the pathology to the median nerve, e.g. sensory alteration or weakness in a median nerve distribution, Tinel's, or Phalen's. Cubital tunnel: Confident clinical diagnosis based on paresthesias or numbness in an ulnar nerve distribution, usually accompanied by weakness in ulnar-innervated muscles. In those patients without weakness on examination, the diagnosis of ulnar neuropathy at the elbow was not made unless there was percussion sensitivity at the cubital tunnel or the ulnar groove, or exacerbation of symptoms with elbow flexion.	None reported
Buehler, 1986 [503]	History and clinical findings consistent with cubital tunnel, confirmed by nerve conduction tests.	Generalized neuropathy, cervical disc disease, arthritis, elbow trauma.
Kimura, 1984 [55]	Patients with frank clinical signs and symptoms suggestive of cubital tunnel syndrome.	History of trauma, clinical or x-ray evidence of joint deformity or disease that predisposed to peripheral neuropathy.
Tackmann, 1984 [54]	Referred to lab with a clinical diagnosis of cubital tunnel syndrome.	None reported
Odusote, 1979 [489]	Symptomatic cubital tunnel syndrome.	Ulnar nerve lesion at the wrist, brachial plexus lesion, thoracic outlet syndrome, disease of the cervical roots, anterior horn cell disease, generalized polyneuropathy, familial multiple entrapment neuropathy, exposure to neurotoxins.
Ring, 1979 [504]	Sample of diamond polishers referred by their union for study participation. Not known to have major illness or ulnar nerve damage at the time of referral.	None reported
Eisen, 1977 [298]	Carpal tunnel patients: Sensory symptoms limited to one or both hands, normal ulnar sensory latency (<2.8 ms), normal ulnar sensory amplitude (>8.4 uV), and at least three of the following five criteria: 1) Sensory signs restricted to median distribution; 2) Weakness or wasting of the APB muscle; 3) Median DML >4.5 ms; 4) Median DSL >2.7 ms; 5) Median SNAP amplitude <8.6 uV or median SNAP duration >2.4 ms. Cubital tunnel patients: Sensory symptoms limited to one or both hands, normal median sensory latency (<2.7 ms), normal median sensory amplitude (>8.6 uV), and at least three of the following six criteria: 1) Sensory signs restricted to ulnar distribution; 2) Weakness or wasting of the ulnar-innervated muscles of the hand; 3) Ulnar DML >4.0 ms; 4) Ulnar proximal motor latency (stimulation just above the elbow) >8.9 ms; 5) Ulnar DSL >2.8 ms; 6) Ulnar SNAP amplitude <8.4 uV or ulnar SNAP duration >2.1 ms. Patients with proximal lesions: Sensory symptoms limited to one or both hands, but did not meet criteria for either carpal tunnel or cubital tunnel.	Subjects were excluded from the control group if there was neuromuscular disease, diabetes, alcoholism, peripheral neuropathy, or systemic dysfunction.
Eisen, 1974 [490]	Referred to lab because of subjective complaints of numbness and tingling limited to the ring and little fingers, and present for three or more weeks.	Definite muscle wasting or weakness, cervical disk disease, thoracic outlet syndrome, carpal tunnel, ulnar compression at the wrist, evidence for generalized neuropathy.

Question #2. What are the specific indications for surgery for cubital tunnel syndrome?

There is no published information available that directly addressed the question of specific indications for surgery for cubital tunnel syndrome. Therefore, this section will present the characteristics of patients who have received surgery as described in published studies. Because patients enrolled in clinical trials may differ from the general population of patients encountered in general practice, these data may not accurately reflect the general population of patients who have received surgery, and may be of limited utility when selecting candidates for surgery in the future. However, the present analysis is the most comprehensive guide available.

Evidence Base

For this question, we examined controlled trials and case series that described patients being surgically treated for cubital tunnel syndrome. We identified thirty-two such studies that included a total of 1,820 patients.

Patient demographics

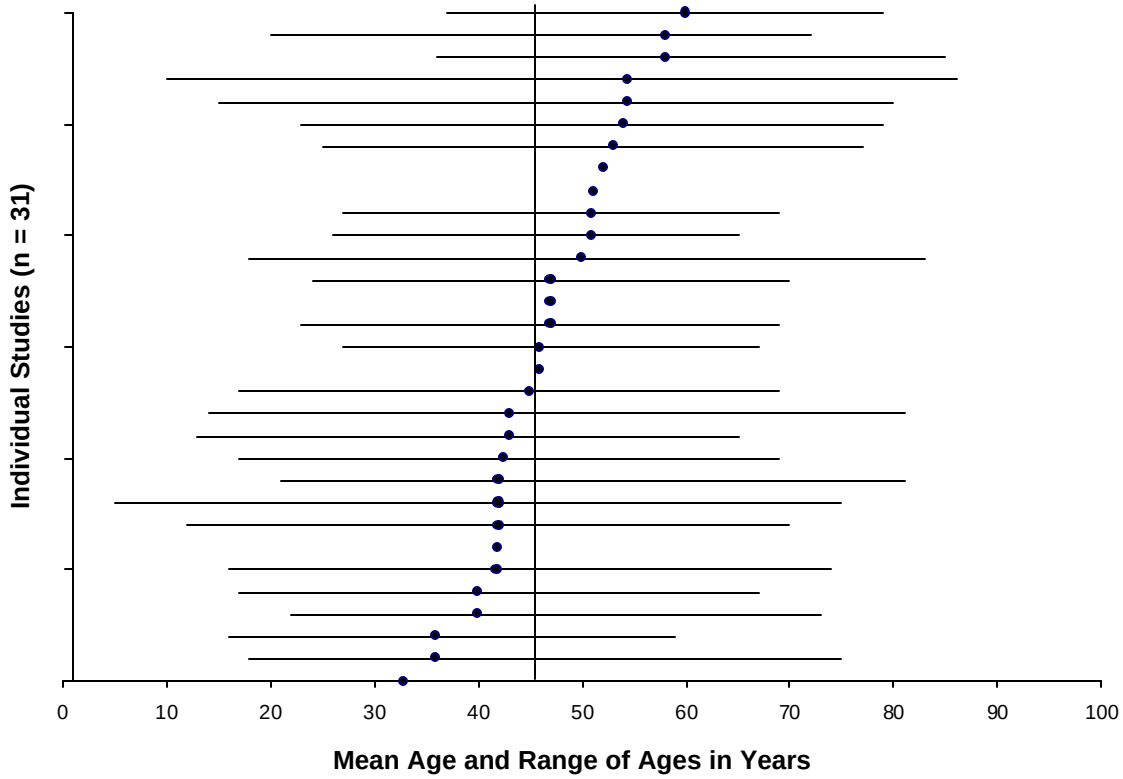
Table 184 shows the mean age, age range, and gender composition of the patient groups included in the trials. Thirty-one of the 32 studies (96.9%) reported information about the ages of the patients, and 29 of the studies (90.6%) reported information about the gender composition of the patient groups. The mean ages and age range are shown in Figure 45. In general, patients surgically treated for cubital tunnel syndrome were middle aged (a mean of 46.4 years of age), but ages ranged from under ten years old to almost 90 years of age. The percentages of women in the patient groups are shown in Figure 46. The patients were predominantly male (62%). None of the studies reported that patients were excluded/included on the basis of either age or gender.

Table 184. Ages and gender composition of patient groups receiving surgery for cubital tunnel syndrome

Study	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Artico 2000 [505]	236	140	96	40.7	Mean	42.5	17	69
Caputo 2000 [506]	20	13	7	35.0	Mean	47	24	70
Lascar 2000 [425]	71	59	12	16.9	Mean	50	18	83
Greenwald 1999 [507]	31	29	2	6.5	Mean	60	37	79
Tsai 1999 [508]	76	29	47	61.8	Median	42	21	81
Asami 1998 [509]	35	25	10	28.5	Mean	54.4	15	80
Seradge 1998 [510]	160	99	61	38.1	Mean	43	14	81
Glowacki 1997 [511]	40	17	23	57.5	Mean	40	17	67
Nouhan 1997 [512]	31	18	13	41.9	Mean	46	27	67
Tada 1997 [513]	50	44	6	12.0	Mean	58	20	72
Geutjens 1996 [514]	52	NR	NR	NR	Mean	58	36	85
Steiner 1996 [515]	41	29	12	29.3	Mean	46	NR	NR
Messina 1995 [516]	30	22	8	26.7	Mean	54	23	79
Nathan 1995 [517]	164	74	90	54.8	Mean	41.9	NR	NR
Pasque 1995 [518]	64	40	24	37.5	Mean	42	5	75
Manske 1992 [519]	26	15	11	42.3	Mean	40	22	73
Barrios 1991 [520]	53	37	16	30.2	Mean	42	12	70
Froimson 1991 [521]	34	6	28	82.4	Mean	47	NR	NR
Rogers 1991 [522]	14	8	6	42.9	Mean	36	16	59
Heithoff 1990 [523]	39	22	17	43.6	Mean	41.8	16	74

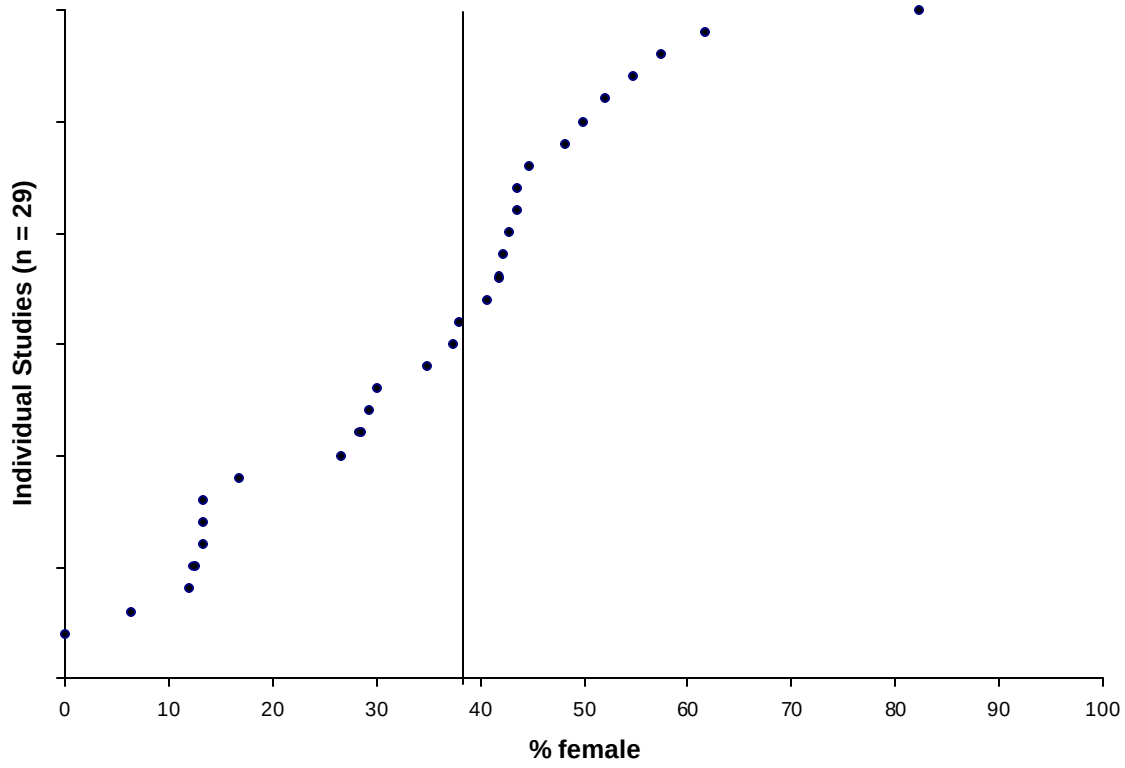
Study	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Goldberg 1989 [524]	46	22	24	52.2	Mean	47	23	69
Janes 1989 [525]	30	26	4	13.3	Mean	51	27	69
Kleinman 1989 [526]	47	26	21	44.7	Mean	45	17	69
Friedman 1986 [527]	22	22	0	0.0	Mean	52.1	NR	NR
Leffert 1982 [528]	38	NR	NR	NR	Mean	32.9	14	73
Foster 1981 [529]	48	29	19	50.0	Mean	51.2	NR	NR
Chan 1980 [530]	235	214	21	43.7	Mean	54.5	10	86
Craven 1980 [531]	30	26	4	13.3	Mean	53	25	77
Eaton 1980 [532]	16	12	4	13.3	Mean	36	18	75
Froimson 1980 [52]	29	27	2	12.5	Mean	43	13	65
Miller 1980 [533]	12	0	12	48.3	Mean	51	26	65

Figure 45. Mean ages and ranges of ages of patients treated surgically for cubital tunnel syndrome



The vertical line indicates the mean age

Figure 46. Gender composition of patient groups treated surgically for cubital tunnel syndrome



The vertical line indicates the mean % of females

Signs and symptoms

The signs and symptoms of patients before surgical treatment for cubital tunnel syndrome are listed in Table 185. The number of studies reporting on the proportion of patients in the study group having each sign and symptom are listed in Table 186 and shown in Figure 47. The mean percentage of patients reported to have each sign and symptom, and the range of reported percentages, are shown in Figure 48. In addition to the clinical signs and symptoms, some studies reported on the conduction velocity of the ulnar nerve. Nine of the 32 studies simply reported that all of the patients treated with surgery had "abnormal" nerve conduction velocities. One of the 32 studies reported that 31% of the patients had "abnormal" nerve conduction velocities. The definition of abnormal varied from study to study, and often no definition was supplied. Five of the 32 studies did not measure the nerve conduction velocity of the ulnar nerve before treating the patients with surgery. In 17 of the 32 studies it was not clear from the reported information whether nerve conduction velocities were measured.

Fifteen of the 32 studies reported how long the patients had had symptoms before being treated with surgery. The reported mean durations and ranges are shown in Figure 49. On average, patients had symptoms for 10 to 24 months before treatment.

Because fewer than 40% of the studies reported information about whether their patients had any specific signs and symptoms or other characteristics, the extent to which the available data reflects the typical cubital tunnel syndrome patient cannot be determined.

Table 185. Signs and symptoms of patients treated with surgery for cubital tunnel syndrome

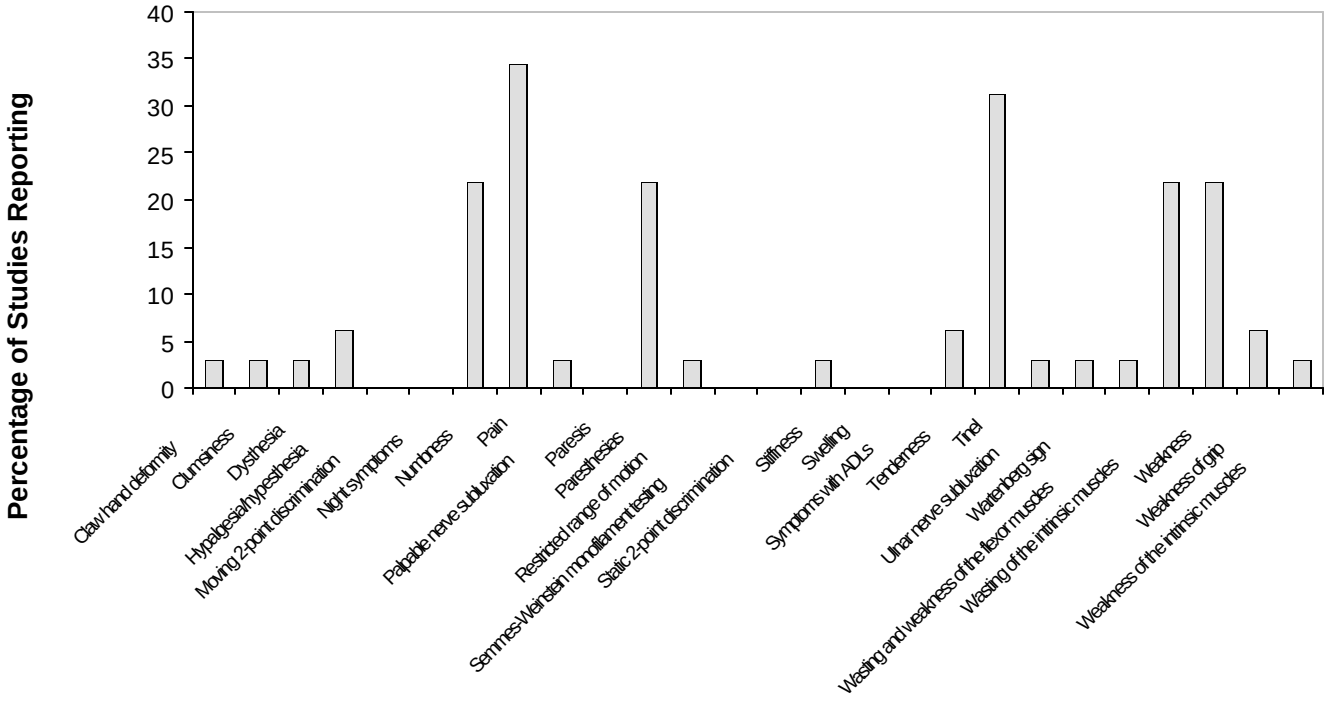
Study	Number of Patients	Sign or symptom	Number of patients with sign or symptom	Percent of Patients
Artico 2000 [505]	236	Pain	104	44.1
Lascar 2000 [425]	71	Pain	13	18.3
Messina 1995 [516]	30	Pain	30	100.0
Nathan 1995 [517]	164	Pain	78	47.6
Manske 1992 [519]	26	Pain	26	100.0
Rogers 1991 [522]	14	Pain	14	100.0
Goldberg 1989 [524]	46	Pain	15	32.6
Foster 1981 [529]	48	Pain	31	64.5
Chan 1980 [530]	235	Pain	102	43.4
Eaton 1980 [532]	16	Pain	14	87.5
Miller 1980 [533]	12	Pain	7	58.3
Lascar 2000 [425]	71	Tinel's sign	45	63.4
Greenwald 1999 [507]	31	Tinel's sign	24	77.4
Seradge 1998 [510]	160	Tinel's sign	160	100.0
Nouhan 1997 [512]	33	Tinel's sign	30	90.9
Nathan 1995 [517]	164	Tinel's sign	43	26.2
Rogers 1991 [522]	14	Tinel's sign	14	100.0
Goldberg 1989 [524]	46	Tinel's sign	37	80.4
Foster 1981 [529]	48	Tinel's sign	27	56.2
Chan 1980 [530]	235	Tinel's sign	48	20.4
Eaton 1980 [532]	16	Tinel's sign	11	68.8
Lascar 2000 [425]	71	Numbness	23	32.4
Steiner 1996 [515]	41	Numbness	24	58.5
Goldberg 1989 [524]	46	Numbness	30	65.2
Foster 1981 [529]	48	Numbness	41	85.4
Chan 1980 [530]	235	Numbness	113	48.0
Eaton 1980 [532]	16	Numbness	4	25.0
Miller 1980 [533]	12	Numbness	12	100
Artico 2000 [505]	236	Paresthesias	219	92.8
Greenwald 1999 [507]	31	Paresthesias	24	77.4
Steiner 1996 [515]	41	Paresthesias	14	34.1
Foster 1981 [529]	48	Paresthesias	42	87.5
Chan 1980 [530]	235	Paresthesias	200	85.1
Craven 1980 [531]	30	Paresthesias	20	66.7
Eaton 1980 [532]	16	Paresthesias	9	56.3
Artico 2000 [505]	236	Wasting of the intrinsic muscles	156	66.1
Seradge 1998 [510]	160	Wasting of the intrinsic muscles	11	6.9
Steiner 1996 [515]	41	Wasting of the intrinsic muscles	30	73.2
Nathan 1995 [517]	164	Wasting of the intrinsic muscles	5	3.0
Goldberg 1989 [524]	46	Wasting of the intrinsic muscles	15	32.6
Foster 1981 [529]	48	Wasting of the intrinsic muscles	10	20.8
Chan 1980 [530]	235	Wasting of the intrinsic muscles	200	85.1
Artico 2000 [505]	236	Weakness	156	66.1
Lascar 2000 [425]	71	Weakness	31	43.7
Steiner 1996 [515]	41	Weakness	36	87.8

Study	Number of Patients	Sign or symptom	Number of patients with sign or symptom	Percent of Patients
Nathan 1995 [517]	164	Weakness	3	1.8
Foster 1981 [529]	48	Weakness	30	62.5
Eaton 1980 [532]	16	Weakness	4	25.0
Miller 1980 [533]	12	Weakness	12	100.0
Chan 1980 [530]	235	Hypalgesia/hypesthesia	216	91.9
Miller 1980 [533]	12	Hypalgesia/hypesthesia	12	100.0
Chan 1980 [530]	235	Tenderness	95	40.4
Eaton 1980 [532]	16	Tenderness	13	81.3
Messina 1995 [516]	30	Weakness of grip	30	100
Chan 1980 [530]	235	Weakness of grip	187	79.6
Chan 1980 [530]	235	Claw hand deformity	20	8.5
Lascar 2000 [425]	71	Clumsiness	6	8.5
Foster 1981 [529]	48	Dysthesia	39	87
Eaton 1980 [532]	16	Palpable nerve subluxation	3	18.8
Eaton 1980 [532]	16	Restricted range of motion	5	31.3
Lascar 2000 [425]	71	Stiffness	7	9.9
Nathan 1995 [517]	164	Ulnar nerve subluxation	4	2.4
Craven 1980 [531]	30	Wartenberg sign	18	60.0
Chan 1980 [530]	235	Wasting and weakness of the flexor muscles	37	15.7
Chan 1980 [530]	235	Weakness of the intrinsic muscles	200	85.1

Table 186. Reporting of signs and symptoms by studies of surgery to treat cubital tunnel syndrome

Sign or symptom	Number of studies reporting
Pain	11
Tinel's sign	10
Numbness	7
Paresthesias	7
Wasting of the intrinsic muscles	7
Weakness	7
Hypalgesia/hypesthesia	2
Tenderness	2
Weakness of grip	2
Claw hand deformity	1
Clumsiness	1
Dysthesia	1
Palpable nerve subluxation	1
Restricted range of motion	1
Stiffness	1
Ulnar nerve subluxation	1
Wartenberg sign	1
Wasting and weakness of the flexor muscles	1
Weakness of the intrinsic muscles	1
Moving 2-point discrimination	0
Night symptoms	0
Paresis	0
Semmes-Weinstein monofilament testing	0
Static 2-point discrimination	0
Swelling	0
Symptoms with ADLs	0

Figure 47. Percentage of studies reporting on the proportion of patients with each sign and symptom



Patient signs, symptoms, and characteristics

Figure 48. Mean percentage and range of percentages of patients reported to have each sign and symptom

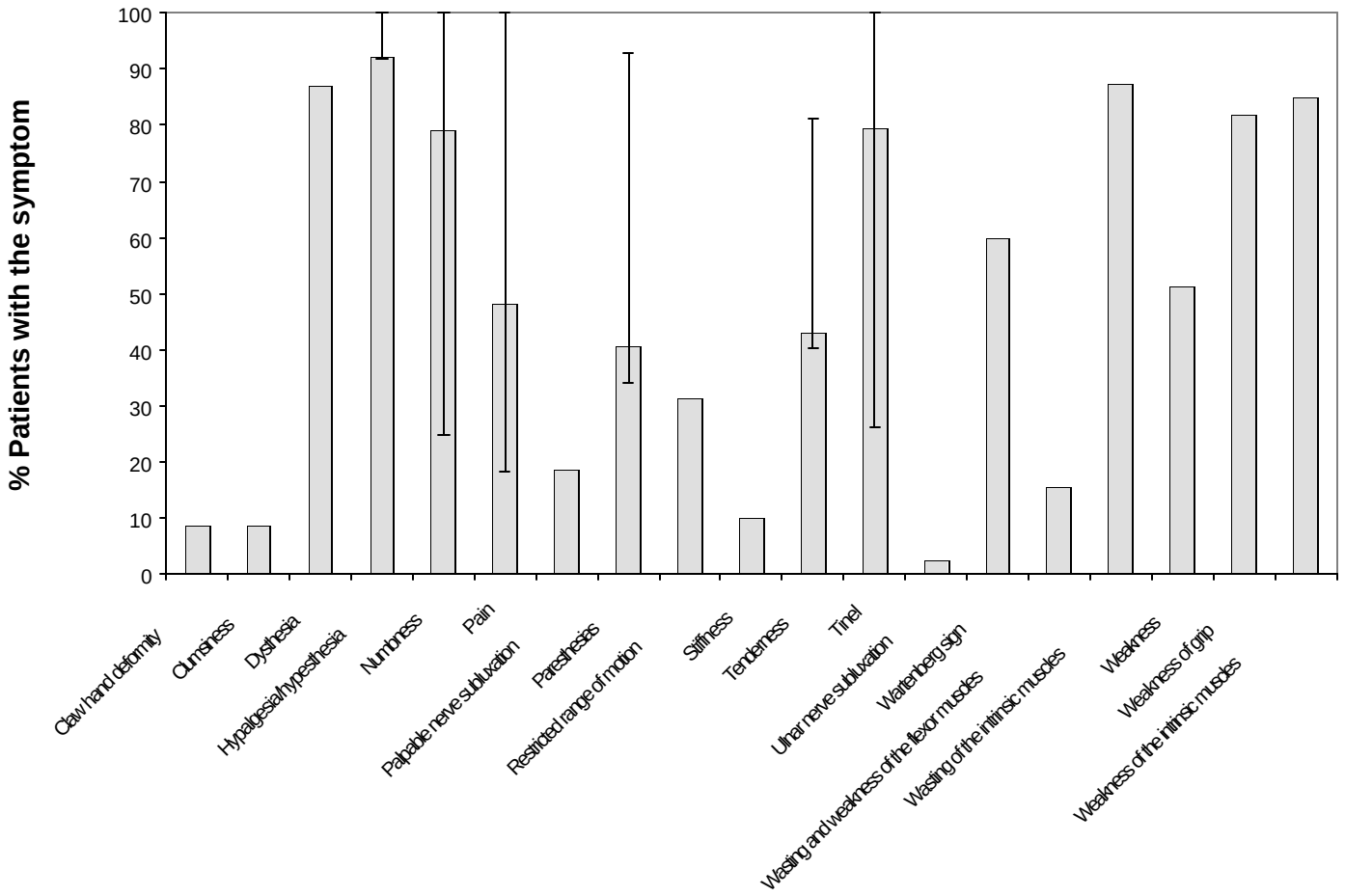
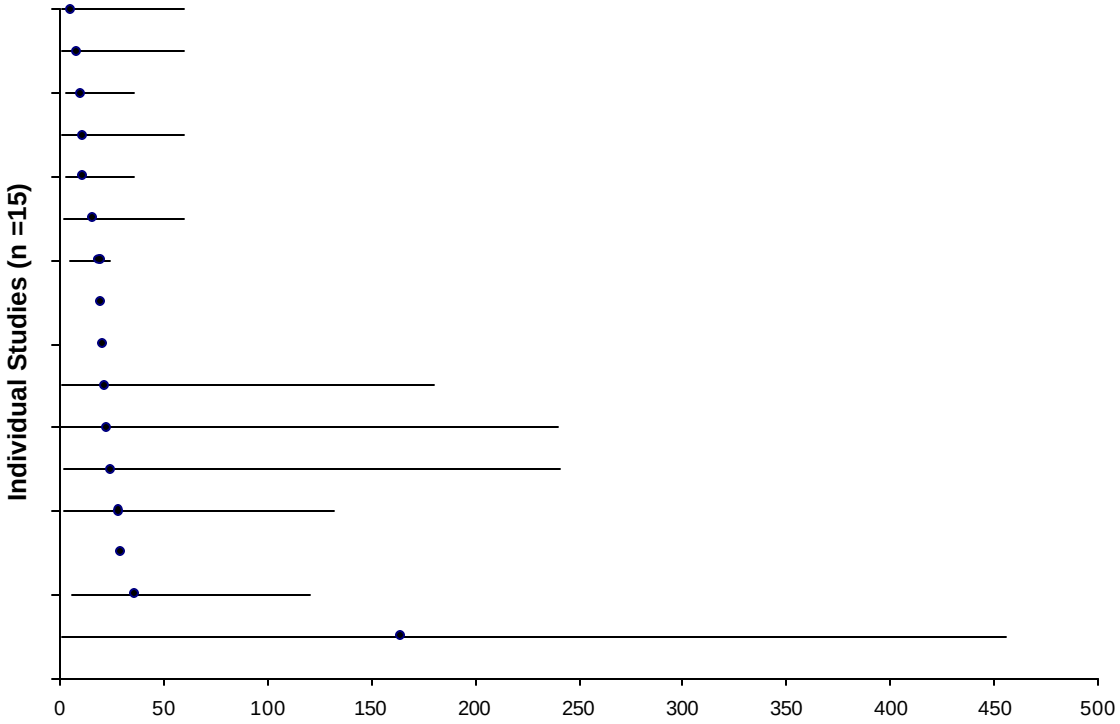


Figure 49. Mean and range of duration of symptoms before treatment



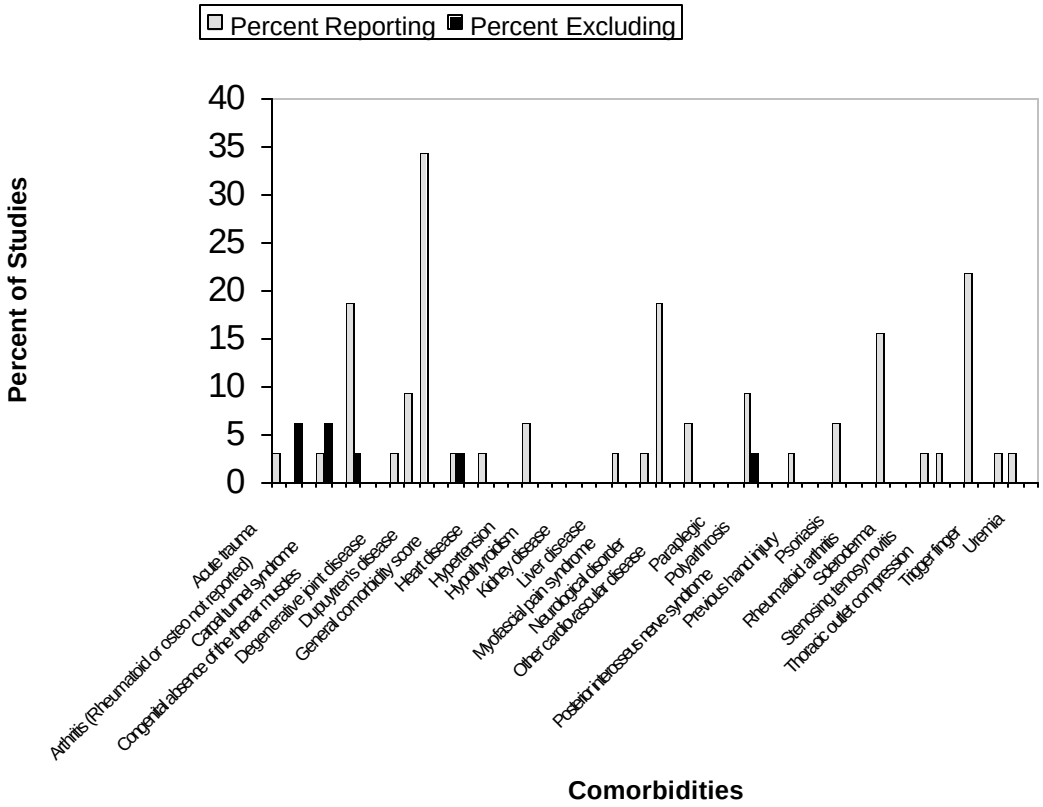
Occupations and work history

Of the 32 studies describing patients receiving surgery for cubital tunnel syndrome only one study reported the specific occupations of its patient group. Six studies reported on the percentages of patients receiving Workers' Compensation. One study reported on the percentage of patients able to work, and one study reported on the percentage of patients not able to work. Because so few studies reported data pertaining to the occupations and work history of their patient groups, it is difficult to make generalizable statements.

Comorbidities

The number of patients with comorbidities is incompletely reported in published studies of surgical treatment for cubital tunnel syndrome, as can be seen in Figure 50. The number of studies reporting the presence of a given comorbidity never exceeds 35% of the available studies. Further complicating analysis is the fact that some studies exclude patients with comorbidities. Because comorbidities are both underreported and patients with them may be excluded from clinical trials, it is difficult to reach conclusions about the presence of comorbidities among patients receiving surgery for cubital tunnel syndrome or the impact of comorbidities on whether a patient is a candidate for surgery.

Figure 50. Percentage of studies reporting and excluding comorbidities



Conclusions

Thirty-two studies of patients who received surgery for cubital tunnel syndrome were identified. Due to a lack of reported data, few trends or characteristics of patients who received surgery could be identified. The mean age of patients who received surgery for cubital tunnel syndrome was 46 years. The patients were slightly more likely to be male (62% male), and on average had symptoms 10 to 24 months before receiving surgical treatment.

Question#3. What are the relative benefits and harms of surgery for persons with cubital tunnel syndrome?

The scope of our answer to this question is determined by the scope of the published literature. The relevant literature consists of one study that compares anterior transposition to decompression surgery, one study that compares anterior transposition to epicondylectomy, and one study that compares variants of anterior transposition (see the Introduction for a description of these surgical procedures). Therefore, one can only address the relative benefits and harms of these surgical procedures. There are no published studies that compared surgery to placebo or untreated groups. Because of this, the absolute benefit of surgery cannot be determined; only the relative benefits of different types of surgery can be inferred.

Evidence base

We considered only controlled trials that evaluated treatments for patients with cubital tunnel syndrome for this section of the report. Six studies were retrieved. Three did not meet the inclusion criteria (See the Inclusion criteria section) and were excluded. These three studies and their reasons for exclusion are listed in Table 187. The remaining three studies, which included a total of 301 patients, were included in the answer to this question. The outcomes reported by these studies are listed in Table 187.

Table 187. Excluded studies

Study	Reason for exclusion
Tsai 1995 [65]	Reports on patients who are reported on elsewhere.[508]
Antoniadis 1997 [534]	Reports on only a subset of the patients entered into the trial.
Gabel 1990 [535]	Reports on only a subset of the patients entered into the trial.

Quality of the literature

Internal validity

Details of the study designs relevant to the internal validity of the trials are shown in Table 188. Two of the three trials did not randomly assign patients to treatment groups. If patients are not randomly assigned to groups, there may be important differences between these groups that could contribute to any observed differences in outcomes.

One of the three trials was prospective and one trial was retrospective. The third trial may have also been retrospective, but the study design was not explicitly described in the published article. Retrospective studies are more prone to bias than are prospective studies because the former are necessarily performed on a select group of patients.

One of the three trials used physicians blinded to the type of treatment to evaluate the patients. The other two trials did not employ any type of blinding. Lack of blinding of the patient to the type of treatment, in particular when using subjective outcome measures, can alter measurements of treatment effect because patients might unconsciously rate their condition differently in order to please the clinician.[474] However, the nature of the surgical treatments used in these trials precludes blinding of the patients so we did not consider this a study weakness. We did consider lack of blinding of the evaluating physician to be a weakness. This is because if the evaluating physician is aware of the treatment given, it is possible that he/she may unconsciously bias the patient's responses by giving leading instructions.[474]

Two of the trials did not analyze their data according to the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a highly conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. For the trial by Geutjens 1996, we were able to re-calculate the data in an intent-to-treat fashion. We were not able to do this for the trial by Chan 1980 because the data were presented in terms of numbers of arms, but the initial total number of arms was not reported, and the attrition data was in terms of numbers of patients.

Both Chan 1980 and Asami 1999 reported data in terms of the number of arms treated, not the number of patients treated. The validity of this approach cannot be determined. It violates the assumption of independence that underlie the statistical tests. This typically leads to underestimation of standard errors and spurious statistically significant results (Type I errors). For the purposes of this analysis, we have ignored the assumption of independence. In the study by Chan 1980, there were only 35 bilateral cases out of 235 cases in total (14.8%), and in the study by Asami 1998 there were only 6 bilateral cases out of 41 cases in total (14.6%). Therefore, the violation of the assumption of independence in these studies may be relatively inconsequential.

Table 188. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Blinding	% Attrition	Intent to treat analysis	% Compliance
Asami 1998 [509]	35	1	NR	CT	No	0	Yes	NA
Geutjens 1996 [514]	52	1	No	RCT	Rater	17.3	No; corrected for	NA
Chan 1980 [530]	214	1	NR	Retro	No	6.5	No	NA

CT = controlled trial
RCT = randomized controlled trial
Retro = retrospective
NA = not applicable
NR = not reported

Generalizability

Characteristics of the patient groups enrolled in the three trials are shown in Table 189. Studies of the epidemiology of cubital tunnel syndrome, and our analysis of patients enrolled in clinical trials of surgery to treat cubital tunnel syndrome (see the answer to Question #2), have found that patients are typically in their forties and fifties, and are more likely to be male than female. The patients enrolled in these three trials fit this profile: the mean ages of the patients in all three trials were in the late fifties, with a range of 15 to 85. The patients were predominantly male. Thus, the results of the trials can be generalized to patients other than those enrolled in the trials.

None of the studies reported any information as to the employment status, work history, or occupations of the patients.

Conclusions

All three trials appear to be generalizable. The trial by Geutjens 1996 appears to be well-designed. However, the other two trials have weaknesses in design (not randomized, not blinded, retrospective) that may introduce bias into the results and weaken the conclusions drawn from the data.

Table 189. Generalizability information: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of conditon mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditons	% Patients with peripheral neruopathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Asami 1998 [509]	35	55 (15-80)	28.5	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Geutjens 1996 [514]	52	58 (36-85)	NR	NR	NR	0	NR	NR	NR	NR	NR	No	No
Chan 1980 [530]	214	54.5 (10-86)	23.4	1.6 (1-456)	2.3	10.7	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Success of Treatment

Three trials of a total of 301 patients reported on the relative success of different surgical techniques. The studies all used patient-rated categorical questionnaires to determine the success of the treatment. The reported results are shown in
Table 190.

Because no studies compared the same therapies, no meta-analysis could be performed. We calculated p-values and effect sizes (Hedges' d) for each study by collapsing the scales into dichotomous outcomes (excellent-better vs. same-worse). For the study by Asami 1999, we calculated the effect size (Hedges' d) using a method described by Torgersen.[536] For the trial by Geutjens 1996, we calculated the effect sizes and the p-value using a conservative method to account for the attrition as discussed in the section on study quality. We were unable to correct for attrition in our analysis of the data from the trial by Chan 1980 as explained in the section on study quality. The results of the studies are summarized in Table 191.

Asami 1998 found that transposition with preservation of extrinsic vessels led to statistically significantly better global outcomes than transposition without preservation of extrinsic vessels, but the calculated effect size did not reach statistical significance. This apparent discrepancy can be attributed to the fact that tests of statistical significance depend upon two factors, an effect size and the number of patients. Thus, a trial with a very small, statistically non-significant effect size can be found to be statistically significant simply by increasing the number of patients.

The success of treatment with anterior transposition as compared to the other types of surgery evaluated (decompression and medial epicondylectomy) is summarized in Figure 51 and Figure 52. Figure 51 displays the p-values of the statistical tests, while Figure 52 shows the effect sizes we calculated. The data from the study by Guetjens 1996 indicates that patients treated with epicondylectomy have statistically significantly improved outcomes compared to patients treated with anterior transposition. The difference between the two groups in the study by Chan 1980 did not reach statistical significance. The study had sufficient statistical power to have detected a relatively small difference between the groups, so it appears that this lack of a statistically significant difference is truly the result of a small or absent difference between the groups, and not due to low statistical power.

Table 190. Results of global assessment

Study	Number of patients	Global assessment patient-reported categories	Statistical significance of difference between groups
Geutjens 1996 [514]	26 medial epicondylectomy 26 anterior transposition	At 54 months Epicondylectomy - 12 excellent, 8 better, 4 same, 1 worse Transposition- 6 excellent, 6 better, 5 same, 3 worse	chi-squared test[a] p = 0.022587
Asami 1998 [509]	8 transposition without extrinsic vessels 27 transposition with extrinsic vessels	In terms of number of arms: At 70 months mean (range 12-147) Without vessels- 3 excellent, 3 better, 4 same With vessels- 16 excellent, 12 better, 3 same	chi-squared test p <0.05
Chan. 1980 [530]	101 decompression 99 anterior transposition	In terms of number of arms: At 22 months Decompression- 34 excellent, 60 better, 18 same, 3 worse Transposition- 22 excellent, 77 better, 19 same, 2 worse	chi-squared test[a] p = 0.879[b]

[a] calculated by ECRI

[b] the authors reported that an undescribed statistical test showed that the difference between the groups was statistically significant.

Table 191. Success of surgical treatment for cubital tunnel syndrome

Study	Number of patients	Time of follow-up	Which treatment was more successful?	Was the difference statistically significant?	Minimal difference between groups the study had statistical power to detect	Effect size Hedges' d (95% CI)[a]
Geutjens 1996 [514]	26 medial epicondylectomy 26 anterior transposition	54 months	Medial epicondylectomy,	Yes	NA	0.74 (0.08 to 1.40)
Asami 1998 [509]	8 transposition without extrinsic vessels 27 transposition with extrinsic vessels	70 months	Transposition with preservation of extrinsic vessels	Yes	NA	-0.66 (-1.38 to 0.07)
Chan 1980 [530]	101 decompression 99 anterior transposition	22 months	Decompression	No	9%	0.21 (-0.05 to 0.47)

a calculated by ECRI

Figure 51. Success of surgical treatment: statistical tests comparing anterior transposition to other types of surgery

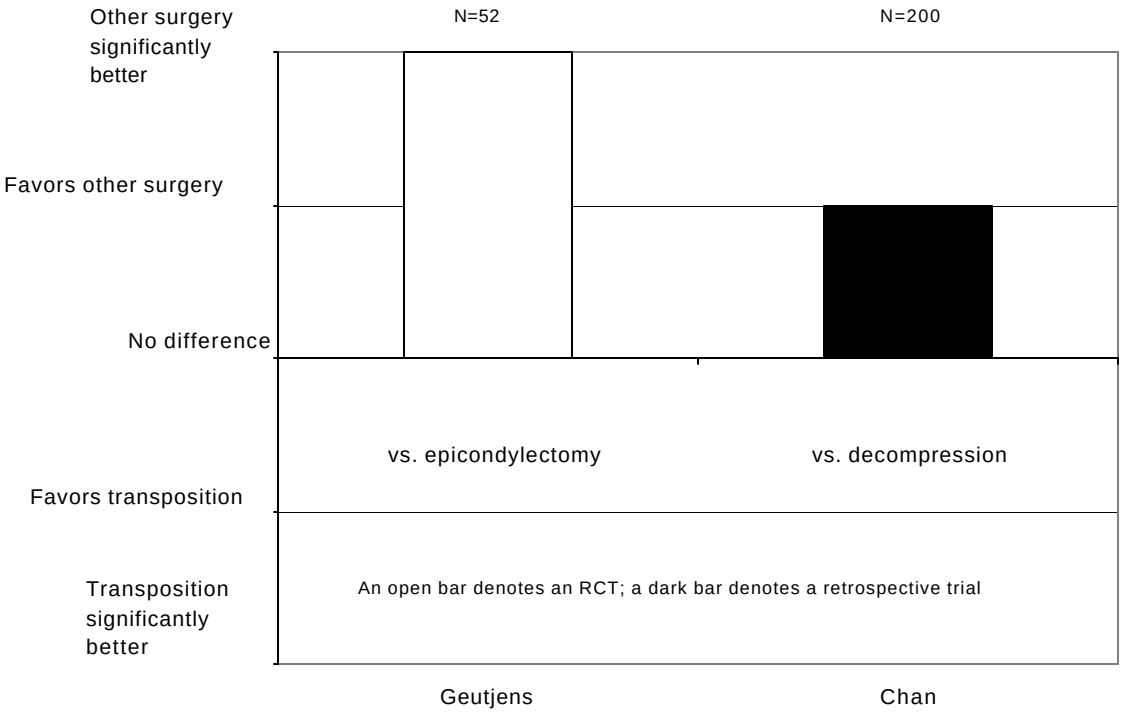
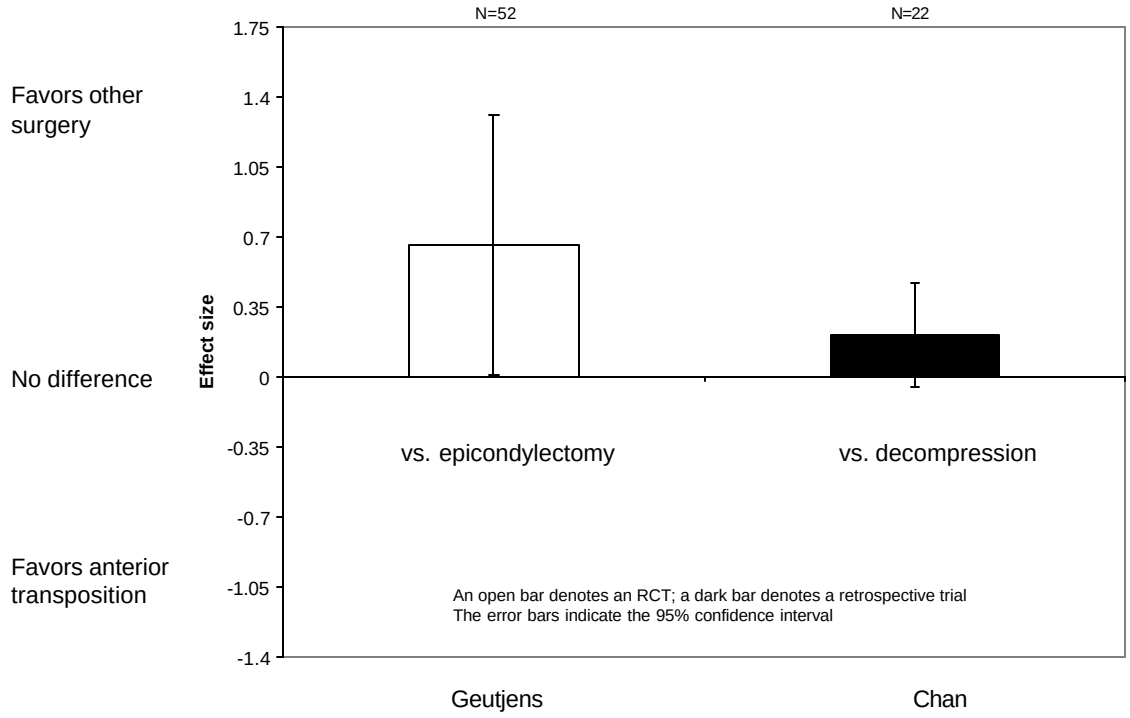


Figure 52. Success of surgical treatment: effect sizes of different types of surgery compared to anterior transposition



Work Status

None of the trials reported on this outcome.

Pain

Three trials of a total of 301 patients reported on the relative success of different surgical techniques in treating the pain of cubital tunnel syndrome. One of the studies had patients rate their pain after treatment on a five-point scale. The other two studies asked the patients whether their pain had been relieved. These two studies reported their data in terms of the number of arms, not the number of patients. The extent to which this affects the validity of the statistical analysis may be small, as was discussed in the section on Study quality. The reported data and effect sizes are summarized in Table 193. We could not compensate for attrition in either study due to the nature of the reported data. The effect of surgical treatment on pain is summarized in Table 193. The results of the statistical tests are shown graphically in Figure 53. The effect sizes we calculated are shown in Figure 54.

Transposition with preservation of the extrinsic vessels was found to relieve pain to a greater extent than without the extrinsic vessels, but the effect size of this result did not reach statistical significance. The data from the study by Geutjens 1996 indicates that patients treated with epicondylectomy had a greater relief of pain than did patients treated with anterior transposition.

The data from the study by Chan 1980 suggests that patients treated with anterior transposition had a greater relief of pain than did patients treated with decompression.

Table 192. Pain results

Study	Number of patients	Reported pain	Statistical significance of difference between groups
Geutjens 1996 [514]	26 medial epicondylectomy 26 anterior transposition	At 54 months, on a 0-5 point pain scale, epicondylectomy - Mean 0 SD 0 Transposition- Mean 0.45 SD 0.86	Test not reported P<0.05
Asami 1998 [509]	8 transposition without extrinsic vessels 27 transposition with extrinsic vessels	At 70 months mean (range 12-147) Without- 8 (80%) arms pain-free With- 29 (93.5%) arms pain free	chi-squared test P<0.05
Chan 1980 [530]	101 decompression 99 anterior transposition	At 22 months, Decompression- 28 (27.7%) arms pain free Transposition- 58 (58.6%) arms pain-free	chi-squared test p <0.000010

a calculated by ECRI

Table 193. Effect of treatments on pain

Study	Number of patients	Time of follow-up	Which treatment was more successful in relieving pain?	Was the difference statistically significant?	Effect size Hedges' d (95% CI)[a]
Geutjens 1996 [514]	26 medial epicondylectomy 26 anterior transposition	54 months	Medial epicondylectomy	Yes	0.73 (0.17 to 1.29)
Asami 1998 [509]	8 transposition without extrinsic vessels 27 transposition with extrinsic vessels	70 months	Transposition with preservation of extrinsic vessels	Yes	-0.70 (-1.86 to 0.47)
Chan 1980 [530]	101 decompression 99 anterior transposition	22 months	Anterior transposition	Yes	-0.68 (-1.00 to -0.35)

a calculated by ECRI

Figure 53. Effect of surgery on pain: statistical tests of anterior transposition vs. other types of surgery

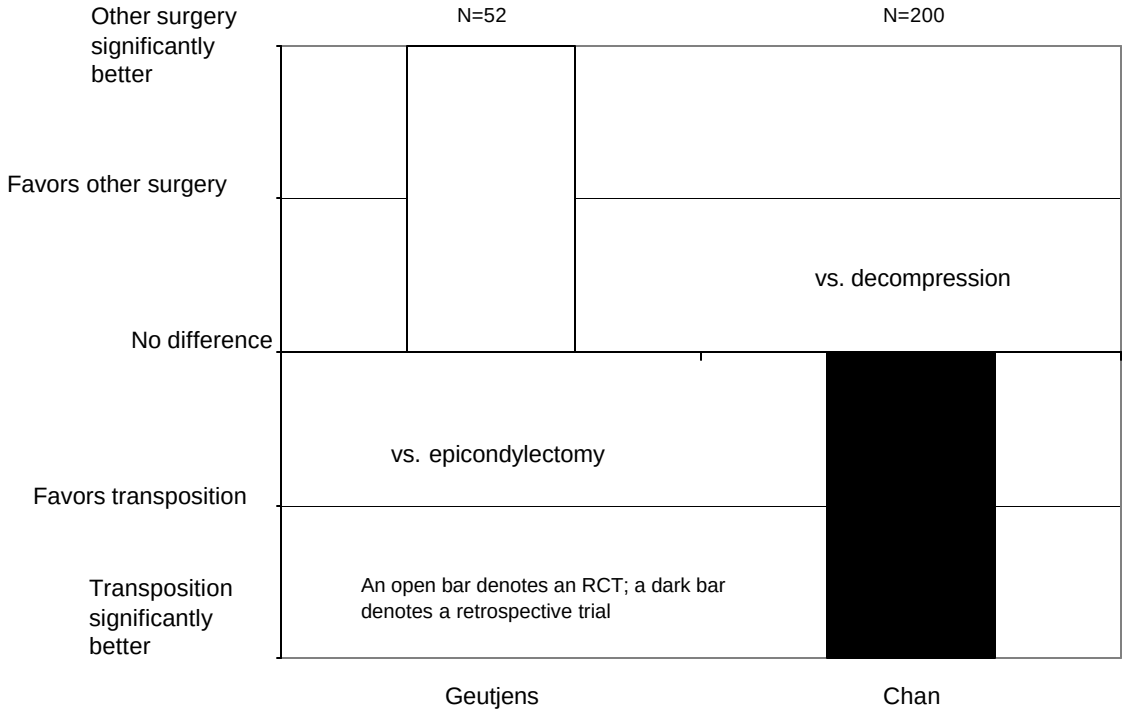
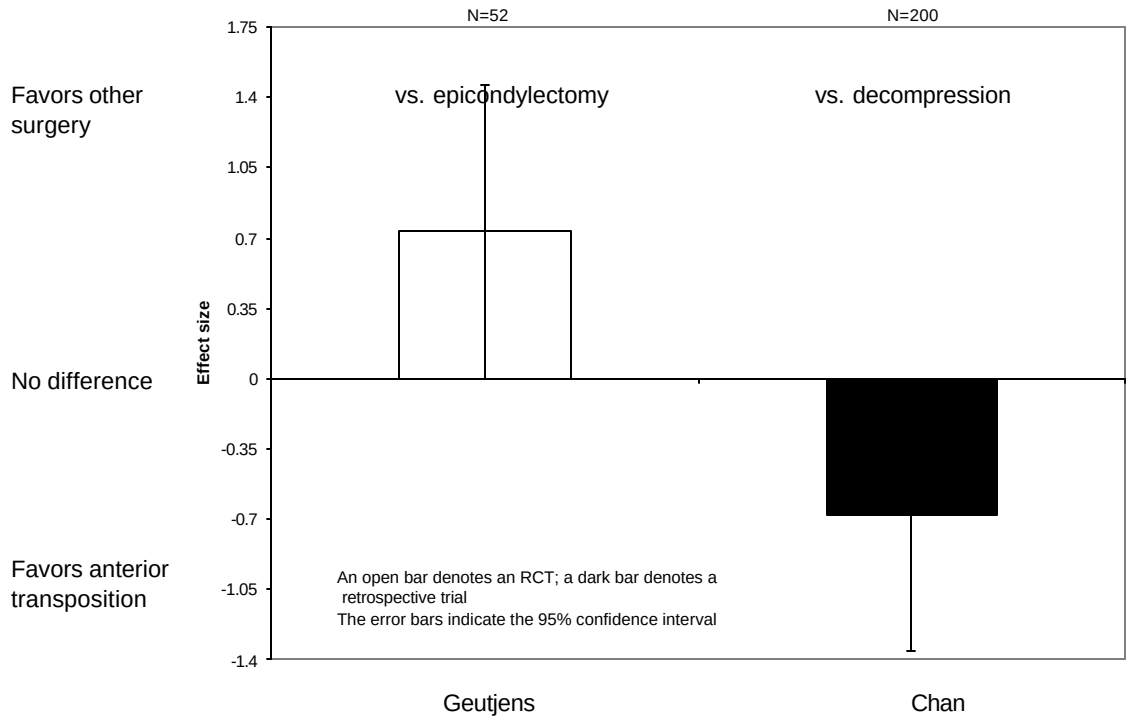


Figure 54. Effect of surgery on pain: effect sizes of anterior transposition vs. other types of surgery



Function and activities

None of the studies reported patient-oriented outcomes addressing the ability of the patient to function and resume normal activities.

Quality of life

None of the studies reported on this outcome.

Morbidity and Complications

None of the included studies reported on this outcome. However, various authors have reported complications that may occur with certain types of surgery. These complications are listed in Table 194. The frequencies with which these complications may occur cannot be determined.

Table 194. Complications reported to occur after surgery for cubital tunnel syndrome

Type of surgery	Complications reported
Decompression	Subluxation of the ulnar nerve [56]
Medial epicondylectomy	Elbow instability [63]
	Trauma and damage to ulnar nerve [66]
Anterior transposition	Compression of the ulnar nerve at a new site [64]
	Extensive scar formation [67]
	Subluxation of the ulnar nerve [64]
	Injury to the flexor carpi ulnaris motor branches [56]
	Injury to the ulnar nerve [56 537 64]
	Disruption of blood flow to the ulnar nerve [64]
	Formation of adhesions that limit elbow mobiltiy [56]

Conclusions

One randomized controlled trial of 52 patients found that medial epicondylectomy was superior to anterior transposition in relieving pain and in improving global outcome scores. Although this study had a relatively high attrition rate, our calculations suggest that this did not influence the conclusions of the study. The results of this study are suggestive, but it is problematic to arrive at a strong evidence-based conclusion from the results of only one trial. Therefore, replication of this study is desirable.

The other two trials, one comparing decompression to anterior transposition and the other comparing anterior transposition with and without preservation of extrinsic vessels, have design weaknesses that could influence interpretation of their results. Because of their design weaknesses the results of these trials cannot be considered definitive in the absence of further study.

There are insufficient data available to definitively determine the rates of surgical complications for any of the described surgical procedures.

Question #4. Is there a relationship between specific clinical findings and specific treatment outcomes among patients with cubital tunnel syndrome?

In addressing this question, we considered whether published literature suggests that there are specific clinical findings that predict positive or negative outcomes after treatment for cubital tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings. Correlations between patient characteristics and outcomes are considered in the answer to Question 6, and correlations between duration of symptoms and outcomes are considered in the answer to Question 5.

Excluded studies

Table 195 shows studies that were retrieved to address this question but did not meet the inclusion criteria.

Table 195. Excluded studies

Study	Reason for exclusion
Glowacki 1997 [511]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Pasque 1995 [518]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Friedman 1986 [527]	Stratified study that did not examine any correlations that were also examined by at least two other studies

Evidence Base

We examined eleven studies describing a total of 544 patients.

Study quality

The evaluation of the quality of the literature for this question differs from quality evaluations of studies of treatments. This is because for the question at hand the randomized controlled trial is not necessarily the most informative study design. Single-arm case series, if appropriately analyzed, can yield valid information for the purposes of addressing this question. However, the method of data analysis, not the study design, is an important consideration when considering the quality of the studies relevant to this question. We emphasize the results of studies that employ multiple regression techniques rather than stratification. We also consider whether a study was prospective or retrospective. We refer the reader to Question 4 Carpal Tunnel Syndrome for a more complete discussion of these issues.

Table 196 shows relevant quality characteristics of studies that met the inclusion criteria for this question.

Table 196. Study quality

Study	Prospective?	Methods used to identify predictor variables
Tada 1997 [513]	Yes	Multiple regression
Froimson 1991 [52] 1980 [521]	No	Stratification
Caputo 2000 [506]	Yes	Multiple regression[a]
Lascar 2000 [425]	No	Stratification
Nouhan 1997 [512]	No	Stratification
Kleinman 1989 [526]	Yes	Stratification
Tsai 1999 [508]	Yes	Stratification
Nathan 1995 [517]	No	Multiple regression
Manske 1992 [519]	Yes	Multiple regression[a]
Miller 1980 [533]	Yes	Multiple regression[a]
Foster 1981 [529]	No	Multiple regression[a]

[a] performed by ECRI

Results

The relationship of specific clinical findings to treatment outcomes in those studies that used regression to identify predictor variables are shown in Table 197. There are six such studies of a total of 278 patients. Also presented in Table 197 are all of the variables used in each multiple regression, including non-clinical outcome variables that do not address this question directly. The variables that do address this question are indicated in bold in the table.

One out of three studies found a statistically significant correlation between less severe pre-treatment symptoms and a higher score on global outcome. One of three studies of nerve conduction velocity found a statistically significant correlation between the presence of normal nerve conduction velocity before treatment and a higher score on global outcome.

We investigated these relationships further by examining the results of studies that stratified their patients according to severity of symptoms or nerve conduction velocity (see Table 198). Three of four studies of symptom severity found a statistically significant correlation between less severe symptoms and a higher score on global outcome. Neither of the studies that stratified by nerve conduction velocity found a statistically significant correlation between this variable and a higher score on global outcome.

One explanation for why some studies found a statistically significant relationship between pretreatment symptom severity and posttreatment global outcome scores and others did not is that the studies that found a statistically significant correlation tended to have more patients than did studies that did not (Figure 55). This suggests that the smaller studies lacked the statistical power to find significance[1]. Thus, it can be tentatively concluded that patients presenting with milder symptoms tend to have better outcomes after surgery, regardless of the type of surgery, than do patients presenting with more severe symptoms.

Similar considerations may explain why not all studies found a significant correlation between nerve conduction velocity and outcomes. The one study that reported a statistically significant correlation was much larger than the other studies that found no statistically significant correlation (Figure 56). It is possible that the other studies did not find a statistically significant correlation because of their small size[1]. However, because only one study found a significant relationship between nerve conduction velocity and global outcome scores, it is difficult to reach a definitive evidence-based conclusion about the relationship between the two variables.

[1] A quantitative analysis of the statistical power of each study could not be performed due to incomplete reporting of data.

Table 197. Relationship between specific clinical findings and treatment outcomes among patients with cubital tunnel syndrome (multiple regression analysis)

Study	N	Type of surgical treatment	Outcomes	Variables examined by at least two studies- is there a significant correlation with the outcome?						Unique study variables
				Age	Gender	Duration of symptoms before treatment	**Severity of symptoms**	**Nerve conduction velocity**	Etiology	
Tada 1997 [513]	40	Epicondylectomy	Global outcome (success of surgery)	NS	-	NS	**Sig.**	**-**	-	Range of motion (NS)
Caputo 2000 [506]	20	Anterior transposition	Global outcome (success of surgery)	NS	NS	NS	**NS**	**-**	Sig.	Workers' compensation (NS), **muscle atrophy (NS)**
Nathan 1995 [517]	131	Decompression	Global outcome (success of surgery)	NR	NR	NR	**NR**	**Sig.**	NR	Normal 2-point discrimination (Sig.)
Manske 1992 [519]	27	Decompression	Global outcome (success of surgery)	-	-	NS	**-**	**NS**	Sig.	
Miller 1980 [533]	12	Mixture of types	Pain relief	-	-	NS	**-**	**NS**	-	
Foster 1981 [529]	48	Mixture of types	Global outcome (success of surgery)	Sig.	NS	NS	**NS**	**-**	-	

Bolded text indicates variables that directly address the current question. NR indicates that the study did not report what variables it included in the mulltiple regression equation

Table 198. Stratified studies (success of surgical treatment)

Study	Type of surgery	N patients	Stratification variable	
			Severity of symptoms	Nerve conduction velocity
Froimson 1991 and 1980 [52] [521]	Epicondylectomy	66	Sig.	-
Lascar 2000 [425]	Anterior transposition	53	Sig.	NS
Nouhan 1997 [512]	Anterior transposition	31	NS	-
Kleinman 1989 [526]	Anterior transposition	40	-	NS
Tsai 1999 [508]	Decompression	76	Sig.	-

Figure 55. Studies reporting no significant correlation between the severity of symptoms and success of treatment may be underpowered

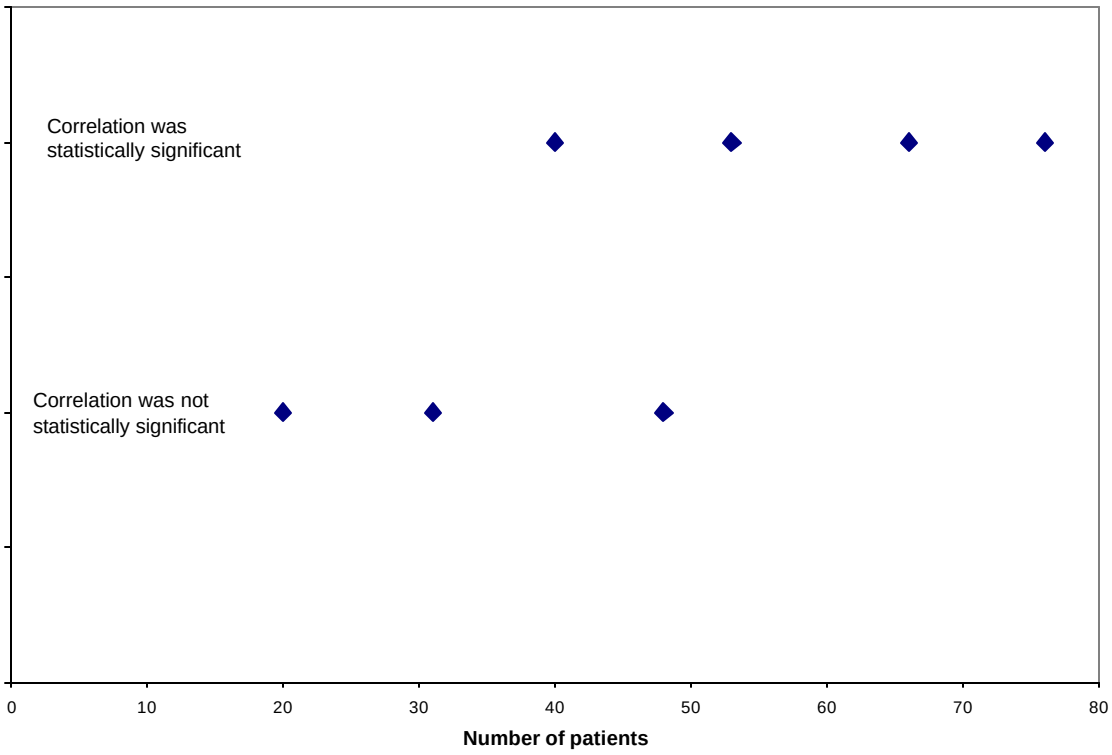
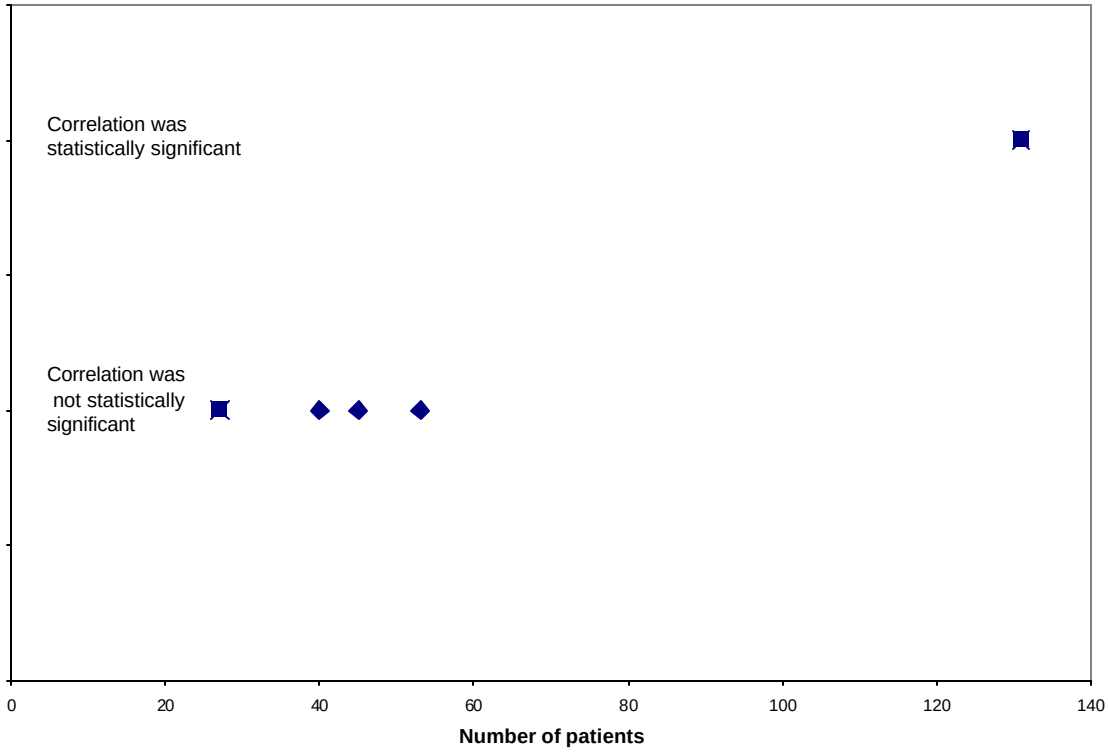


Figure 56. Studies reporting no significant correlation between nerve conduction velocity and success of treatment may be underpowered

Squares denote studies that performed multiple regressions. Diamonds denote studies that used stratification.



Conclusions

The only clinical finding variable shown by more than one study to significantly predict treatment outcomes was severity of symptoms. This correlation was statistically significant in four out of seven studies that examined it. The studies that did not find a statistically significant correlation may have been underpowered. Therefore, currently available evidence tentatively suggests that there is a correlation between having less severe symptoms and having a higher global outcome score after surgical treatment for cubital tunnel syndrome. There are insufficient data to reach evidence-based conclusions about the relationships between other clinical findings and treatment outcomes.

Question #5. Is there a relationship between duration of symptoms and specific treatment outcomes among patients with cubital tunnel syndrome?

In addressing this question, we considered whether published literature suggests that there are specific treatment outcomes that can be predicted by duration of symptoms before treatment for cubital tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings.

Evidence Base

We identified fourteen studies of 843 patients that addressed this question. All retrieved studies met the inclusion criteria.

Study quality

The evaluation of the quality of the literature for this question differs from quality evaluations of studies of treatments. This is because for the question at hand the randomized controlled trial is not necessarily the most informative study design. Single-arm case series, if appropriately analyzed, can yield valid information for the purposes of addressing this question. However, the method of data analysis, not the study design, is an important consideration when considering the quality of the studies relevant to this question. We emphasize the results of studies that employ multiple regression techniques rather than stratification. We also consider whether a study was prospective or retrospective. We refer the reader to Question 4 Carpal Tunnel Syndrome for a more complete discussion of these issues.

Table 199 shows relevant quality characteristics of studies that met the inclusion criteria for this question.

Table 199. Study quality

Study	Prospective?	Methods used to identify predictor variables
Seradge 1998 [510]	No	Stratification
Tada 1997 [513]	Yes	Multiple regression
Caputo 2000 [506]	Yes	Multiple regression[a]
Glowacki 1997 [511]	Yes	Stratification
Pasque 1995 [518]	No	Stratification
Barrios 1991 [520]	Yes	Stratification
Kleinman 1989 [526]	Yes	Stratification
Friedman 1986 [527]	Yes	Stratification
Manske 1992 [519]	Yes	Multiple regression[a]
Miller 1980 [533]	Yes	Multiple regression[a]
Mannerfelt 1997 [538]	Yes	Multiple regression[a]
Bimmler 1996 [539]	Yes	Stratification
Chan 1980 [530]	No	Stratification
Foster 1981 [529]	No	Multiple regression[a]

[a] performed by ECRI

Results

The relationship between patient outcomes and duration of symptoms before treatment in those studies that used regression to identify predictor variables are shown in Table 200. There are six such studies of a total of 195 patients. Also presented in Table 200 are all of the variables used in each multiple regression. None of these studies reported that there was a statistically significant correlation between the duration of symptoms before treatment and treatment outcomes.

In order to extend these data, we examined the results of the studies that stratified according to duration of symptoms (Table 201). Six out of eight of these studies found the same result, namely that there was no statistically significant correlation between duration of symptoms before treatment and global outcome score. There was no consistent relationship between the size of the study and the statistical significance of its findings. Likewise, there was no consistent relationship between whether the study was prospective and the statistically significance of its findings.

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Table 200. Relationship between duration of symptoms and treatment outcomes among patients with cubital tunnel syndrome (multiple regression analysis)

Study	N	Type of surgical treatment	Outcomes	Mean duration of symptoms (range)	Statistical significance	Other variables examined
Tada 1997 [513]	40	Epicondylectomy	Global outcome (success of surgery)	22 months (1-180 months)	NS	Age (NS), severity of symptoms (Sig), range of motion (NS)
Caputo 2000 [506]	20	Anterior transposition	Global outcome (success of surgery)	12.6 months (1-72 months)	NS	Age (NS), gender (NS), severity of symptoms (NS), etiology (Sig), workers' compensation (NS), muscle atrophy (NS)
Mannerfelt 1997 [538]	48	Mixed types	Global outcome (success of surgery)	14.6 months (2-73 months)	NS	Age (NS), Gender (NS)
Manske 1992 [519]	27	Decompression	Global outcome (success of surgery)	10.5 months (3-36 months)	NS	Nerve conduction velocity (NS), etiology (Sig)
Miller 1980 [533]	12	Mixture of types	Pain relief	19.2 months (4-48 months)	NS	Nerve conduction velocity (NS)
Foster 1981 [529]	48	Mixture of types	Global outcome (success of surgery)	23.5 months (0.3-240 months)	NS	Age (Sig), gender (NS), severity of symptoms (NS)

Table 201. Stratified studies (success of treatment)

Study	Type of surgery	N	Mean duration of symptoms (range)	Statistical significance (duration associated with better outcome)
Seradge 1998 [510]	Epicondylectomy	160	8 months (2-57 months)	NS
Glowacki 1997 [511]	Anterior transposition	45	5.5 months (0.75-72 months)	Sig (Shorter duration, ≤2.5 months)
Pasque 1995 [518]	Anterior transposition	48	25 months (2-241 months)	NS
Barrios 1991 [520]	Anterior transposition	19	14 months	Sig (Shorter duration, <12 months)
Kleinman 1989 [526]	Anterior transposition	40	Reported only for separate subgroups	NS
Friedman 1986 [527]	Anterior transposition	22	11.3 months (3-36 months)	NS
Bimmler 1996 [539]	Surgery, mixed types	79	NR	NS
Chan 1980 [530]	Surgery, mixed types	235	18.6 months (<1-456 months)	NS

Conclusions

Fourteen studies of three different types of surgical treatment reported on the relationship between duration of symptoms and outcomes. Six studies analyzed their results using multiple regression, but all did not find a statistically significant relationship between duration of symptoms and outcomes. Eight studies stratified patients according to symptom duration. Five of these latter studies, including the two largest ones, also did not find a statistically significant relationship. Consequently, currently available evidence does not suggest a clear-cut relationship between the duration of symptoms before treatment and the success of surgery. There are insufficient data available to reach evidence-based conclusions about the relationship between symptom duration and other treatment outcomes.

Question #6. Is there a relationship between patient characteristics and specific treatment outcomes among patients with cubital tunnel syndrome?

In addressing this question, we considered whether published literature suggests that there are specific clinical findings that predict positive or negative outcomes after treatment for cubital tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings.

Excluded studies

Table 202 shows studies that were retrieved to address this question but did not meet the inclusion criteria.

Table 202. Excluded studies

Study	Reason for exclusion
Nathan 1995 [517]	Stratified study with no patient characteristics-outcome comparisions reported by at least three studies
Miller 1980 [533]	Stratified study with no patient characteristics-outcome comparisions reported by at least three studies

Evidence Base

Subsequent to these exclusions, we examined fifteen studies of 942 patients that addressed this question.

Study quality

The evaluation of the quality of the literature for this question differs from quality evaluations of studies of treatments. This is because for the question at hand the randomized controlled trial is not necessarily the most informative study design. Single-arm case series, if appropriately analyzed, can yield valid information for the purposes of addressing this question. However, the method of data analysis, not the study design, is an important consideration when considering the quality of the studies relevant to this question. We emphasize the results of studies that employ multiple regression techniques rather than stratification. We also consider whether a study was prospective or retrospective. We refer the reader to Question 4 Carpal Tunnel Syndrome for a more complete discussion of these issues.

Table 203 shows relevant quality characteristics of studies that met the inclusion criteria for this question.

Table 203. Study quality

Study	Prospective?	Methods used to identify predictor variables
Seradge 1998 [510]	No	Stratification
Tada 1997 [513]	Yes	Multiple regression
Goldberg 1989 [524]	No	Stratification
Caputo 2000 [506]	Yes	Multiple regression[a]
Lascar 2000 [425]	No	Stratification
Glowacki 1997 [511]	Yes	Stratification
Nouhan 1997 [512]	No	Stratification
Pasque 1995 [518]	No	Stratification
Kleinman 1989 [526]	Yes	Stratification
Friedman 1986 [527]	Yes	Stratification
Manske 1992 [519]	Yes	Multiple regression[a]
Mannerfelt 1997 [538]	Yes	Multiple regression[a]
Bimmler 1996 [539]	Yes	Stratification
Chan 1980 [530]	No	Stratification
Foster 1981 [529]	No	Multiple regression[a]

[a] performed by ECRI

Results

The relationship of specific patient characteristics to treatment outcomes in those studies that used regression to identify predictor variables are shown in Table 204. There are five such studies of a total of 183 patients. Also presented in Table 204 are all of the variables used in each multiple regression.

One out of four studies of age found a statistically significant correlation between age and patient outcomes. This study (Foster 1981) was the only retrospective multiple regression study. None of the three studies that examined the relationship between gender and patient outcomes found a statistically significant correlation. Both studies that looked for a relationship between traumatic causes of cubital tunnel syndrome and higher scores on global outcomes after treatment found a statistically significant relationship. One study reported that there was no statistically significant relationship between workers' compensation status and patient outcomes.

We further investigated these possible relationships further by examining the results of studies that stratified their patients according to patient characteristics (see Table 205). Six out of nine studies of age found no statistically significant relationship between this variable and patient outcomes. In these studies, there was no apparent relationship between study size or whether the study was prospective and whether it obtained statistical significance. None of the three studies that looked at the relationship between sex and global outcomes found a statistically significant correlation. Four out of five studies that looked for a relationship between workers' compensation status and patient outcomes found no statistically significant correlation. Three out of three studies reported no statistically significant relationship between etiology and patient outcomes.

Table 204. Relationship between patient characteristics and treatment outcomes among patients with cubital tunnel syndrome (multiple regression analysis)

Study	N	Type of surgical treatment	Outcomes	Variables examined by at least two studies – is there a significant correlation with the outcome?						Unique study variables
				Age	**Gender**	Duration of symptoms before treatment	Severity of symptoms	Nerve conduction velocity	**Etiology**	
Tada 1997 [513]	40	Epicondylectomy	Global outcome (success of surgery)	**NS**	**-**	NS	Sig.	-	**-**	Range of motion (NS)
Caputo 2000 [506]	20	Anterior transposition	Global outcome (success of surgery)	**NS**	**NS**	NS	NS	-	**Sig.**	**Workers' compensation (NS)**, muscle atrophy (NS)
Mannerfelt 1997 [538]	48	Mixed types	Global outcome (success of surgery)	**NS**	**NS**	NS	-	-	**-**	
Manske 1992 [519]	27	Decompression	Global outcome (success of surgery)	**-**	**-**	NS	-	NS	**Sig.**	
Foster 1981 [529]	48	Mixture of types	Global outcome (success of surgery)	**Sig.**	**NS**	NS	NS	-	**-**	

Bolded text indicates variables that address the curent question

Table 205. Relationship between patient characteristics and success of surgical treatment of cubital tunnel syndrome-stratified studies

Study	Treatment	N patients	Age	Sex	Workers' compensation	Etiology
Seradge 1998 [510]	Epicondylectomy	160	<41 and >50	-	-	-
Goldberg 1989 [524]	Epicondylectomy	46	NS	NS	NS	NS
Lascar 2000 [425]	Anterior transposition	53	Younger	-	-	-
Glowacki 1997 [511]	Anterior transposition	45	Younger	-	NS	-
Nouhan 1997 [512]	Anterior transposition	31	-	-	NS	-
Pasque 1995 [518]	Anterior transposition	48	NS	NS	NS	NS
Kleinman 1989 [526]	Anterior transposition	40	NS	-	Not on workers' compensation	-
Friedman 1986 [527]	Anterior transposition	22	NS	-	-	NS
Bimmler 1996 [539]	Surgery, mixed types	79	NS	-	-	-
Chan 1980 [530]	Surgery, mixed types	235	NS	NS	-	-

Conclusions

Seventeen studies were identified that addressed the relationship between various patient characteristics and specific treatment outcomes. The available data do not suggest a substantial correlation between the age, sex, or workers' compensation status of the patient and the success of surgery. Two studies that used multiple regression found that patients whose cubital tunnel syndrome is caused by an acute trauma have better global outcomes after surgical treatment than patients with cubital tunnel syndrome from other causes. However, three studies that stratified by etiology found no statistically significant relationship between cause and patient outcomes. The studies that used multiple regression techniques are of better quality than the stratified studies; thus, current data suggest that there may be a correlation between etiology and patient outcomes, but this cannot be regarded as definitive.

Question #7: What are the surgical and nonsurgical costs or charges for treatment of cubital tunnel syndrome?

According to Medicare Provider Analysis and Review (MEDPAR), average total charges per patient for the DRG (diagnosis-related group) of major shoulder/elbow procedures with comorbidities or complications are $9,008.94 (calculated by dividing total charges by number of discharges). For the DRG shoulder, elbow or forearm procedures, except major joint procedures, without comorbidities or complications, average total charges per patient are $7729.16. For the DRG peripheral and cranial nerve and other nerve procedures without complications or comorbidities, the average total per patient charges are $14,357.65 (with complications or comorbidities the charges are $24,288). These DRGs may include procedures that are used to treat disorders other than cubital tunnel syndrome. The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for a decompression fasciotomy of the forearm and/or wrist is $603.85. The reported median cost for application of a long-arm splint is $80.48.

Question #8. For persons who have had surgery to treat cubital tunnel syndrome, what are the appropriate methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

No studies were identified that addressed this question.

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with cubital tunnel syndrome?

No trials were identified that evaluated instruments to assess functional limitations in patients with cubital tunnel syndrome.

Question #10: What are the functional limitations for an individual with cubital tunnel syndrome before treatment?

There were no studies that addressed this question.

Question #11: What are the functional limitations of an individual with cubital tunnel syndrome after treatment?

There were no studies that addressed this question.

Chapter 3. Results (continued)

Epicondylitis

Question #1: What are the appropriate methods and approaches for the early identification and diagnosis of epicondylitis?

Evidence Base

Articles were included for this question if they reported data that could be used for evaluation of the test in diagnosing epicondylitis, and they included ten or more patients.

Sixteen studies met the initial inclusion criteria. Six of those studies were excluded because they selected only patients who had had unsuccessful treatment for their condition (see Table 206). This is likely to engender a spectrum bias in the results, because such patients may have more severe conditions. Furthermore, the patient inclusion criteria for these trials imply that they were not intended to evaluate the diagnostic tests used, and that the diagnostic information provided was only incidental.

Ten studies remained for analysis after these exclusions. They included a total of 251 epicondylitis patients and 97 control subjects. Two (20%) were multi-center studies; the rest were conducted at a single institution. Six articles (60%) came from institutions outside the United States.

Internal Validity and Generalizability of Results

Because of the small size of the evidence base on diagnosis of epicondylitis, we will discuss the quality of literature issues related to both internal validity and generalizability of study results in the same section of this report.

Information related to these aspects of study quality was incompletely reported (see Table 207 and Table 208). The relevant data are summarized in Table 209 and Table 210. Some study aspects affect both internal validity and generalizability (e.g. age), so they were included in both sets of tables. Basic demographic information about patients (e.g. age and sex) was usually reported, but in some studies, this was not reported for the control subjects. Comorbidities were reported in only 3 of the 10 articles. Indicators of reliability in diagnostic studies (such as blinding of test operators) were rarely reported. Six studies (60%) had a potential selection bias for patients with relatively easy to diagnose conditions.

None of these studies focused exclusively on medial epicondylitis (golfer's elbow). One study[540] combined patients with lateral and medial epicondylitis (22 lateral and

2 medial). All other studies focused exclusively on lateral epicondylitis (tennis elbow).

Four articles (40%) reported only summary data on groups of patients(i.e., mean test results for cubital tunnel syndrome group and for control group), so sensitivity and specificity could not be determined from them. Two articles reported counts of positive and negative results, but did not report them both on patients and controls. There were only four articles (40%) from which both sensitivity and specificity of at least one test for epicondylitis could be calculated. Studies that report only one of these characteristics (sensitivity or specificity) are not reliable evidence on the effectiveness of a test, because they do not give assurance that the threshold was set to favor the reported characteristic at the expense of the unreported one.

Because so few articles reported sensitivity and specificity for any test for epicondylitis, and the poor quality of reporting study design and patient characteristics in these articles make it inadvisable to draw conclusions on the basis of a single study, we did not perform quantitative analyses of diagnostics for epicondylitis.

Results

A tabulation of patient selection and types of controls appears in Table 211. Nerve conduction tests are not used for diagnosis of epicondylitis because epicondylitis is not a nerve impairment syndrome. Therefore, patient selection was done on the basis of signs and symptoms (3 of the 10 articles), or by unspecified diagnostic criteria (7 of the 10 articles). Table 212 summarizes the reported types of tests and patient selection in those articles. Detailed information on study design, tests reported, patient groups, and patient inclusion/exclusion criteria for each article is found in Table 215, Table 216, Table 217 and Table 218.

Nine of the 10 articles (90%) reported only clinical signs and symptoms to diagnose epicondylitis. Table 213 lists the specific signs and symptoms that were reported as inclusion criteria for epicondylitis patients. Three studies performed clinical diagnosis but did not report the specific signs and symptoms that were assessed. Nerve conduction tests are not used for diagnosis of epicondylitis because epicondylitis is not a nerve impairment syndrome.

The only study that did not use clinical signs and symptoms to diagnose epicondylitis was Bredella[74]. This was an MRI study in which patients were "referred for MR imaging of the elbow to rule out lateral epicondylitis." The authors stated that epicondylitis is typically diagnosed clinically, and that the need for MRI only arises when "symptoms are resistant to medical management."

The resisted wrist extension test (RWE) was used most frequently in operational definitions of epicondylitis (six of the 10 articles). This test is positive if the patient feels pain or tenderness upon resisted extension of the wrist. Only 4 of the 6

actually reported RWE findings (Table 214). However, it was not possible to determine both sensitivity and specificity of the RWE test for any of these four studies. Two studies[541,542] required positive RWE findings in all patients included in the study, thus they cannot be used to assess the effectiveness of the RWE test because of selection bias. Friedman et al. did not report RWE findings in their control group, so specificity could not be determined. Wright et al. [72] had no control group, so specificity could not be determined.

Thus there were no articles in the evidence base we examined that reported sensitivity and specificity of the RWE test.

Conclusions

For diagnosis of epicondylitis, the evidence base is small and heterogeneous. None of the relevant studies are sufficiently large or well-designed to permit one to draw a strong evidence-based conclusion from them on any individual test for epicondylitis.

Table 206. Excluded Articles

Article	Reason for Exclusion
Pfaler, 1999 [543]	All patients previously treated
Pienimaki, 1998 [544]	All patients previously treated
De Smet, 1997 [545]	All patients previously treated
Pienimaki, 1997 [546]	All patients previously treated
Pienimaki, 1997 [547]	All patients previously treated
Potter, 1995 [548]	All patients previously treated

Table 207. Study Characteristics Relating to Internal Validity

Article	Funded by for-profit institution?	Inclusion criteria reported?	Exclusion criteria reported	Method of diagnosis reported	Patient selection	Comorbidity reported	Sex reported	Possible sex bias	Ages reported	Possible age bias	Duration of condition reported	Test operator blinded	Test reader blinded	Multiple readers	Method for multiple readers	Independent reference standard	Were patients given both test and reference
Benjamin, 1999 [549]	NR	Yes	Yes	Yes	Prospective	No	Yes	NC	Yes	NC	No	No	No	NR	NR	No	No
Bredella, 1999 [74]	NR	Yes	NR	Yes	Prospective	No	Yes	NC	Yes	NC	No	No	No	3	NR	No	No
Steinborn, 1999 [71]	NR	Yes	Yes	Yes	Retrospective	No	Yes	No	Yes	P	Yes	No	No	2	NR	No	No
Bauer, 1998 [550]	NR	Yes	NR	Yes	NR	No	Yes	No	Yes	No	No	No	No	NR	NR	No	No
Friedman, 1998 [73]	No	Yes	Yes	Yes	NR	Yes	Yes	No	Yes	No	Yes	Yes	No	NR	NR	No	No
Martin, 1998 [540]	NR	Yes	NR	Yes	Prospective	No	NR	GNR	Yes	P	Yes	No	Yes	2	Indep	No	No
Smith, 1994 [541]	NR	Yes	Yes	Yes	NR	No	Yes	NC	Yes	NC	Yes	No	Yes	3	Indep	No	No
Wright, 1992 [72]	NR	Yes	Yes	Yes	Prospective	Yes	Yes	NC	Yes	NC	No	Yes	No	NR	NR	No	No
Hyland, 1990 [551]	NR	Yes	Yes	Yes	Prospective	No	Yes	NC	NR	NC	Yes	No	Yes	2	Indep	No	No
Binder, 1984 [542]	NR	Yes	Yes	Yes	NR	Yes	Yes	GNR	Yes	ANR	Yes	No	No	NR	NR	No	No

Key:
Possible sex bias: No—proportion women in epicondylitis group within 20% of proportion of women in control group; P—Patients were more likely to be female; C—Controls were more likely to be female; GNR—Genders not reported for both groups; NC—Study did not contain a separate control group
Possible age bias: No—mean age of epicondylitis group within 5 years of mean age of control group; P—Patients were older than controls; C—Controls were older than patients; ANR—Ages not reported for both groups; NC—Study did not contain a separate control group
Method for multiple test readers: Indep—Independent

NR-Not reported

Table 208. Study Characteristics Relating to Generalizability of Results

Article	Years in which trial was conducted	Number of centers	Country(s) where trial was conducted	Inclusion criteria reported	Exclusion criteria reported	Are patient comorbidity reported?	Sex reported	Age reported	Duration of condition reported	Did all patients have previous conservative treatment?	Did any patients have previous surgical treatment?	Source of patients adequately described and generalizable to broader clinical practice?	Potential selection bias for easy cases?	Potential selection bias for difficult cases?
Benjamin, 1999 [549]	NR	Single	USA	Yes	Yes	No	Yes	Yes	No	No	No	No	Yes	No
Bredella, 1999 [74]	NR	Multiple (<5)	USA	Yes	NR	No	Yes	Yes	No	No	No	No	No	No
Steinborn, 1999 [71]	NR	Single	Germany	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	No
Bauer, 1998 [550]	NR	Single	USA	Yes	NR	No	Yes	Yes	No	No	No	No	Yes	No
Friedman, 1998 [73]	NR	Single	New Zealand	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	No
Martin, 1998 [540]	NR	Single	USA	Yes	NR	No	NR	Yes	Yes	No	No	No	Yes	No
Smith, 1994 [541]	NR	Single	United Kingdom	Yes	Yes	No	Yes	Yes	Yes	No	No	No	No	No
Wright, 1992 [72]	NR	Single	Australia	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes	No
Hyland, 1990 [551]	NR	Multiple (>5)	Australia	Yes	Yes	No	Yes	NR	Yes	No	No	No	No	No
Binder, 1984 [542]	NR	Single	United Kingdom	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	No	No

Key:
NR—not reported

Table 209. Quality of Reporting and Internal Validity of Results

Study characteristic	N studies reporting	Details
Whether trial was funded by a for-profit institution	1 (10%)	No for-profit funding: 1 (10%)
Patient inclusion criteria	10 (100%)	See Table 218
Patient exclusion criteria	7 (70%)	See Table 218
Method of diagnosis	10 (100%)	Clinical: 9 (90%) Non-clinical: 1 (10%)
Was selection of patients prospective or retrospective?	6 (60%)	Prospective: 5 (50%) Retrospective: 1 (10%)
Were patient comorbidities reported?	3 (30%)	Various
Was the sex distribution of patients reported?	9 (90%)	a–Percentage female: 55.5%
Was the percentage of females in the patient group within 20 percentage points of the control group?	3 (30%)	Yes: 3 (30%)
Were patient ages reported?	9 (90%)	a–Mean age: 42.3 years
Was the mean patient age within 5 years of the mean control age?	4 (40%)	Yes: 2 (20%) No, patients were = 5 years older: 2 (20%)
Was the duration of patients' condition reported?	6 (60%)	a–Mean duration: 14.6 months
Was the test operator blinded?	2 (20%)	Yes: 2 (20%)
Was the test reader blinded?	3 (30%)	Yes: 3 (30%)
Were there multiple test readers?	5 (50%)	2 readers: 3 (30%) 3 readers: 2 (20%)
What was the method for multiple test readers?	3 (30%)	Independent: 3 (30%)
Was the test compared to an independent reference standard?	0 (0%)	NA
Were all patients given the study test and the reference standard?	0 (0%)	NA

Key:
NA-not applicable
a–Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)

Table 210. Quality of Reporting and Generalizability of Results

Study characteristic	N studies reporting	Details
Years in which study was conducted	0 (0%)	NA
Number of centers in which trial was conducted	10 (100%)	Single: 8 (80%) Multiple (<5): 1 (10%) Multiple (>5): 1 (10%)
Country(s) were trial was performed	10 (100%)	USA: 4 (40%) Other: 6 (60%)
Patient inclusion criteria	10 (100%)	See Table 218
Patient exclusion criteria	7 (70%)	See Table 218
Were patient comorbidities reported?	3 (30%)	Various
Was the sex distribution of patients reported?	9 (90%)	a–Percentage female: 55.5%
Were patient ages reported?	9 (90%)	a–Mean age: 42.3 years
Was the duration of patients' condition reported?	6 (60%)	a–Mean duration: 14.6 months
Did all patients have previous conservative treatment?	10 (100%)	No: 10 (100%)
Did any patients have previous surgical treatment?	10 (100%)	No: 10 (100%)
Adequate reporting of study's source of patients	0 (0%)	NA
Was there a potential selection bias for easy cases?	6 (60%)	Yes: 6 (60%)
Was there a potential selection bias for hard cases?	0 (0%)	NA

Key:
NA-not applicable
a–Calculated on a per-patient basis (i.e., weighted by number of patients in each study reporting this characteristic)

Table 211. Patient and Control Group Selection in Epicondylitis Diagnosis

Type of controls	Patient selection (number of articles)		
	Symptoms/ presented	Unspecified diagnosis	Total
0	4		4
0	1		1
1	2		3
2	0		2
3	7		10

Table 212. Epicondylitis Tests and Patient Groups

Legend:

Numeric entries in each cell— Total number of articles, articles from which sensitivity and specificity can be calculated

Tests Reported	Patient selection	
	Symptoms/presented	Unspecified diagnosis
Nerve Conduction	0, 0	0, 0
Composite Nerve Conduction	0, 0	0, 0
Imaging	1, 0	2, 2
Sensory	1, 0	0, 0
Signs/Symptoms	2, 0	3, 1
Other	0, 0	3, 2

See **Table 3** for the definition of these groups

Table 213. Reported Clinical Inclusion Criteria in Studies of Lateral Epicondylitis

Article	Signs and symptoms used in diagnosis								
	RWE	RS	GR	RFE	WT	SE	MW	EA	Other
Benjamin, 1999 [549]									Clinical diagnosis
Bredella, 1999 [74]									MRI signal intensity
Steinborn, 1999 [71]	✓	✓			✓		✓		
Bauer, 1998 [550]									Clinical diagnosis
Friedman, 1998 [73]	✓	✓		✓					
Martin, 1998 [540]									Clinical diagnosis
Smith, 1994 [541]	✓								
Wright, 1992 [72]	✓		✓	✓		✓			
Hyland, 1990 [551]	✓		✓			✓		✓	
Binder, 1984 [542]	✓	✓	✓		✓				
Totals	6	3	3	2	2	2	1	1	4

Key:
RWE-pain or tenderness upon resisted wrist extension
RS-pain or tenderness upon resisted supination of forearm (also called Mill's test)
GR-grip strength
RFE-pain or tenderness upon resisted extension of middle finger
WT- weights test
SE-stretching of extensors
MW-muscle weakness
EA-pain or tenderness with extension adduction test

Table 214. Resisted Wrist Extension for the Diagnosis of Lateral Epicondylitis

Article	N	Was positive RWE a criterion for inclusion of patients in the study?	How many patients had pain or tenderness upon RWE?	Could sensitivity and specificity be derived from the published results?
Steinborn, 1999 [71]	23	No	NR	No
Friedman, 1998 [73]	17	No	4 (24%)	No
Smith, 1994 [541]	40	Yes	40 (100%)	No
Wright, 1992 [72]	17	No	16 (94%)	No
Hyland, 1990 [551]	25	No	NR	No
Binder, 1983 [542]	50	Yes	50 (100%)	No

RWE-Resisted wrist extension
NR-Not reported

Table 215. Epicondylitis–Study Design

Article	N centers	Epicon. groups	Epicon. patients	Negative groups	Negative subjects	Was the design prospective or retrospective?	What was the level of reporting?	Could sensitivity and specificity be determined?
Benjamin, 1999 [549]	Single	1	10	0	0	Prospective	Summary	No: only summary statistics reported
Bredella, 1999 [74]	Multiple (<5)	1	35	0	0	Prospective	Counts	No control group
Steinborn, 1999 [71]	Single	1	23	1	7	Retrospective	Counts	Reported by authors
Bauer, 1998 [550]	Single	1	10	1	7	NR	Summary	No: only summary statistics reported
Friedman, 1998 [73]	Single	1	17	1	7	NR	Summary	No: only summary statistics reported
Martin, 1998 [540]	Single	1	24	1	16	Prospective	Counts	Calculated by ECRI
Smith, 1994 [541]	Single	1	40	0	0	NR	Counts	Calculated by ECRI
Wright, 1992 [72]	Single	1	17	0	0	Prospective	Summary	No: only summary statistics reported
Hyland, 1990 [551]	Multiple (>5)	1	25	0	0	Prospective	Counts	No control group
Binder, 1984 [542]	Single	1	50	1	60	NR	Counts	Calculated by ECRI

Table 216. Epicondylitis–Tests Reported

Article	Signs/ Symptoms	Sensory Tests	Nerve Conduction	Composite Nerve Cond.	Imaging	Other
Benjamin, 1999 [549]	☑	☐	☐	☐	☐	☐
Bredella, 1999 [74]	☐	☐	☐	☐	☑	☐
Steinborn, 1999 [71]	☐	☐	☐	☐	☑	☐
Bauer, 1998 [550]	☐	☐	☐	☐	☐	☑
Friedman, 1998 [73]	☑	☐	☐	☐	☐	☐
Martin, 1998 [540]	☐	☐	☐	☐	☑	☐
Smith, 1994 [541]	☐	☐	☐	☐	☐	☑
Wright, 1992 [72]	☑	☑	☐	☐	☐	☐
Hyland, 1990 [551]	☑	☐	☐	☐	☐	☐
Binder, 1984 [542]	☑	☐	☐	☐	☐	☑

Table 217. Epicondylitis–Patient Groups

Article	Disorder type	Patient selection	Number of patients for which results are reported	Percent female	Mean age	Age of youngest	Age of oldest	Duration of condition be-fore treatment (months)	Shortest duration	Longest duration	Are patient comorbidities reported?
Benjamin, 1999 [549]	Epicondylitis	Unspecified diagnosis	10	30	42						No
Bredella, 1999 [74]	Epicondylitis	Symptoms/ presented	35	51	45	22	63		3	36	No
Steinborn, 1999 [71]	Normal	Healthy volunteers	7	71	25	22	29				No
Steinborn, 1999 [71]	Epicondylitis	Unspecified diagnosis	23	65	47	29	58	17.1	1	84	No
Bauer, 1998 [550]	Normal	Healthy volunteers	7	0	38.8						No
Bauer, 1998 [550]	Epicondylitis	Unspecified diagnosis	10	0	40.8						No
Friedman, 1998 [73]	Normal	Healthy volunteers	7	100	34.6						Yes
Friedman, 1998 [73]	Epicondylitis	Unspecified diagnosis	17	100	38.9			26			Yes
Martin, 1998 [540]	Normal	Healthy volunteers	16	NR	31	22	46				No
Martin, 1998 [540]	Epicondylitis	Unspecified diagnosis	24	NR	38	29	62	5.5	1	24	No
Smith, 1994 [541]	Epicondylitis	Unspecified diagnosis	40	55	40			23			No
Wright, 1992 [72]	Epicondylitis	Symptoms/ presented	17	65	44.7	36	54		2	120	Yes
Hyland, 1990 [551]	Epicondylitis	Symptoms/ presented	25	24				21.9	2	156	No
Binder, 1984 [542]	Normal	Healthy volunteers	60	NR							Yes
Binder, 1984 [542]	Epicondylitis	Unspecified diagnosis	50	68	43			4.5	1	12	Yes

Table 218. Epicondylitis–Reported Inclusion and Exclusion Criteria

Article	Reported Patient Inclusion Criteria	Reported Patient Exclusion Criteria
Benjamin, 1999 [549]	Clinical diagnosis of lateral epicondylitis.	Prior elbow surgery, bilateral symptoms
Bredella, 1999 [74]	Patients referred for MRI imaging of the elbow to rule out lateral epicondylitis. All had symptoms. None had corticosteroid injection in the 3 months prior to MRI.	None reported
Steinborn, 1999 [71]	Clinical diagnosis of lateral epicondylitis, based on clinical findings and history including muscle weakness, pain localized to the lateral epicondyle,and aggravation of pain by weight-bearing and resisted supination and wrist extension.	Steroid injections in the 2 months before MRI.
Bauer, 1998 [550]	Clinical diagnosis of tennis elbow.	None reported
Friedman, 1998 [73]	Patients who had been assessed or treated at a rehabilitation clinic. Inclusion criteria were clinical features such as 1) tenderness at the lateral eipcondyle; 2) pain in the elbow or lateral forearm on resisted wrist extension; 3) pain in the elbow or lateral forearm on resisted finger extension; 4) pain in the elbow or lateral forearm on resisted wrist supination.	Bilateral symptoms, history of fibromyalgia or other disability involving upper extremity.
Martin, 1998 [540]	Diagnosis of either lateral or medial epicondylitis based on history and physical exam.	None reported
Smith, 1994 [541]	Patients with unilateral epicondylitis recruited from rheumatology outpatient clinics. Localized pain and lateral epicondylar tenderness, increased pain on wrist extension.	Bilateral symptoms, cervical spine symptoms.
Wright, 1992 [72]	Patients reported lateral elbow pain of at least 6 weeks duration, and if they experienced pain during two or more of the following five tests: 1) Palpation of the lateral epicondyle; 2) Resisted wrist extension; 3) Passive stretching of the extensor muscle group; 4) Pain on gripping a hand dynamometer; 5) Pain on resisted extension of the middle finger.	Bilateral symptoms, neurological impairment, serious injury or fracture to the upper limbs, cervical or thoracic spine, history of any arthritic condition.
Hyland, 1990 [551]	Lateral elbow pain. Non-irritable symptomatic elbows in which pain provoked by activity or examination was quickly relieved with a short period of rest. Positive extension-adduction test with the forearm in supination position, and at least one of the following: pain upon resisted wrist extension, or pain upon passive stretch of the forearm extensors.	Pain of cervical origin or contribution.
Binder, 1984 [542]	Localized tenderness near the lateral epicondyle and pain on resisted wrist dorsiflexion.	Localized or generalized arthritis, abnormal ESR (undefined), positive Rose-Waaler, or neurological symptoms or signs in the affected limb.

Question #2. What are the specific indications for surgery for epicondylitis?

No published studies directly address specific indications for surgery for epicondylitis. Therefore, in this section we present the characteristics of patients who have received surgery as described in published studies. Because patients enrolled in clinical trials may differ from the general population of patients encountered in general practice, these data may not accurately reflect the characteristics of most patients who have received surgery for epicondylitis. However, they represent the most comprehensive set of available information.

Evidence base

For this question, we included controlled trials and case series that described patients being surgically treated for epicondylitis. We identified 19 such studies.

Failure of conservative treatment

Nine of the 19 available studies (47.4%) reported that the main criterion for entry into the trial was the presence of epicondylitis that had failed to respond to conservative treatment. Eight of the 19 available studies (42.1%) reported no details about patient inclusion/exclusion criteria for entry into the trial.

Patient demographics

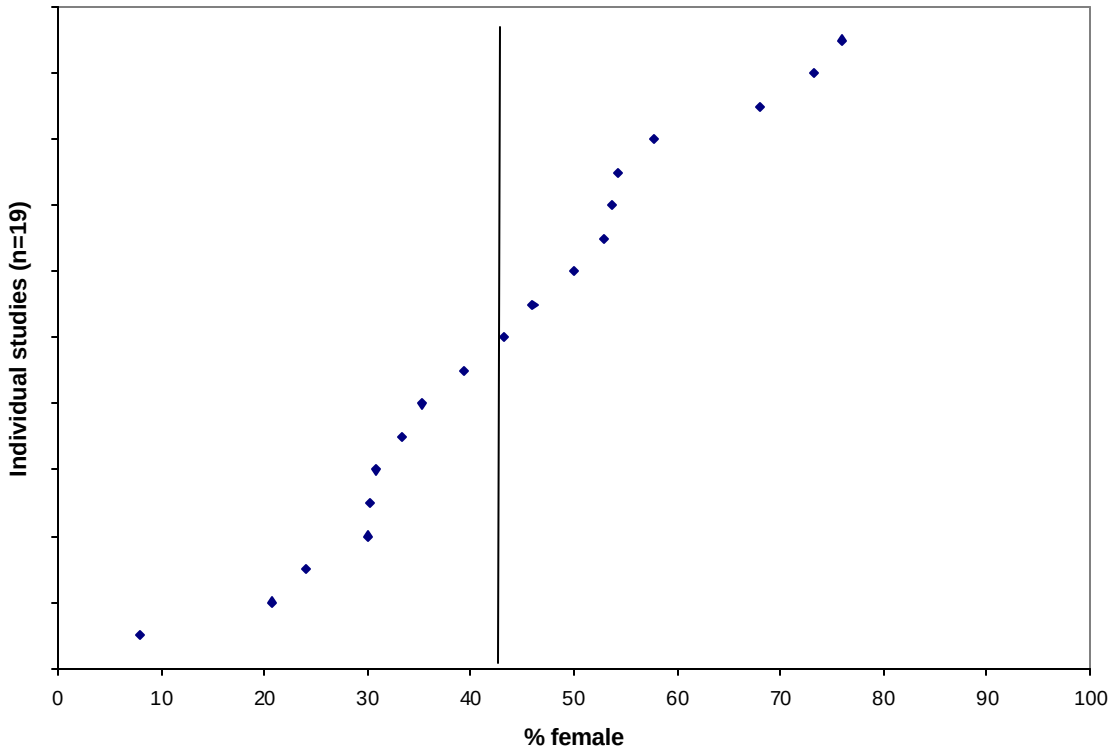
The ages and gender composition of the patient groups included in the studies are listed in Table 219. All 19 of the studies provided information about the sex of their patients. The sexes were almost equally represented in the patient groups. Overall, 43.61% of the patients were female, with a range from 7.9 to 76% female. The gender compositions of patient groups from the individual studies are shown in Figure 57. Fifteen of the 19 available studies reported information about the ages of the patients. Patients who received surgery for epicondylitis were predominantly of middle age. The mean age of the patients was 44.3 years old, with a range from 16 to 70 years of age. The mean ages and range of ages of each individual study are shown in Figure 58.

Table 219. Age and sex of patients receiving surgery for epicondylitis

Study	Number of patients	Number of males	Number of females	Percent female	Age reported as mean or median?	Age	Age of youngest patient	Age of oldest patient
Grundberg 2000 [552]	34	17	17	50.0	Mean	43	27	64
Almquist 1998 [83]	61	37	24	39.3	Mean	43.3	27	63
Bankes 1998 [553]	24	11	13	54.2	Mean	45.3	32	54
Organ 1997 [554]	34	16	18	52.9	Mean	40	28	70
Wilhelm 1996 [84]	166	70	96	57.8	Mean	44.5	21	62
Gabel 1995 [555]	26	18	8	30.8	Mean	43	17	64
Kurvers 1995 [556]	40	28	12	30.0	Mean	42	22	56
Ollivierre 1995 [557]	48	38	10	20.8	Mean	42	16	66
Newey 1994 [558]	28	13	15	53.6	Mean	44.8	NR	NR
Verhaar 1993 [559]	63	42	21	33.3	Mean	45	25	67
Wittenberg 1992 [560]	86	60	26	30.2	Mean	47.5	25	67
Vangsness 1991 [561]	38	35	3	7.9	Mean	43	21	65
Tan 1989 [562]	25	8	17	68.0	NR	NR	NR	NR
Goldberg 1988 [563]	30	8	22	73.3	NR	NR	NR	NR
Chotigavanich 1986 [564]	50	12	38	76.0	NR	NR	NR	NR
Calvert 1985 [565]	37	21	16	43.2	Mean	43.7	NR	NR
Baumgard 1982 [566]	34	22	12	35.3	Mean	48	30	67
O'Neil 1980 [567]	50	27	23	46.0	NR	NR	NR	NR
Rosen 1980 [568]	50	38	12	24.0	Mean	49	18	64

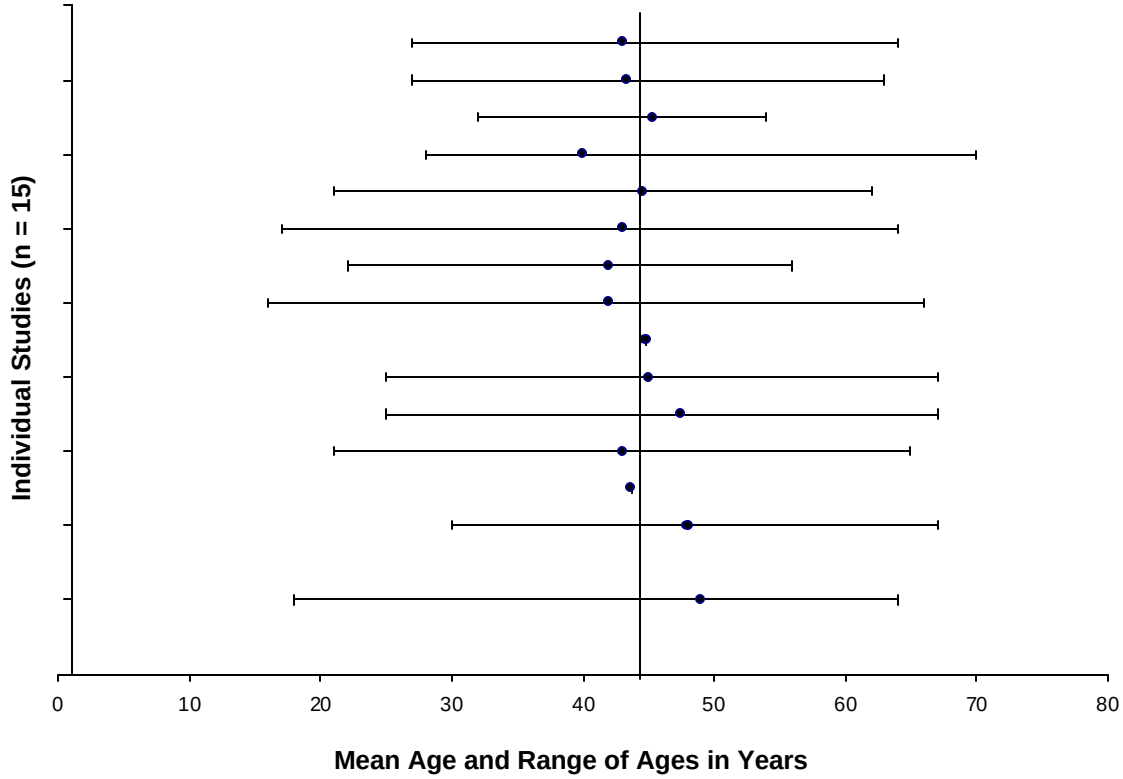
NR = not reported

Figure 57. Sex distribution in trials of surgical treatment for epicondylitis



The vertical line indicates the mean % of females

Figure 58. Distribution of patient ages in studies of surgical treatment for epicondylitis



The vertical line indicates the mean age

Signs and symptoms

Descriptions of signs and symptoms of the patients before treatment were incompletely reported. The number of studies reporting on each sign and symptom are listed in Table 220. Only six different signs and symptoms were reported on, and less than 16% of the studies reported on the presence of any given symptom or sign, as is shown in Figure 59. The mean percentages of patients with each sign and symptom reported by the studies are listed in Table 221 and shown in Figure 60.

Only three out of the 19 studies reported the duration of symptoms before treating the patients with surgery. These data are listed in Table 222. The mean duration before treatment was 27.7 months, with a range of 3 to 126 months.

Because so few studies reported on signs and symptoms, or duration of symptoms, it is difficult to arrive at a generalized characterization of patients who received surgical treatment for epicondylitis.

Table 220. Reporting of signs and symptoms in studies of surgical treatment for epicondylitis

Sign or symptom	Number of studies reporting
Clumsiness	0
Lifting test	0
Middle finger test	0
Pain	2
Resisted pronation	3
Resisted supination	1
Resisted wrist extension	1
Restricted range of motion	0
Stiffness	0
Swelling	1
Symptoms with ADLs	0
Tenderness	3
Weakness	0
Weakness of grip	0

ADL = activities of daily living

Figure 59. Reporting of symptoms and signs in studies of surgical treatment for epicondylitis

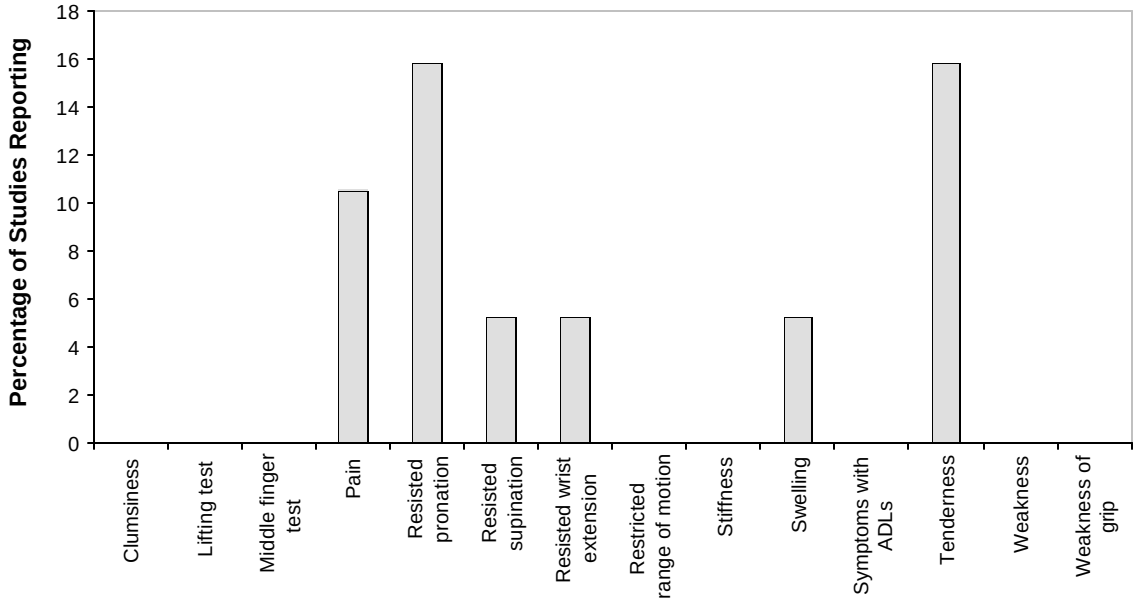


Table 221. Signs and symptoms of patients treated with surgery for epicondylitis

Study	Number of patients	Sign or symptom	Number of patients with sign or symptom	Percentage of patients
Almquist 1998 [83]	61	Pain	61	100.0
Goldberg 1988 [563]	30	Pain	30	100.0
Gabel 1995 [555]	26	Resisted pronation	26	100.0
Verhaar 1993 [559]	63	Resisted pronation	34	54.0
Baumgard 1982 [566]	34	Resisted pronation	34	100.0
Verhaar 1993 [559]	63	Resisted supination	31	49.2
Verhaar 1993 [559]	63	Resisted wrist extension	63	100.0
Goldberg 1988 [563]	30	Swelling	3	10.0
Almquist 1998 [83]	61	Tenderness	61	100.0
Gabel 1995 [555]	26	Tenderness	26	100.0
Verhaar 1993 [559]	63	Tenderness	63	100.0

Figure 60. Symptoms of patients with epicondylitis

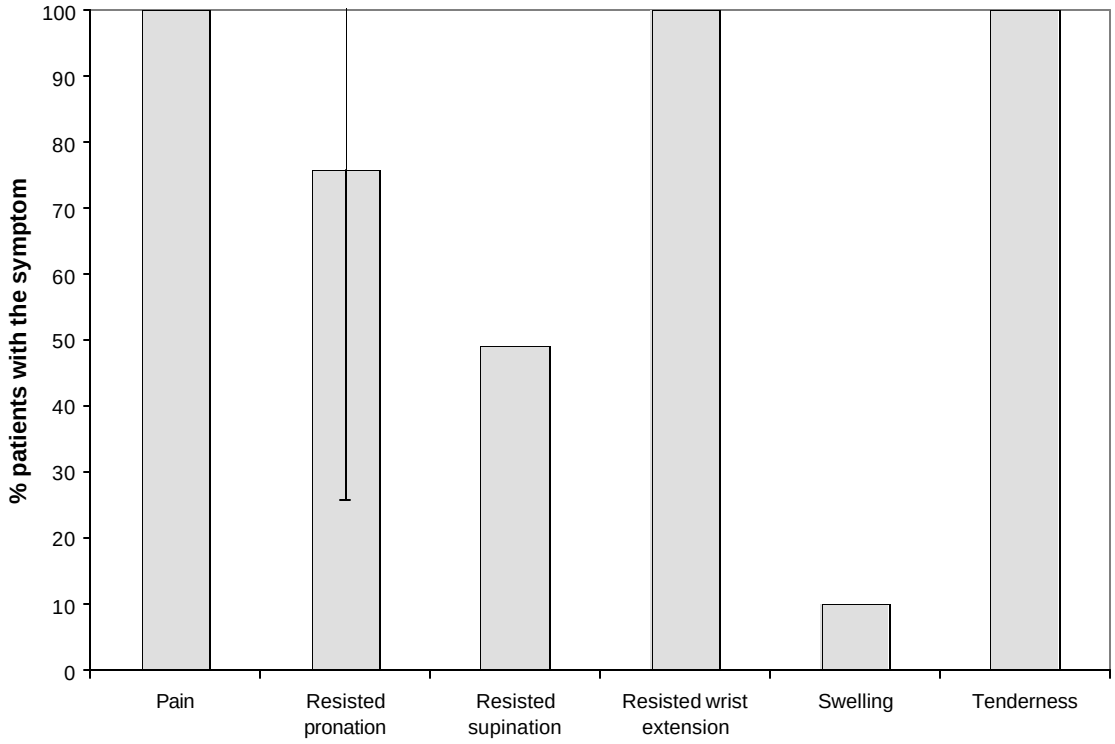


Table 222. Duration of symptoms before surgical treatment for epicondylitis

Study	Number of patients	Mean duration, months	Shortest duration, months	Longest duration, months
Grundberg 2000 [552]	34	18	3	66
Almquist 1998 [83]	61	31.3	6	72
Bankes 1998 [553]	24	32.2	11	126

Employment characteristics

Only five of the 19 studies reported employment-related data on their patients. The occupations of patients receiving surgery for epicondylitis and the percentage of patients in each study with that occupation are listed in Table 223. The number of studies reporting each occupational category are shown in Figure 61, and the reported percentages of patients with each occupation are shown in Figure 62.

The categorization of occupations used by the studies was not uniform, but in some cases, categories can be combined across studies. However, in many cases, descriptions of types of employment are unclear and there may be considerable overlap between groups. From the reported information it is not possible to determine the amount and type of arm/hand use required on a regular basis for any of the occupational groups.

Table 223. Reported occupations of patients receiving surgery for epicondylitis

Study	Occupation	Number of Patients	Number of patients with occupation	Percent of patients with occupation
Verhaar 1993 [559]	Assistive living services	63	4	6.3
Kurvers 1995 [556]	Beauty specialist	40	1	2.5
Chotigavanich 1986 [564]	Businessman	50	9	18.0
Verhaar 1993 [559]	Cleaning services	63	4	6.3
Kurvers 1995 [556]	Clerical and administrative support	40	4	10.0
Tan 1989 [562]	Clerical and administrative support	25	3	12.0
Verhaar 1993 [559]	Clerk	63	1	1.6
Verhaar 1993 [559]	Construction	63	7	11.1
Wittenberg 1992 [560]	Domestic workers	86	12	14.0
Tan 1989 [562]	Factory operator	25	3	12.0
Verhaar 1993 [559]	Farmer/gardener	63	4	6.3
Chotigavanich1986 [564]	Government officer	50	10	20.0
Kurvers 1995 [556]	Homemaker	40	8	20.0
Verhaar 1993 [559]	Homemaker	63	10	15.9
Tan 1989 [562]	Homemaker	25	7	28.0
Chotigavanich 1986 [564]	Homemaker	50	27	54.0
Tan 1989 [562]	Laborer	25	2	8.0
Chotigavanich 1986 [564]	Laborer	50	4	8.0
Verhaar 1993 [559]	Machine operator/mechanic	63	11	17.5
Kurvers 1995 [556]	Manual Worker	40	15	37.5
Wittenberg 1992 [560]	Manual Worker	86	31	36.0
Kurvers 1995 [556]	Music (organ) student	40	1	2.5
Kurvers 1995 [556]	Nurse	40	4	10.0
Tan 1989 [562]	Nurse	25	3	12.0
Verhaar 1993 [559]	Piano player	63	1	1.6
Kurvers 1995 [556]	Psychologist	40	1	2.5
Kurvers 1995 [556]	Sales workers - manager/supervisors	40	1	2.5
Wittenberg 1992 [560]	Sales workers - manager/supervisors	86	12	14.0
Verhaar 1993 [559]	Sculptor	63	1	1.6
Kurvers 1995 [556]	Teacher	40	1	2.5
Verhaar 1993 [559]	Teacher	63	1	1.6
Tan 1989 [562]	Teacher	25	4	16.0
Tan 1989 [562]	Technical	25	3	12.0
Wittenberg 1992 [560]	Typists	86	13	15.1
Kurvers 1995 [556]	Unemployed	40	2	5.0
Wittenberg 1992 [560]	Unemployed	86	6	7.0

Figure 61. Percentage of studies reporting occupations of patients with epicondylitis

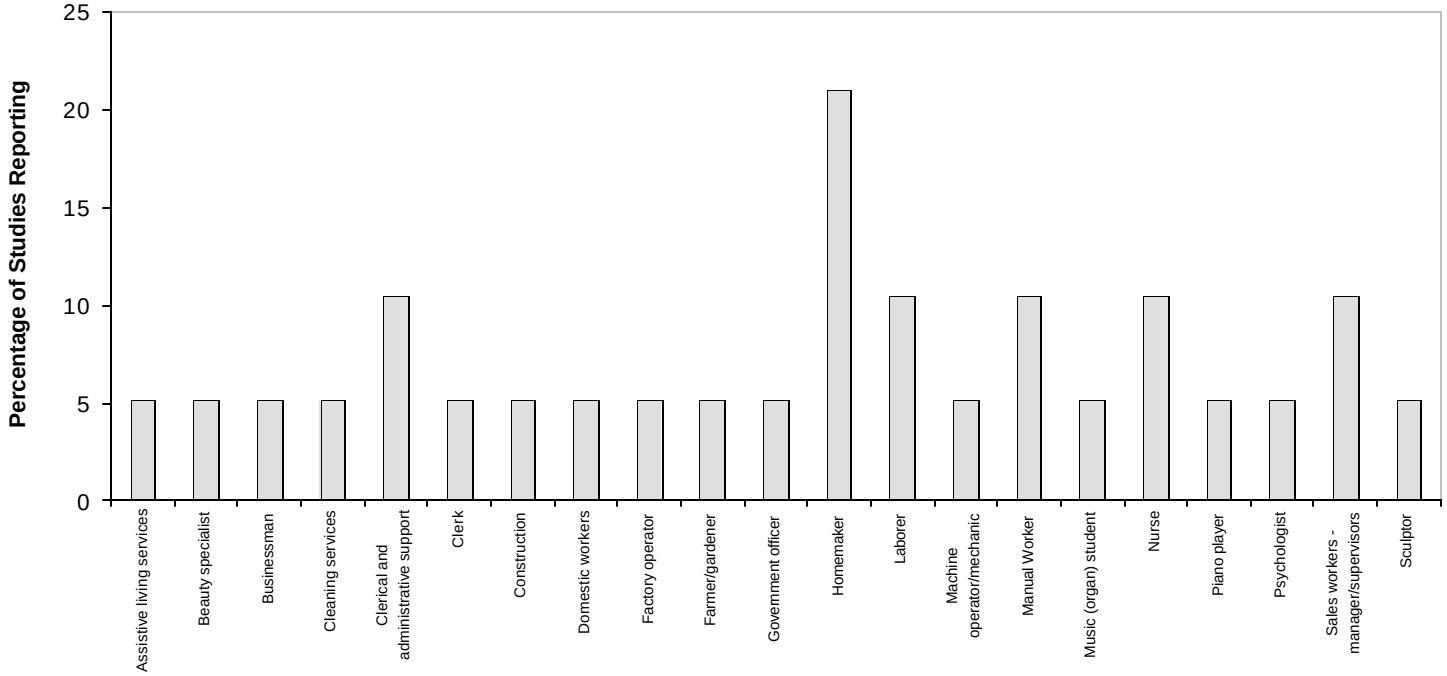
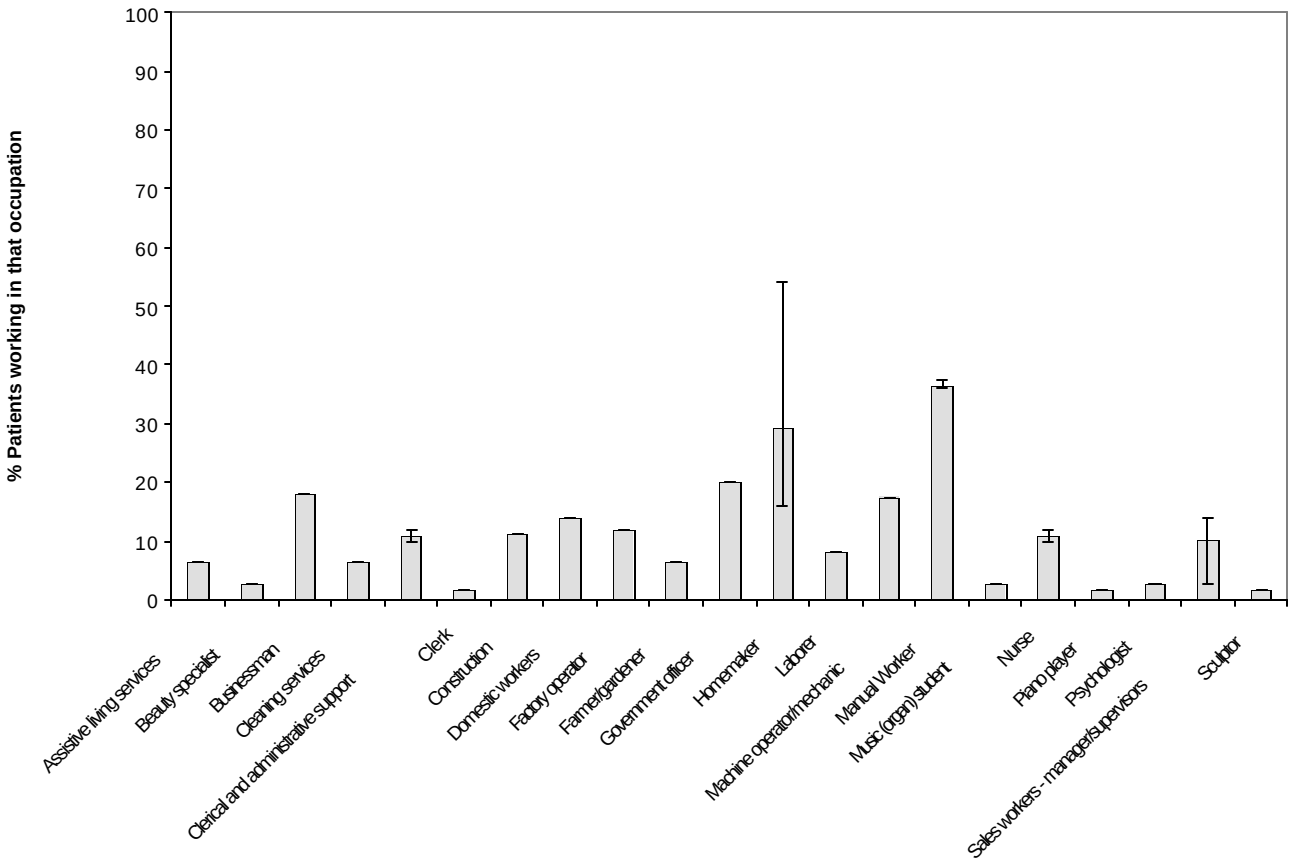


Figure 62. Percentage of patients with reported occupations receiving surgery for epicondylitis



Comorbidities

Comorbid conditions were not reported by any of the 19 studies. One study excluded patients who had carpal or cubital tunnel syndrome in addition to epicondylitis. Because of the lack of information, no conclusions can be drawn regarding the presence of comorbidities among patients receiving surgery for epicondylitis or the impact of comorbidities on whether a patient is a candidate for surgery.

Conclusions

Nineteen studies of patients who received surgery for epicondylitis were identified. A typical patient who received surgery for epicondylitis was middle-aged and equally likely to be male or female, but due to a lack of reported data, few trends or characteristics of patients who received surgery could be identified.

Question #3. What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with epicondylitis?

Evidence base

We considered only controlled trials that evaluated therapies as treatments for patients with epicondylitis for this section of the report. We retrieved 57 studies that met the inclusion criteria (see the section Inclusion Criteria). Six were excluded because they contained reporting or design difficulties serious enough to preclude interpretation of the results. These studies, and the reasons for their exclusion, are shown in Table 224. Thirty-eight randomized controlled trials, four randomized crossover trials, and eight controlled trials that evaluated eighteen different types of therapies as treatments for epicondylitis were included in the answer to this question. These trials are listed in Table 225. All of the trials studied only patients with lateral epicondylitis except for that of Stahl 1997, who studied patients with medial epicondylitis, and Brattberg 1983, who studied a mixed population of patients with lateral or medial epicondylitis. We have organized our answer to this question into sub-sections, one for each type of treatment.

Table 224. Excluded studies

Study	Reason for exclusion
Simunovic 1998 [569]	Patients were treated until they improved, and only then were they crossed over to the placebo treatment. This creates a bias in favor of improvement.
Burton 1985 [570]	Insufficient details to allow comparison of patient groups. Data from control group not reported.
Heyse-Moore 1984 [571]	Patients were allocated into different treatment groups on the basis of what symptoms they presented with, and thus the treatment groups cannot be directly compared.
Rosenthal 1982 [572]	It is unclear from the few details provided whether the patients actually had lateral epicondylitis.
Day 1978 [573]	Patients were treated until they improved. This creates a bias in favor of improvement.
Baily 1957 [574]	Many patients received confounding co-interventions, such as extra injections, physiotherapy, etc. that are incompletely described.

Table 225. Trials evaluating interventions for epicondylitis

Therapies evaluated	Study	Trial Design
Acupuncture	Molsberger 1994 [575]	Randomized controlled trial
	Haker 1990 [576]	Randomized controlled trial
Bracing	Wuori 1998 [577]	Randomized controlled crossover
	Forbes 1990 [578]	Crossover
Bracing compared to physiotherapy	Solveborn 1997 [579]	Controlled trial
Bracing plus physiotherapy	Clements 1993 [580]	Controlled trial
ESWT	Rompe 1996 [581,582]	Randomized controlled trial
GAGPs injections	Akermark 1995 [583]	Randomized controlled trial
Laser	Basford 2000 [584]	Randomized controlled trial
	Papadopoulos 1996 [585]	Randomized controlled trial
	Krasheninnikoff 1994 [586]	Randomized controlled trial
	Vasseljen 1992 [587]	Randomized controlled trial
	Haker 1991 [588]	Randomized controlled trial
	Haker 1991 [589]	Randomized controlled trial
	Haker 1990 [590]	Randomized controlled trial
Laser compared to ultrasound plus massage	Vasseljen 1992 [591]	Randomized controlled trial
Manipulations	Vicenzino 1996 [592]	Randomized controlled crossover
Manipulations compared to Ultrasound plus physiotherapy	Drechsler 1997 [593]	Randomized controlled trial
Manipulations Manipulations plus bracing Manipulations plus topical NSAIDs Manipulations plus topical NSAIDs plus bracing	Burton 1988 [594]	Randomized controlled trial
Oral NSAIDs	Labelle 1997 [595]	Randomized controlled trial
	Adelaar 1987 [596]	Randomized controlled trial
	Stull 1986 [597]	Randomized controlled trial
PEMF	Devereaux 1985 [598]	Randomized controlled trial
Physiotherapy compared to ultrasound	Pienimaki 1996 [599 600]	Randomized controlled trial
Steroid injections	Stahl 1997 [601]	Randomized controlled trial
	Solveborn 1995 [602]	Randomized controlled trial
	Price 1991 [603]	Randomized controlled trial
	Kivi 1982 [604]	A-B trial
	Clarke 1975 [605]	Controlled trial

Therapies evaluated	Study	Trial Design
Steroid injection TENS Ultrasound Phonophoresis	Halle 1986 [606]	Randomized controlled trial
Steroid injections compared to manipulation	Verhaar 1995 [607]	Randomized controlled trial
Steroid injections compared to acupuncture	Brattberg 1983 [608]	Controlled trial
Steroid injection compared to Oral NSAIDs	Hay 1999 [609]	Randomized controlled trial
	Saartok 1986 [610]	Randomized controlled trial
Steroid injections Bracing Immobilization	Haker 1993 [611]	Randomized controlled trial
Surgery	Almquist 1998 [83]	Controlled trial
	Wilhelm 1996 [84]	Controlled trial
TENS	Johannsen 1993 [612]	Randomized controlled trial
Topical DMSO	Percy 1981 [613]	Randomized controlled trial
Topical NSAIDs	Demirtas 1998 [614]	Randomized controlled trial
	Schapira 1991 [615]	Randomized controlled trial
	Burnham 1998 [616]	Randomized controlled crossover
Ultrasound	Lundeberg 1988 [617]	Randomized controlled trial
	Binder 1985 [618]	Randomized controlled trial
	Haker 1991 [619]	Randomized controlled trial
Ultrasound Phonophoresis Ultrasound plus bracing Phonphoresis plus bracing	Holdsworth 1993 [620]	Randomized controlled trial
Ultrasound Phonophoresis Ultrasound plus massage Phonophoresis plus massage	Stratford 1989 [621]	Randomized controlled trial

ESWT = extracorporal shock wave therapy
GAGPs = glucosaminoglycan polysulfate
NSAID = non steroidal anti -inflammatory drug
PEMF = pulsed electromagnetic field
TENS = transcutaneous electrical nerve stimulation
DMSO = dimethylsulfoxide

What are the relative benefits and harms of low-level laser therapy for persons with epicondylitis?

The literature addressing this question consists of seven studies that compared low level laser treatment to sham laser treatment. Therefore, in this section we address the benefits and harms of laser therapy relative to sham treatment, but the literature included in this section does not allow one to determine the effectiveness of laser therapy relative to any other type of therapy.

Low level red or infrared lasers have been used to treat pain and speed healing. The lasers are thought to possess biostimulating and regenerative properties; however, the physiological basis of such properties is uncertain. Low-level lasers have also been claimed to decrease pain by increasing serotinin metabolism and by slowing nerve conduction.[584,586]

Internal validity

We identified seven studies that included a total of 320 patients that evaluated low-level laser therapy for treating epicondylitis. All seven studies were prospective double-blinded randomized controlled trials that compared laser therapy to sham laser therapy. Details of the designs of the studies relevant to the internal validity of the studies are shown in Table 226.

Two of the studies had statistically significant differences in the gender compositions between their patient groups. The Papadopoulos 1994 trial contained a sham group that was 86.7% female, and a laser group that was 57.1% female (chi-squared test, calculated by ECRI, p = 0.002426). The Haker 1991[589] trial contained a sham group that was 13.8% female and a laser group that was 37.9% female (chi-squared test, calculated by ECRI, p = 0.035808). These differences are surprising in a randomized controlled trial, and could suggest that the randomization process was not optimal. This may have influenced the reported results.

Neither the three studies by Haker, nor the study by Basford 2000, did not use intent-to-treat analysis. The three studies by Haker had quite high attrition rates (over 20%). Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle for the trials by Haker, but not for the trial Basford 2000. Our compensation did not change the conclusions of any of the trials.

Table 226. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Basford 2000 [584]	52	1	No	RCT	Yes	Double	9.6	No	NA
Papadopoulos 1996 [585]	29	1	No	RCT[a]	Yes	Double	0	Yes	NA
Krasheninnikoff 1994 [586]	48	1	NR	RCT	Yes	Double	4.2	Yes	NA
Vasseljen 1992 [587]	30	1	NR	RCT	Yes	Double	3.3	Yes	NA
Haker 1991 [588]	52	1	NR	RCT	Yes	Double	26.9	No	NA
Haker 1991 [589]	60	1	NR	RCT[a]	Yes	Double	28.3	No	NA
Haker 1990 [590]	49	1	NR	RCT	Yes	Double	20.4	No	NA

[a] may have been improperly randomized
NA = not applicable
NR = not reported
RCT = randomized controlled trial

Generalizability

Details about the patients enrolled in these trials are shown in Table 227. The mean patient age in these trials ranged from 44.3 to 48.5. Krasheninnikoff 1994 did not report the gender composition of the patient groups; the other studies reported that their patient groups were 25.0% to 72.4% female. These patient characteristics approximate those reported in published studies of the epidemiology of epicondylitis (see the Introduction), suggesting that the results of the studies are broadly generalizable beyond their particular patient groups.

The presence of various co-morbidities is incompletely reported in these studies. Some studies excluded patients with co-morbidities, indicated in Table 227 by a zero under that comorbidity. This somewhat limits the generalizability of these studies, as comorbidities are not exclusion criteria for laser treatment.

None of the studies reported any information about the occupations or employment status of the patients. The extent to which the employment characteristics of these patients may be generalized to the overall population of epicondylitis patients cannot be determined.

Table 227. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Basford 2000 [584]	52	45.1	51.9	6.4	NR	NR	NR	NR	NR	NR	NR	No	No
Papadopoulos 1996 [585]	29	45	72.4	5.8	NR	0	0	0	0	0	0	No	No
Krasheninnikoff 1994 [586]	48	48.5 (37-64)	NR	3 (1-12)	NR	0	0	NR	0	0	NR	No	No
Vasseljen 1992 [587]	30	45.5 (25-63)	50.0	3.5 (1-12)	NR	0	NR	NR	NR	NR	NR	No	No
Haker 1991 [589]	60	45.3 (33-65)	25.0	5.5 (1-60)	NR	0	NR	0	0	NR	NR	No	No
Haker 1991 [588]	52	44.3 (22-66)	34.6	9.5 (1-60)	NR	NR	NR	NR	NR	NR	NR	No	No
Haker 1990 [590]	49	46.7 (24-70)	42.8	7 (1-36)	NR	0	NR	0	0	NR	NR	No	No

NR = not reported

Results

Success of Treatment

Four studies that enrolled a total of 173 patients reported on success of treatment. This outcome was evaluated by asking the patients to rate their symptoms on categorical scales. The results are shown in Table 228 and summarized in Table 229. Effect sizes (Hedges' d) were calculated for each study using a conservative correction for attrition as discussed previously. The effect sizes of the one to 1.5 month followup time and the longest followup time for each study were combined meta-analytically using a fixed-effect model. The results of these analyses are shown in Table 230. The studies were found to not be heterogeneous by the Q-test at either time point, and thus a summary effect size is statistically valid. The summary effect sizes for both meta-analyses were positive, indicating a trend towards laser therapy being more successful, but both 95% confidence intervals contained zero, indicating that there was no statistically significant difference between success of treatment when comparing laser therapy to sham treatment. The effect sizes of are shown graphically in Figure 63 and Figure 64. A U-test of the data showed that the distribution of the effect sizes of the laser treatment groups and the sham treatment groups overlapped by 89.9% at the one to 1.5 month followup time, and 83.7% at the longest followup times. This is shown graphically in Figure 65 and Figure 66.

Because the attrition rates in the studies by Haker are high at the longest followup times (>20%), we performed an analysis to see how attrition might have affected the overall results. We originally assumed that all of the patients lost to followup had failed treatment. Using the opposite assumption, that all of the patients lost to followup had been cured, our conclusions did not change. The summary effect size was not statistically significant under either of our assumptions (Table 230). However, using the the conservative assumption, a trend towards laser therapy being more effective was observed, while under the opposite assumption a trend towards sham therapy being more effective was observed.

Data from other times of followup were not combined meta-analytically because only one or two studies reported data for each of the other times of followup.

Table 228. Results of the success of treatment with laser therapy

Study	Number of patients	Global outcome, patient-rated	Statistical significance of the difference between groups[a]
Krasheninnikoff 1994 [586]	18 sham 18 laser	Sham- at one month, 3 cured, 7 more effective, 8 unchanged. At 2.5 months, 6 cured, 5 more effective, 7 unchanged. Laser- at one month, 2 cured, 9 more effective, 7 unchanged. At 2.5 months, 6 cured, 4 more effective, 8 unchanged.	Chi-squared test At one month, p = 0.772338 At 2.5 months, p = 0.914947 Not statistically significantly different
Vasseljen 1992 [587]	13 sham 15 laser	Sham- at two weeks, 0 cured, 8 more effective, 5 no change, 2 worse. At 1.5 months, 3 cured, 5 more effective, 5 no change, 2 worse. At 5.5 months, 4 (30.7%) were successfully treated. Laser- at two weeks, 3 cured, 7 more effective, 3 no change, 2 worse. At 1.5 months, 7 cured, 5 more effective, 1 no change, 2 worse. At 5.5 months, 8 (53.3%) were successfully treated.	Chi-squared test At 2 weeks, p = 0.456057 At 1.5 months, p = 0.121335 At 5.5 months, p = 0.136037 Not statistically significantly different
Haker 1991 [589]	29 sham 29 laser	Sham: at 1.5 months, 0 excellent, 5 good, 17 improved,10 some improvement, 7 unchanged. At 3 months, 4 excellent, 7 good, 8 improved, 2 some improvement, 6 unchanged. At 6 months, 3 excellent, 6 good, 10 improved, 4 some improvement, 0 unchanged. Laser- at 1.5 months, 1 excellent, 7 good, 16 improved, 9 some improvement, 5 unchanged. At 3 months, 2 excellent, 11 good, 10 improved, 1 some improvement, 4 unchanged. At 6 months, 3 excellent, 15 good, 5 improved, 1 some improvement, 0 unchanged.	Chi-squared test At 1.5 months, p = 0.097781 At 3 months, p = 0.023323 At 6 months, p = 0.006687 Difference is statistically significant for 3 and 6 months of followup
Haker 1990 [590]	26 sham 23 laser	Sham: at 1.5 months, 1 excellent, 11 good, 9 improved, 4 some improvement, 5 unchanged. At 3 months, 1 excellent, 12 good, 6 improved, 1 some improvement, 6 unchanged. At one year, 8 excellent, 6 good, 6 improved, 3 some improvement, and 1 unchanged. Laser: at 1.5 months, 1 excellent, 4 good, 12 improved, 7 some improvement, 6 unchanged. At 3 months, 5 excellent, 7 good, 8 improved, 3 some improvement, 2 unchanged. At one year, 6 excellent, 8 good, 4 improved, 2 some improvement, 8 unchanged.	Chi-squared test At 1.5 months, p = 0.065075 At 3 months, p = 0.015251 At one year, p = 0.107943 Difference is statistically significant for 3 months of followup

[a] calculated by ECRI

Table 229. Success of treatment with laser therapy for epicondylitis

Study	Number of patients	Followup time	Which procedure was more effective?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Krasheninnikoff 1994 [586]	18 sham 18 laser	1 month	Laser	No	0.19 (-0.46 to 0.85)
		2.5 months	Sham	No	-0.11 (-0.77 to 0.54)
Vasseljen 1992 [587]	15 sham 15 laser	2 weeks	Laser	No	0.64 (-0.09 to 1.38)
		1.5 months	Laser	No	0.73 (-0.01 to 1.47)
		5.5 months	Laser	No	0.61 (-0.23 to 1.46)
Haker 1991 [589]	29 sham 29 laser	1.5 months	Laser	No	0.28 (-0.24 to 0.80)
		3 months	Laser	Yes	0.24 (-0.28 to 0.76)
		6 months	Laser	Yes	0.50 (-0.03 to 1.02)
Haker 1990 [590]	26 sham 23 laser	1.5 months	Sham	No	-0.44 (-1.01 to 0.13)
		3 months	Laser	Yes	0.43 (-0.13 to 1.00)
		12 months	Sham	No	-0.01 (-0.58 to 0.55)

[a] calculated by ECRI

Table 230. Results of meta-analysis of effect of laser therapy vs. sham therapy on global outcome

Analysis	Study	N	Effect size	95% CI	P value	Standardized residual	Outlier by std. Residual?
One to 1.5 months	Krasheninnikoff 1994 [586]	36	0.19	-0.46 to 0.85	0.56	0.20	No
	Vasseljen 1992 [587]	30	0.73	-0.01 to 1.47	0.053	1.74	No
	Haker 1991 [589]	58	0.28	-0.24 to 0.80	0.29	0.68	No
	Haker 1990 [590]	49	-0.44	-1.01 to 0.13	0.13	-2.34	Yes
Longest followup time, conservative correction for attrition	Krasheninnikoff 1994 [586]	36	-0.11	-0.77 to 0.54	0.73	-1.15	No
	Vasseljen 1992 [587]	30	0.61	-0.23 to 1.46	0.15	0.98	No
	Haker 1991 [589]	58	0.50	-0.03 to 1.02	0.062	1.26	No
	Haker 1990 [590]	49	-0.01	-0.58 to 0.55	0.96	-1.00	No
Longest followup time, opposite correction for attrition	Krasheninnikoff 1994 [586]	36	-0.11	-0.77 to 0.54	0.73	0.15	No
	Vasseljen 1992 [587]	30	-0.51	-0.51 to 1.09	0.48	1.19	No
	Haker 1991 [589]	58	-0.85	-0.85 to 0.19	0.21	-0.81	No
	Haker 1990 [590]	49	-0.77	-0.77 to 0.35	0.47	-0.21	No
Summary 1 to 1.5 months	4 RCT's	173	0.13	-0.17 to 0.43	0.39	Q = 6.77	P of Q = 0.079
Summary, longest, conservative	4 RCT's	173	0.22	-0.08 to 0.53	0.15	Q = 3.59	P of Q = 0.31
Summary longest, opposite	4 RCT's	173	-0.16	-0.46 to 0.15	0.31	Q = 1.68	P of Q = 0.64

Figure 63. Effect sizes of laser therapy compared to sham therapy as a treatment for epicondylitis, 1 to 1.5 months of followup

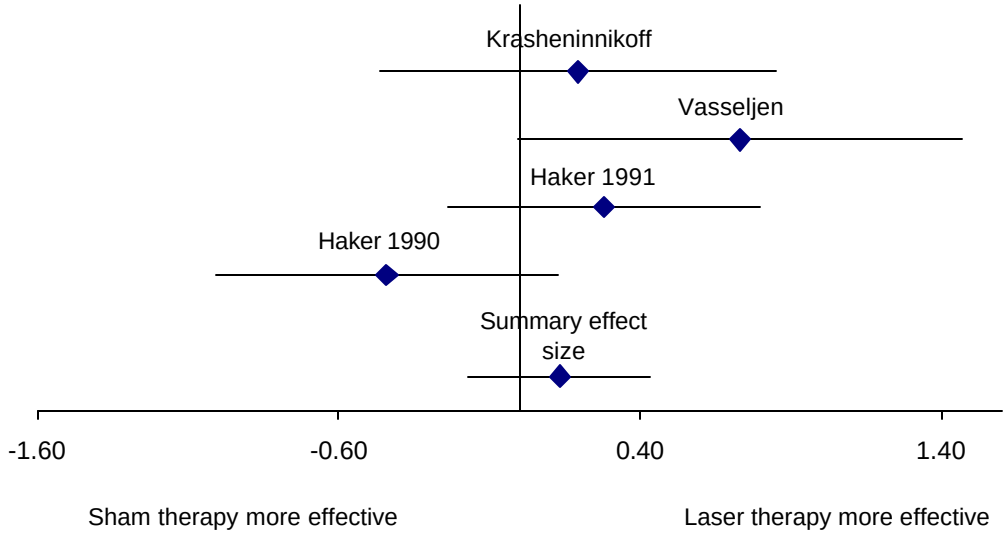


Figure 64. Effect sizes of laser therapy compared to sham therapy as a treatment for epicondylitis, longest times of followup

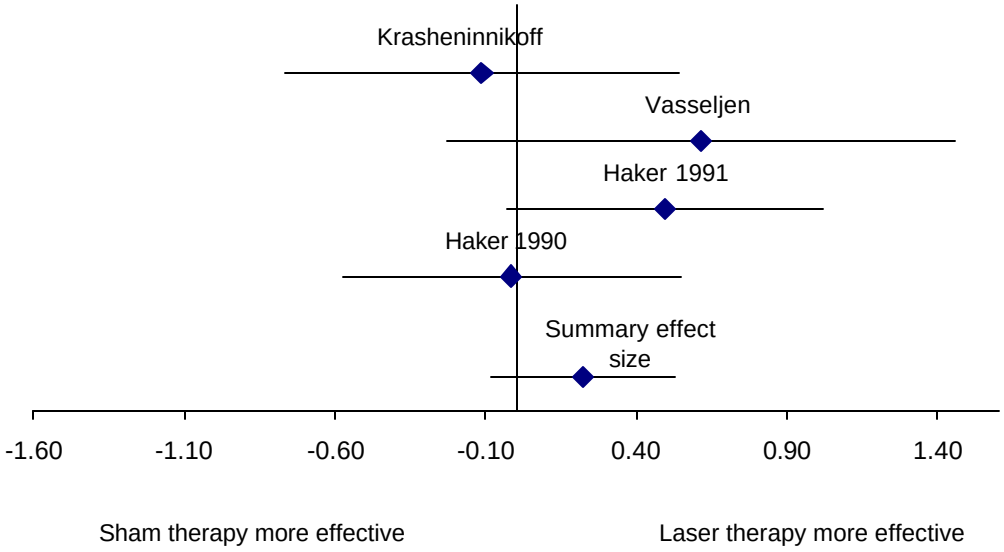


Figure 65. Overlap of effect size distributions in patients receiving laser or sham therapy, 1-1.5 months of followup

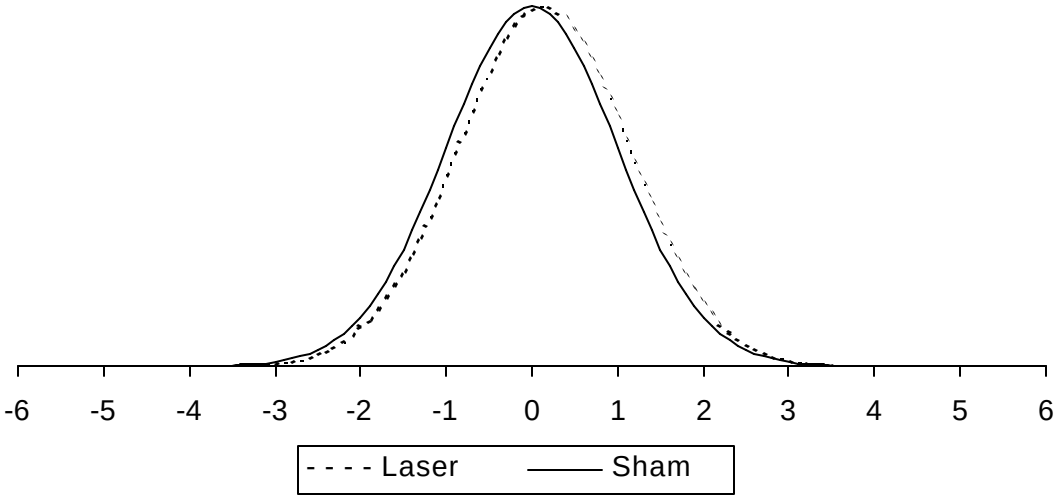
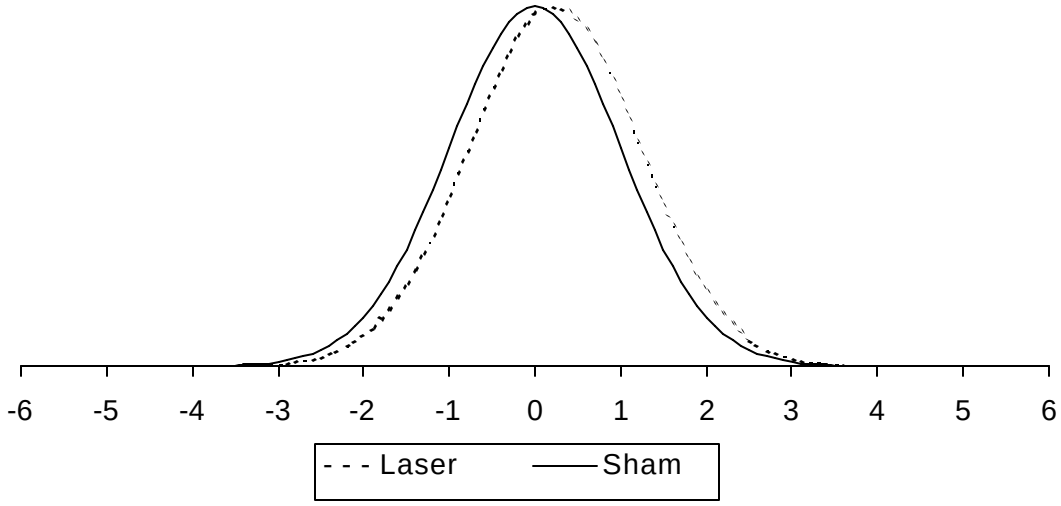


Figure 66. Overlap of effect size distributions in patients receiving laser or sham therapy, longest times of followup



Work Status

Only one study of 30 patients reported this outcome. The study counted the number of patients working or not working 5.6 months after the study began. The data from this study are summarized in Table 231 and Table 232. A statistically nonsignificant difference in work status was reported between sham treated and laser treated patients. This study could have detected a 26% or greater difference between groups, so statistical power may not be a substantial issue with it.

Table 231. Results of work status after treatment with laser therapy

Study	N patients	Time of followup	Number of patients working	Statistical significance of the difference between groups
Vasseljen 1992 [587]	13 Sham 15 Laser	5.5 months	9 sham treated patients were working and 13 laser treated patients were working	Chi-squared test [a] p = 0.262

[a] calculated by ECRI

Table 232. Work status after treatment with laser therapy

Study	Number of patients	Which procedure had more patients working?	Was the difference statistically significant?	Effect size d (95% CI)[a]	What is the minimal difference between groups the study had the statistical power to detect?
Vasseljen 1992 [587]	Sham 13 Laser 15	Laser	No	0.57 (-0.48 to 1.61)	26%

[a] calculated by ECRI

Pain

The effect of laser treatment on pain was reported by four studies of 143 patients in total. All four studies reported pain rated by the patients on visual analog scales (VAS). The data reported by the studies is shown in Table 233 and summarized in Table 234. The reported results of the studies are shown graphically in Figure 67 and the effect sizes (Hedges' d) of the longest followup times are shown graphically in Figure 68. The results for all other time points are similar to that found for the longest followup times.

Because an effect size could be calculated for only three of the studies, we did not perform a meta-analysis. None of the studies reported a statistically significant difference in pain outcomes between the two groups. However, all of the studies are small. Due to limitations in the reported data, we were only able to perform a power analysis for one of the studies. Our calculations show that the study by Vasseljen 1992 could have detected only an 86% or larger difference between the treatment groups. The other studies are of similar sizes. Thus, it is unlikely that they would have found a statistically significant difference even if the difference between groups were rather large. Therefore, these studies cannot be taken as proof that laser therapy provides no pain relief.

Table 233. Results of the effect of laser treatment on pain

Study	N patients	Pain measurements	Statistical significance of the difference between groups
Basford 2000 [584]	24 sham 23 laser	No data reported	Wilcoxon's rank sum test At 2 weeks, p = 0.551 At 1 month, p = 0.371 At 2 months, p = 0.488
Papadopoulos 1994 [585]	15 sham 14 laser	No data reported	Test not reported NS
Krasheninnikoff 1994 [586]	18 sham 18 laser	At one month, Sham- 22 median 95% CI (12 to 63) Laser- 27 median 95% CI (5 to 50)	Mann-Whitney rank sum test p >0.05
Vasseljen 1992 [587]	15 sham 15 laser	Mean (95% CI) Sham- at time 0, 3.8 (2.75 to 4.8). At 2 weeks, 3.8 (2.75 to 4.7). At 1.5 months, 3.2 (2.4 to 4.2). At 5.5 months, 0.7 (0.4 to 1.0) Laser- at time 0, 4.2 (3.2 to 5.2). At 2 weeks, 3.6 (2.2 to 4.95). At 1.5 months, 2.65 (1.5 to 3.8). At 5.5 months, 0.49 (0.2 to 0.75)	t-test at time 0, p = 0.591 at 2 weeks, p = 0.814 at 1.5 months, p = 0.504 at 5.5 months, p = 0.317

Table 234. Summary of the effect of laser treatment on pain

Study	N patients	Which procedure was most effective at treating pain?	Was the difference statistically significant?	Effect size d (95% CI)[a]	What is the minimal difference between groups that the study had the statistical power to detect?
Basford 2000 [584]	24 Sham 23 Laser	No difference	No at all followup times	0.20 (-0.37 to 0.77)[b]	NC
Papadopoulos 1994 [585]	15 Sham 14 Laser	No difference	No at all followup times	NC	NC
Krasheninnikoff 1994 [586]	18 Sham 18 Laser	Sham	No at all followup times	-0.66 (-1.33 to 0.01)	NC
Vasseljen 1992 [587]	15 Sham 15 Laser	Laser	No at all followup times	1.41 (0.61 to 2.21)	86%

[a] calculated by ECRI

[b] the direction of this effect size was chosen at random and is not to be interpreted as supporting one treatment group over the other

NC = could not be calculated from reported data

Figure 67. Effectiveness of laser therapy at treating pain

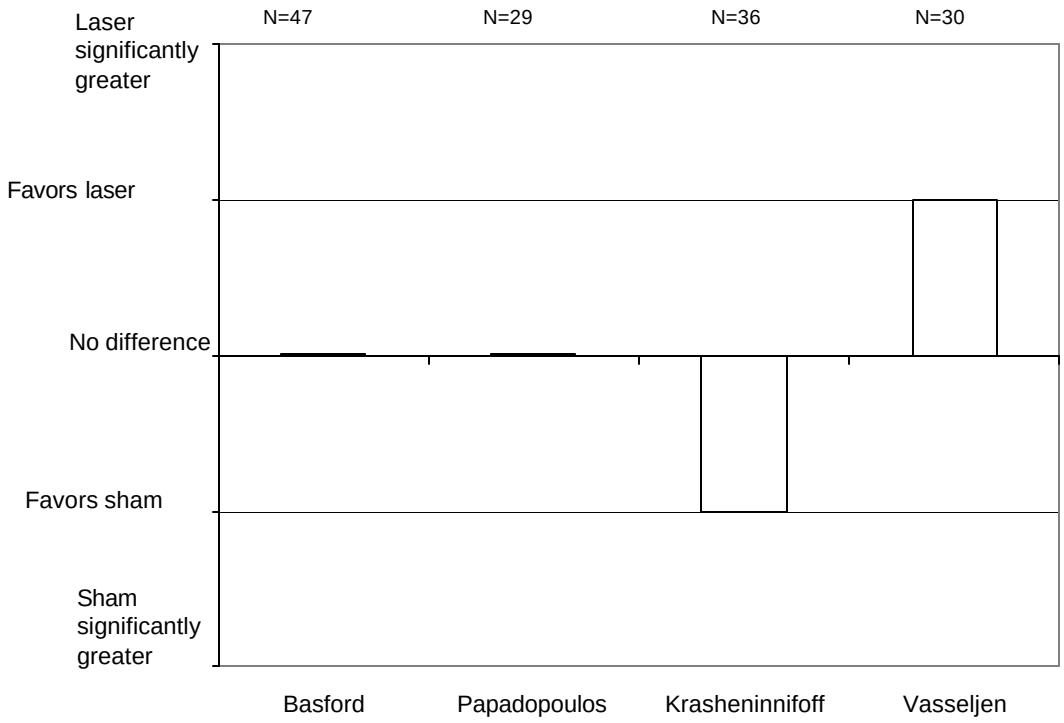
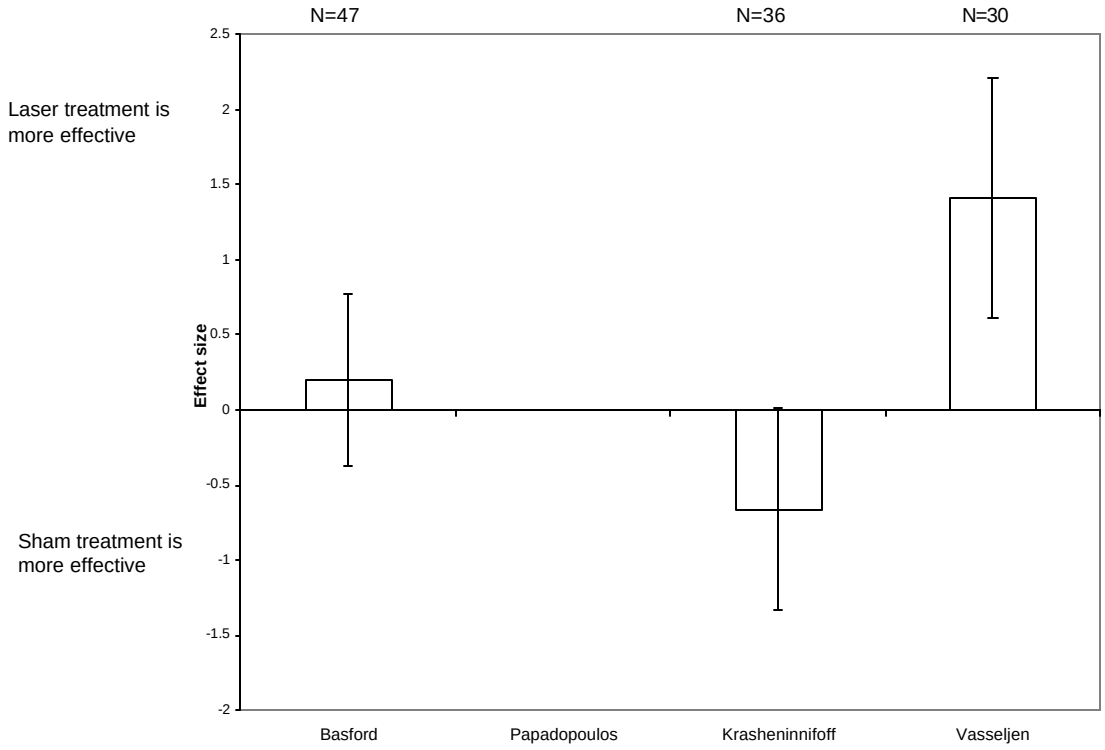


Figure 68. Effect sizes: laser treament on pain



Function and Activites of Daily Living

None of the studies reported a patient-oriented measure of these outcomes.

Quality of Life

None of the studies reported on this outcome.

Morbidity and Complications

None of the studies reported any side effects or complications of laser therapy.

Conclusions

Seven studies that included a total of 320 patients were identified that evaluated low-level laser therapy for treating epicondylitis. All seven studies were double-blinded randomized controlled trials that compared laser therapy to sham laser therapy.

A meta-analysis of the results of the four studies that reported "success of treatment" did not find a statistically significant difference in outcome between laser and sham treated patients. The four studies that reported the effect of laser treatment on pain also did not find a statistically significant difference in outcome between laser and sham treated patients. However, we were unable to perform a meta-analysis of the outcome pain, and because all of these studies were small their individual results cannot be taken as definitive proof that laser therapy has no effect on the pain of epicondylitis. Only one study examined work status of patients after laser treatment. It failed to find a statistically significant effect of laser treatment on work status and did have sufficient statistical power to detect medium or large differences between groups. However, it is difficult to draw firm evidence-based conclusions from the results of a single study.

The results of all seven small randomized double-blinded controlled trials are consistent with the results of our meta-analysis, and suggest that if there is an effect of laser therapy on epicondylitis, it is not large.

What are the relative benefits and harms of oral and topical anti-inflammatory drug therapy for persons with epicondylitis?

Non-steroidal anti-inflammatory drugs (NSAIDs) are a class of drugs that act to reduce inflammation. Most are also potent analgesics. NSAIDs used to treat epicondylitis can be taken orally or applied topically to the elbow joint. Common NSAIDs used to treat epicondylitis include diclofenac, salicylate, diflunisal, and naproxen.

Dimethylsufoxide (DMSO), although not an NSAID, has been included in this section. DMSO can be applied topically. It rapidly penetrates the skin and spreads throughout the body. It has been reported to have anti-inflammatory and analgesic properties.

The relevant literature consists of seven trials. One trial evaluated the use of DMSO as compared to placebo. Three trials compared the relative effectiveness of different types of NSAIDs. Three trials compared the effectiveness of different types of NSAIDs to placebo.

Internal validity

Seven randomized controlled trials that enrolled a total of 405 patients were included in this section of the report. The therapies used by the different trials are summarized in Table 235. Details of the designs of these trials are shown in Table 236. One double-blinded trial of 51 patients evaluated the use of topical DMSO as compared to placebo. One double-blinded trial of 206 patients compared oral diclofenac to placebo. Two double-blinded trials of 47 patients, one of which was a crossover trial, compared topical diclofenac to placebo. Two unblinded trials of 62 patients compared the effectiveness of oral diflunisal to oral naproxen. We do not consider lack of blinding in these two particular trials to be a serious design flaw. It is unlikely that knowledge of which type of NSAID was administered, by either the patients or the evaluating physician, would affect the results of the trial.

Three of the trials did not analyze their data according to the intent-to-treat principle. Two of these studies (Adelaar 1987 and Percy 1981) had attrition rates over 15%. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle for the trial by Adelaar 1987 for one outcome, but not for any other outcomes, and we were unable to compensate for not following the intent-to-treat principle for Percy 1981 or for Stull 1986. For the one outcome of Adelaar 1987 that we were able to compensate for, the conclusions of the trial did not change.

Table 235. Summary of the treatments evaluated

Study	Group 1	Group 2
Burnham 1998 [616]	Topical diclofenac	Placebo
Schapira 1991 [615]	Topical diclofenac	Placebo
Demirtas 1998 [614]	Topical diclofenac	Topical salicylate
Labelle 1997 [595]	Oral diclofenac	Placebo
Adelaar 1987 [596]	Oral diflunisal	Oral naproxen
Stull 1986 [597]	Oral dilfunisal	Oral naproxen
Percy 1981 [613]	Topical DMSO	Placebo

Table 236. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Demirtas 1998 [614]	40	1	NR	RCT	Yes	No	0	Yes	NR
Burnham 1998 [616]	14	1	NR	RCT Xover	Yes	Double	0	Yes	NR
Labelle 1997 [595]	206	Multiple	Yes	RCT	Yes	Double	0.49	Yes	49.5
Schapira 1991 [615]	32	1	Yes	CT	Yes	Double	0	Yes	NR
Adelaar 1987 [596]	22	1	NR	RCT	Yes	No	18.2	No	NR
Stull 1986 [597]	40	1	Yes	RCT	Yes	No	5.0	No	NR
Percy 1981 [613]	51	1	Yes	RCT	Yes	Double	21.6	No	NR

RCT = randomized controlled trial
Xover = crossover
CT = controlled trial
NR = not reported

Generalizability

Characteristics of the patients are shown in Table 237. Studies of the epidemiology of epicondylitis (see the Introduction) have found that typical patients are in their mid-forties and are equally likely to be of either sex. All of the trials included patients that are similar to these characteristics except the trials by Stull 1986 and Schapira 1991 which did not report the mean age of their patient groups and the trial by Adelaar 1987 which had a mean age of 34.5 years (This is younger than the general population of patients with epicondylitis; see the epidemiology subsection of the introduction to this evidence report, as well as the answer to question two regarding epicondylitis).

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated by a zero in Table 237 under that comorbidity. This somewhat limits the generalizability of these studies, as comborbidites may not be exclusion criteria for treatment with anti-inflammatories.

Only one of the trials reported information on the occupations of the patients (Table 238). Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 237. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Burnham 1998 [616]	14	42.5	42.8	8.3 (2-24)	NR	NR	NR	NR	NR	NR	NR	No	No
Demirtas 1998 [614]	40	45.0 (25-61)	65	5.0 (2-13)	NR	NR	NR	NR	NR	NR	NR	No	No
Labelle 1997 [595]	206	43.7	59	NR		0	NR	0	0	NR	NR	No	No
Schapira 1991 [615]	32	(34-78)	65.6	NR	NR	NR	NR	NR	NR	NR	0	No	No
Adelaar 1987 [596]	22	34.5 (20-49)	54.5	NR	NR	NR	0	NR	NR	0	0	No	No
Stull 1986 [597]	40	NR	42.5	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Percy 1981 [613]	51	47.9 (28-64)	29.4	NR	NR	NR	NR	NR	NR	NR	0	No	No

NR = not reported

Table 238. Generalizability: patient occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Burnham 1998 [616]	14	NR	NR	NR	NR	NR
Demirtas 1998 [614]	40	NR	NR	NR	NR	NR
Labelle 1997 [595]	206	NR	NR	NR	NR	NR
Schapira 1991 [615]	32	NR	NR	NR	NR	NR
Adelaar 1987 [596]	22	NR	NR	NR	9.1	13.6% blue-collar worker 13.6% custodial worker 9.1% student 9.1% nurse 9.1% clerical worker 9.1% health care worker 4.5% broker 4.5% computer programmer
Stull 1986 [597]	40	NR	NR	NR	NR	NR
Percy 1981 [613]	51	NR	NR	NR	NR	NR

NR = not reported

Results

Success of Treatment-NSAIDs

Three studies reported on the success of treatment as rated by patients. The results of these trials are summarized in Table 239. Because there were two or fewer studies comparing the same NSAID treatments, no meta-analysis could be performed. The conclusions of the trials are summarized in Table 240. Two trials of a total of 51 patients reported on the relative success of treating with naproxen as compared to diflunisal. Both trials measured success by asking the patients to rate their symptoms after the course of drugs. Neither trial found a statistically significant difference between the treatment groups. However one study reported a slight advantage to taking naproxen, while the other study reported a slight advantage to taking diflunisal (Figure 69 and Figure 70). One trial of a total of 128 patients reported on the recurrence of symptoms three months after taking a course of diclofenac or placebo. There was no statistically significant difference in the rates of recurrence of symptoms between treatment groups. The statistical power of these studies suggest that they could have detected, depending on the trial, a 17% or 22% difference between groups. Therefore, if there is a difference between any of the treatments, it is unlikely to be large.

The trial by Demirtas 1998 compared topical salicylate treatments to topical diclofenac treatments. This trial did not report any patient-oriented outcomes, and for this reason we have not tabled any of its results. Demirtas 1998 reported that topical diclofenac was more effective at treating the symptoms of epicondylitis than was topical salicylate.

Table 239. Results of the success of treatment with NSAIDs

Study	Number of patients	Success of treatment	Statistical significance of difference between groups
Labelle 1997 [595]	64 Placebo 64 NSAIDs	At 3 months: Placebo: 27 patients still had symptoms NSAIDs: 23 patients still had symptoms	Test NR P = 0.52
Adelaar 1987 [596]	9 naproxen 9 diflunisal	At 0.5 months, patient-rated global outcome: Naproxen- 0 excellent, 7 improved, 2 no change, 0 worse Diflunisal- 0 excellent, 7improved, 1 no change, 1 worse	Exact chi-squared t test NS
Stull 1986 [597]	16 naproxen 17 diflunisal	At 0.5 months, patient-rated global outcome: Naproxen- 1 excellent, 11 improved, 3 no change, 1 worse Diflunisal- 3 excellent, 13 improved, 1 no change, 0 worse	Pearson chi-squared P = 0.368

Table 240. Success of treating epicondylitis with NSAIDs

Study	Number of patients	Time of follow-up	Which treatment was more successful?	Was the difference statistically significant?	What is the minimal difference between groups the study had the power to detect?	Effect size d (95% CI)[a]
Labelle 1997 [595]	64 oral diclofenac 64 placebo	3 months	diclofenac	No	17%	1.44 (1.05 to 1.83)
Adelaar 1987 [596]	9 oral diflunisal 9 oral naproxen	0.5 months	naproxen	No	22%	0.70 (-0.20 to 1.6)
Stull 1986 [597]	17 oral diflunisal 16 oral naproxen	0.5 months	diflunisal	No	22%	-0.40 (-1.09 to 0.29)

[a] calculated by ECRI

Figure 69. Success of treating epicondylitis with NSAIDs: naproxen vs. diflunisal

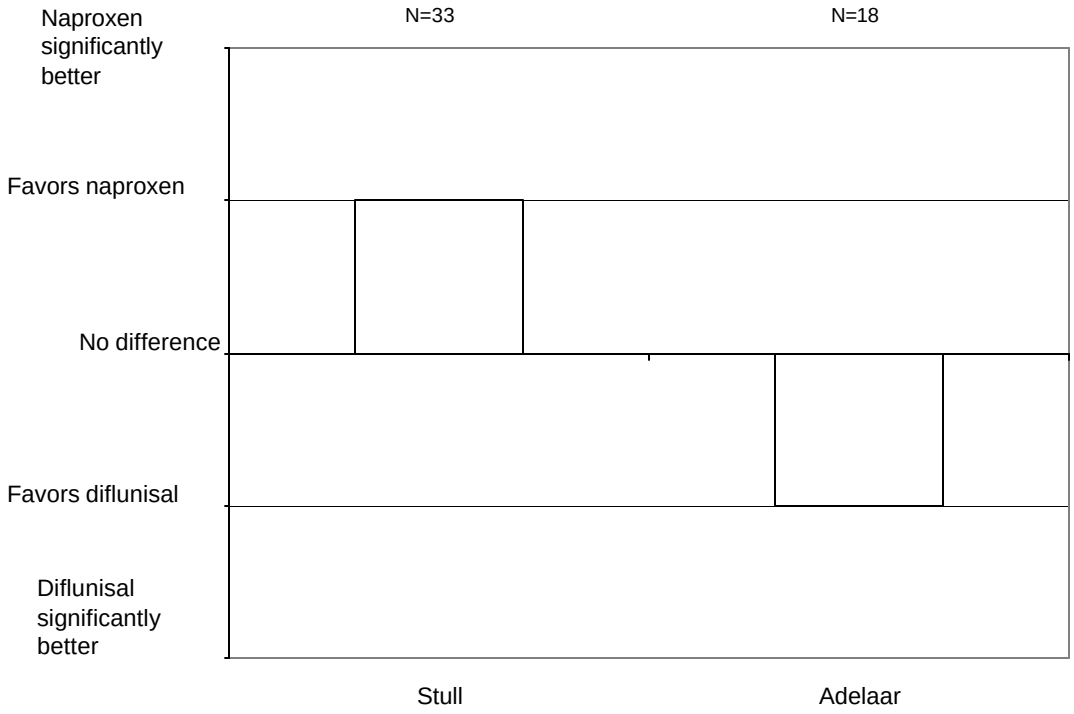
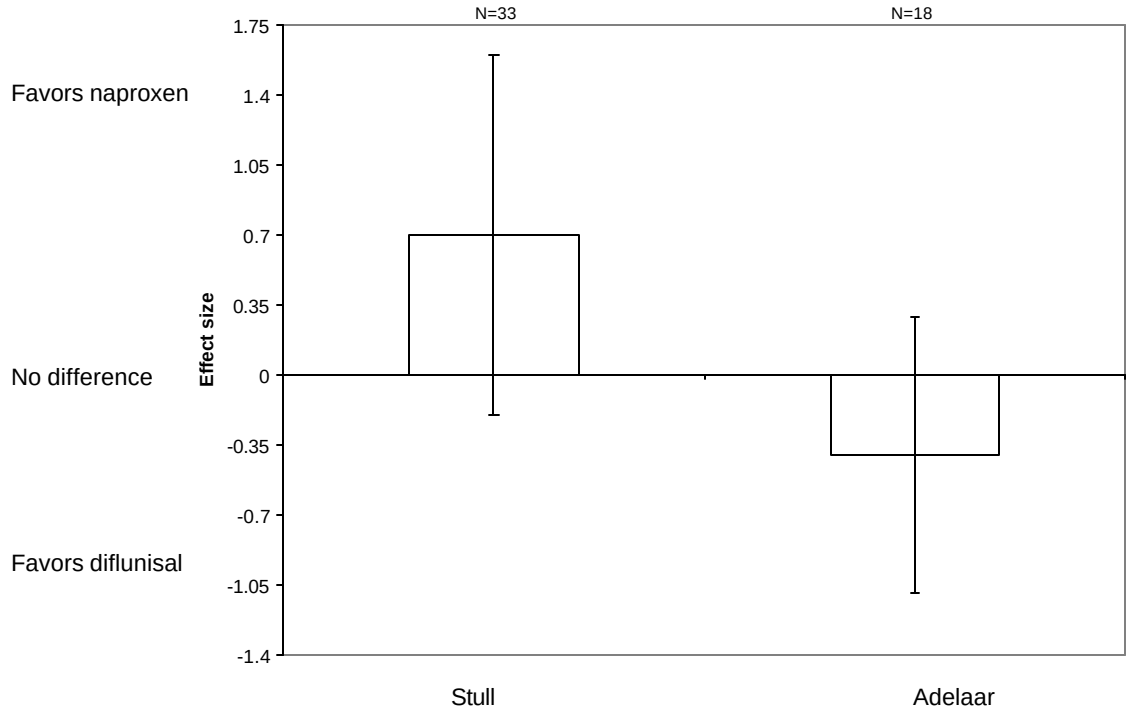


Figure 70. Effect sizes of diflunisal vs. naproxen



Success of treatment- DMSO

The trial by Percy 1981, which compared topical DMSO treatments to sham topical treatments, did not report any patient-oriented outcomes. For this reason, we have not tabled results or calculated effect sizes. However, this trial did report global outcome as rated by the treating physician. There was a trend towards the sham topical group being rated as having better outcomes than the topical DMSO group, but the difference was not statistically significant. There was insufficient information for us to calculate the statistical power of this study to detect differences between groups.

Work Status

One trial of 128 patients reported that there was no statistically significant difference in the number of work days missed due to epicondylitis between a group treated with diclofenac and a group treated with placebo. These data are shown in Table 241.

Table 241. Effect of NSAID treatment on work status

Study	N patients	Which treatment resulted in fewer sick days?	Was the difference significant?	Did the study have sufficient power?	Effect size d (95% CI)
Labelle 1997 [595]	64 oral diclofenac 64 placebo	No difference	No t-test	Could not calculate from reported information	Could not calculate from reported information

Pain

Four trials reported on pain. These studies are shown in Table 242. One of the trials, including 28 patients, compared topical diclofenac to a placebo. Two studies of a total of 62 patients compared oral naproxen to oral diflunisal. One study of 128 patients compared oral diclofenac to placebo. Because there were two or fewer trials of each combination of NSAIDs, no meta-analysis could be performed. The results reported by the studies are summarized in Table 243. Diclofenac, either topically applied or taken orally, was found to relieve pain more effectively than placebo. There was a tendency for diflunisal to relieve pain more effectively than naproxen, but only the results of the Stull study were statistically significant.

Table 242. Results of the effect of NSAIDs on pain

Study	Number of patients	Pain	Statistical significance of difference between groups
Burnham 1998 [616]	14 topical diclofenac 14 placebo	Patient-rated by VAS, mean (SD) At time 0, NSAIDs = 3.5 (1.7) Placebo = 3.5 (1.7) At 1 week, NSAIDs = 2.1 (2.1) Placebo = 3.6 (2.0)	ANOVA NS at time 0 P = 0.007 at 1 week
Labelle 1997 [595]	64 oral diclofenac 64 placebo	Patient-rated pain by VAS, mean (SD) At 1 month NSAIDs = 29.9 (26.3) Placebo = 16 (27.4)	Student t test p <0.005
Adelaar 1987 [596]	9 diflunisal 9 naproxen	Patient-rated pain, mean At time 0, diflunisal = 1.9 Naproxen = 2.1 At 2 weeks, diflunisal = 0.9 Naproxen = 1.1	Exact chi-squared t-test NS
Stull 1986 [597]	16 diflunisal 17 naproxen	Patient-rated pain relief At 2 weeks Diflunisal: 4 no pain, 9 mild pain, 3 moderate pain, 0 severe pain Naproxen: 5 no pain, 8 mild pain, 3 moderate pain, 1 severe pain	Pearson chi-squared P = 0.019

Table 243. Effect of treatment with NSAIDs on pain related to epicondylitis

Study	Number of patients	Time of follow up	Which treatment resulted in less pain?	Was the difference significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Burnham 1998 [616]	14 topical diclofenac 14 placebo	1 week	Topical diclofenac	Yes	NA	0.71 (-0.05 to -1.47)
Labelle 1997 [595]	64 oral diclofenac 64 placebo	1 month	Oral diclofenac	Yes	NA	0.51 (0.16 to 0.87)
Adelaar 1987 [596]	9 oral diflunisal 9 oral naproxen	2 weeks	Oral diflunisal	No	Cannot calculate from the reported data	Cannot calculate from the reported data
Stull 1986 [597]	17 oral diflunisal 17 oral naproxen	2 weeks	Oral diflunisal	Yes	NA	0.02 (-0.66 to 0.71)

[a] calculated by ECRI

Function

Three studies of 180 patients in total reported data relevant on patient function. The results of the studies are shown in Table 244. The results reported by the studies are summarized in Table 245. One study reported a trend, that did not reach statistical significance, towards fewer functional limitations when patients were treated with oral diclofenac as compared to placebo. The low statistical power of this study may have contributed to its failure to detect a statistically significant difference. Only large (>68.7%) differences could be detected. Two studies compared oral diflunisal to oral naproxen. One study reported no difference in functional limitations, while the other reported a statistically significant advantage in function after treatment with diflunisal.

Table 244. Results of function

Study	Number of patients	Functional assessment	Statistical significance of difference between groups
Labelle 1997 [595]	64 Placebo 64 Oral diclofenac	At one month, mean (SD) ADL: placebo -2.4 (2.8) Diclofenac- -3.3 (2.8) Arm function by VAS: placebo 21.8 (27.6) Diclofenac 18.5 (29.1)	Student t-test ADL, p = 0.52 VAS, p = 0.1
Adelaar 1987 [596]	9 Oral diflunisal 9 Oral naproxen	Patient rated function mean At time zero, dilfunisal 1.7 Naproxen 1.7 At 2 weeks, dilfunisal 0.4 Naproxen 0.4	Exact chi-squared t-test NS
Stull 1986 [597]	17 Oral naproxen 17 Oral diflunisal	Number of patients with self-reported functional limitations at 2 weeks Naproxen = 11 Diflunisal = 5	Chi-squared test[a] P = 0.039

[a] calculated by ECRI
ADL = activities of daily living

Table 245. Effect of NSAIDs on hand/arm function

Study	Number of patients	Which treatment resulted in fewer functional limitations?	Was the difference significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Labelle 1997 [595]	64 oral diclofenac 64 placebo	Oral diclofenac	No	68.7%	ADL: 0.32 (-0.03 to 0.67) VAS: 0.12 (-0.23 to 0.46)
Adelaar 1987 [596]	9 oral diflunisal 9 oral naproxen	No difference	No difference	Cannot calculate from the reported data	Cannot calculate from the reported data
Stull 1986 [597]	17 oral diflunisal 17 oral naproxen	Oral diflunisal	Yes	NA	0.80 (0.00 to 1.59)

[a] calculated by ECRI

Quality of life

None of the studies reported this outcome.

Morbidity and complications

Percy 1981 reported that topical DMSO irritated the skin at the site of application in 94% of the patients.[613] The irritation consisted of burning, itching, pain, congestion, edema, urticaria, vesicles, and dermatitis. Topical NSAIDs were reported to have few side effects except for occasional mild rashes.[615, 616] Oral NSAIDs were reported to occasionally cause gastrointestinal problems such as nausea and vomiting.[596, 595]

Conclusions

Seven randomized controlled trials of a total of 405 patients evaluated the use of oral NSAIDs, topical NSAIDs, and topical DMSO as treatments for epicondylitis. Because there were two or fewer trials studying each combination of drugs, no meta-analysis could be performed. General trends reported by the trials can be described. However, because these trends are based on the results of at most two trials, they may be subject to over-interpretation. Confirmatory studies would increase our confidence in their results. In addition, the small size of most of these studies may have contributed to their failure to reach statistical significance.

One double-blinded randomized controlled trial of 51 patients reported that physicians believed that patients treated with placebo tended to have better outcomes than did patients treated with topical DMSO. However, this trend was not statistically significant.

Two randomized controlled trials of a total of 62 patients compared oral naproxen to oral diflunisal. One study reported no statistically significant difference in outcomes when comparing patients treated with the two different drugs, and did not find a consistent trend in favor of one drug. The other study reported that diflunisal treatment consistently resulted in better outcomes. For some outcomes (pain, function) the difference reached statistical significance.

One randomized controlled trial of 128 patients compared oral diclofenac to placebo. The group treated with diclofenac had statistically significantly less pain than the placebo group, but the NSAID treatment had no statistically significant effect on hand/arm function, number of days of missed work, or global outcome. Oral NSAIDs were reported to occasionally cause gastrointestinal side effects.

One double-blinded randomized controlled trial and one double blinded randomized crossover trial, of a total of 47 patients, compared topical diclofenac to placebo. One of the studies reported no differences between the two groups for any of the outcomes, while the other study reported the group treated with the NSAID may have had some statistically significant benefit from the treatment. One randomized controlled trial of 40 patients compared topical diclofenac to topical salicylate, and reported that diclofenac was more effective for treating epicondylitis. Topical NSAIDs were reported to occasionally cause mild skin rashes.

What are the relative benefits and harms of injections of steroids, anesthetics, and other substances for persons with epicondylitis?

Injections of glucocorticoid steroids have been used to give long-lasting (days to weeks) relief from pain and inflammation at localized sites. Steroids used for this purpose include hydrocortisone, prednisone, prednisolone, methylprednisolone, triamcinolone, and betamethasone. Local anesthetics temporarily block sensory nerve conduction at the site of injection. Anesthetics used for this purpose include lidocaine, bupivacaine, lignocaine, and procaine. Injections of glucosamines are said to promote the healing of damaged joints, in particular, the damage associated with osteoarthritis.

The relevant literature consists of one trial that compared injections of glucosamines to placebo, one trial that compared the relative effectiveness of injections of different types of steroids, one trial that compared injections of anesthetics alone to injections of steroids plus anesthetics, one trial that compared injections of steroids alone to injections of steroids plus anesthetics, and two trials that compared the relative effectiveness of injections of different combinations of steroids and anesthetics.

Internal validity

The treatments evaluated by each of the studies are summarized in Table 246. Details of the study designs are shown in Table 247. One randomized double-blinded controlled study of 65 patients evaluated the effect of injections of glucosaminoglycan polysulfate as compared to placebo injections. One randomized double-blinded controlled trial of 58 patients compared a combination of methylprednisolone plus lidocaine to lidocaine alone. Two double-blinded randomized controlled trials of a total of 254 patients compared different combinations of steroids plus local anesthetics. One double-blinded controlled trial of 46 patients compared injections of hydocortisone to injections of methylprednisolone. If patients are not randomly assigned to groups, there may be important differences between these groups that could contribute to any observed differences in outcomes.

One trial compared injections of a steroid to injections of a steroid plus a local anesthetic. This trial (Kivi 1982) was an unblinded A-B trial, in which the patients were given steroid injections for 6 months, and then were given a steroid plus an anesthetic for an additional 6 months. In addition, another group of patients was treated with injections of steroid plus anesthetic only, but the results from this group were pooled with that of the cross-over treatment group. Lack of blinding of the patient and the evaluating physician to the treatment type can alter measurements of treatment effect as discussed previously.

Three of the seven trials did not analyze their data according to the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results.

Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. Due to incomplete data reporting, we were unable to compensate for attrition in any of these trials.

Table 246. Summary of the treatments

Study	Injections group 1	Injections group 2
Akermark 1995 [583]	glucosamines	Placebo injection
Clarke 1975 [605]	hydrocortisone	methylprednisolone
Stahl 1997 [601]	methylprednisolone plus lidocaine	lidocaine
Solveborn 1995 [602]	triamcinolone plus lidocaine	triamcinolone plus bupivacaine
Price 1991 [603]	lignocaine plus triamcinolone or lignocaine plus hydrocortisone	lignocaine
Kivi 1982 [604]	methylprednisolone	lidocaine plus betamethasone

Table 247. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Akermark 1995 [583]	65	Multiple	NR	RCT	Yes	Double	7.7	No	NA
Stahl 1997 [601]	58	1	No	RCT	Yes	Double	0	Yes	NA
Solveborn 1995 [602]	109	1	NR	RCT	Yes	Double	42.2	No	NA
Price 1991 [603]	145	1	Yes	RCT	Yes	Double	0	Yes	51.7
Kivi 1982 [604]	88	1	NR	A-B	Yes	No	13.6	No	NA
Clarke 1975 [605]	46	1	Yes	CT	Yes	Double	0	Yes	NA

RCT = randomized controlled trial
CT = controlled trial
NA = not applicable
NR = not reported

Generalizability

Characteristics of the patients included in these studies are shown in Table 248. Studies of the epidemiology of epicondylitis (see the Introduction) have found that typical patients are in their mid-forties and are equally likely to be of either sex. All

of the trials included patients similar to the typical epicondylitis patient except for the study by Stahl 1997, which included a group of patients who were predominantly male (76% male). The trial by Clarke 1975 did not report sufficient data on sex or age to be able to determine whether the results of the study are generalizable or not.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 248 by a zero under that comorbidity. This somewhat limits the generalizability of these studies, as comorbidities may not be exclusion criteria for receiving injections of anethestics, steroids, or glucosamines.

Occupations and employment status of the patients are shown in Table 249. Only two of the studies reported any data on the occupations of their patient groups. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 248. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Stahl 1997 [601]	58	42	24.1	4.5	NR	0	0	0	0	NR	NR	No	No
Akermark 1995 [583]	65	44 (27-60)	44.6	11 (3-36)	NR	NR	NR	NR	NR	0	NR	No	No
Solveborn 1995 [602]	109	43.8	NR	8.2	NR	NR	NR	NR	NR	NR	NR	No	No
Price 1991 [603]	145	46 (19-65)	48.9	6 (2-38)	NR	NR	NR	NR	NR	NR	NR	No	No
Kivi 1982 [604]	88	43 (22-64)	43.2	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Clarke 1975 [605]	46	NR	NR	NR	NR	0	NR	NR	NR	NR	NR	No	No

NR = not reported

Table 249. Generalizability: patient occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Stahl 1997 [601]	58	NR	NR	NR	NR	46.6% white collar workers 29.3% manual laborers
Akermark 1995 [583]	65	NR	NR	NR	NR	NR
Solveborn 1995 [602]	109	NR	NR	NR	NR	NR
Price 1991 [603]	145	NR	NR	NR	NR	NR
Kivi 1982 [604]	88	NR	NR	NR	18.1	18.1% heavy manual labor 29.5% office work
Clarke 1975 [605]	46	NR	NR	NR	NR	NR

NR = not reported

Results

Glucosamines

One double-blinded randomized controlled trial of a total of 65 patients evaluated the effect of injections of glucosamines as compared to placebo injections on epicondylitis. The patients received weekly injections for five weeks. The study evaluated two different patient-oriented outcomes: success of the treatment, and pain when carrying out activities of daily living (ADL), as rated by the patient on a visual analog scale (VAS). The reported data are shown in Table 250 and summarized in Table 251. For both outcomes, glucosamine injections had a statistically significant effect 1 to 3 months after treatment, but by six months the differences between the two groups had become statistically insignificant.

The study reported that 40.6% of the patients treated with glucosamines experienced pain at the site of the injection and 6.3% developed hematomas at the site of injection, compared to 17.9% of the placebo group who experienced pain, and 0% who developed hematomas at the site.

Table 250. Results of treating epicondylitis with injections of glucosamines

Study	Outcome measurement	Treatment group	N patients	Time in months	Number of failures (%)		Statistical test	P value
Akermark 1995 [583]	Number of treatment failures	GAGPS	32	1	11 (34.4%)		Mantel-Haenszel	0.12
		placebo	28	1	17 (60.7%)			
		GAGPS	32	1.5	4 (12.5%)			0.011
		placebo	28	1.5	12 (42.9%)			
		GAGPS	32	3	6 (18.8%)			0.051
		placebo	28	3	12 (10.7%)			
		GAGPS	32	6	9 (28.1%)			0.22
		placebo	28	6	13 (46.4%)			
	Pain-patient rated	**Treatment group**	**N**	**Months**	**Mean**	**SD**	**Statistical test**	**P value**
		GAGPS	32	0	62.8	15.4	ANOVA	NS
		placebo	28	0	58.6	17.9		
		GAGPS	32	1	44.1	19.9		0.051
		placebo	28	1	48.4	20.8		
		GAGPS	32	1.5	30.3	20.7		0.0053
		placebo	28	1.5	40.5	25.6		
		GAGPS	32	3	30.7	24.7		0.021
		placebo	28	3	40.8	27.7		
		GAGPS	32	6	33	25.3		0.18
		placebo	28	6	37.3	30.1		

[a] calculated by ECRI

Table 251. Results of treating epicondylitis with injections of glucosamines

Study	Number of patients	Outcome	Followup time	Which treatment was more effective?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Akermark 1995 [583]	32 GAGPS 28 placebo	Number of treatment failures	1 month	GAGPs	No	0.59 (0.01 to 1.17)
			1.5 months	GAGPs	Yes	0.90 (0.19 to 1.61)
			3 months	GAGPs	No	0.64 (0.00 to 1.28)
			6 months	GAGPs	No	0.43 (-0.16 to 1.02)
	32 GAGPS 28 placebo	Patient rated pain	1 month	GAGPs	No	0.21 (-0.08 to 0.95)
			1.5 months	GAGPs	Yes	0.44 (-0.08 to 0.95)
			3 months	GAGPs	Yes	0.38 (-0.13 to 0.89)
			6 months	GAGPs	No	0.15 (-0.35 to 0.66)

GAGPS = glucosaminoglycan polysulfate

[a] calculated by ECRI

Different types of steroids

One double-blinded controlled trial of 46 patients compared injections of hydrocortisone to injections of methylprednisolone for treating epicondylitis. The data reported from this trial are shown in Table 252 and summarized in Table 253. The trial reported on whether the treatments were successful in treating the pain of epicondylitis, and on whether the pain recurred after six months. No statistically significant difference in either of these outcomes was found between treatment with the two different steroids. Injections of these steroids were reported to cause pain and bruising in a low percentage of patients. There was no statistically significant difference in the rates of such side effects between the two steroids. The study had the statisticaly power to detect fairly small (19-23%) differences between groups. This suggests that if there is a difference between groups, it is not large.

Table 252. Hydrocortisone compared to methylprednisone for treating epicondylitis

Study	Outcome measured	Number of patients	Number of patients considered to have a successful treatment	Statistical signficance of the difference between groups
Clarke 1975 [605]	A success was two pain-free visits; a failure was three injections without improvement over the course of 2 months	48 methylprednisone 55 hydrocortisone	21 methylprednisone 20 hdrocortisone	Test NR NS
	Recurrence of symptoms by mailed questionnaire 6 months later	24 methylprednisone 23 hydrocortisone	16 methylprednisone 10 hydrocortisone	Test NR NS

Table 253. Hydrocortisone compared to methylprednisone for treating epicondylitis

Study	Outcome measured	Number of patients	Which steroid was more effective?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Clarke 1975 [605]	Success of treatment	48 methylprednisone 55 hydrocortisone	methylprednisone	No	19%	0.17 (-0.27 to 0.61)
	Recurrence of symptoms by mailed questionnaire	24 methylprednisone 23 hydrocortisone	methylprednisone	No	23%	0.52 (-0.13 to 1.2)

[a] calculated by ECRI

Glucocorticoids plus anesthetics compared to anesthetics

One randomized double-blinded controlled trial of 58 patients compared a combination of methylprednisolone plus lidocaine to lidocaine alone. In addition to the injections, all patients in this trial received oral NSAIDs, physical therapy, and were advised to rest the affected arm. The patients each received a single injection. The trial evaluated the pain the patients were experiencing as rated by the patient.

The data are shown in Table 254 and summarized in Table 255. The patients treated with the steroid plus the anesthetic had statistically significantly less pain at 1.5 months, but not at longer followup times, than did patients treated only with an anesthetic.

Table 254. Results of treating epicondylitis with anesthetics compared to anesthetics plus glucocorticoids

Study	Outcome measured	Treatment group	N patients	Time in months	Outcome mean (SE)	Statistical significance of difference between groups
Stahl 1997 [601]	Patient-rated pain	Methylprednisolone plus lidocaine	43	0	3.7 (0.26)	T test p >0.5
		lidocaine	30	0	3.5 (0.24)	
		Methylprednisolone plus lidocaine	43	1.5	1.5 (0.3)	T test p <0.03
		lidocaine	30	1.5	2.2 (0.29)	
		Methylprednisolone plus lidocaine	43	12	0.5 (0.18)	T test p >0.5
		lidocaine	30	12	0.6 (0.17)	

Table 255. Effectiveness of treating epicondylitis with anesthetics compared to anesthetics plus glucocorticoids

Study	Number of patients	Time of followup	Which treatment was most effective?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Stahl 1997 [601]	43 Methylprednisolone plus lidocaine 30 lidocaine	0 months	No difference	No	-0.13 (-0.60 to 0.33)
		1.5 months	Methylprednisolone plus lidocaine	Yes	0.39 (-0.08 to 0.86)
		12 months	Methylprednisolone plus lidocaine	No	0.09 (-0.37 to 0.56)

[a] calculated by ECRI

Glucocorticoids plus anesthetics compared to glucocorticoids

One A-B trial compared injections of lidocaine plus betamethasone to injections of methylprednisolone. The data reported by the trial are shown in Table 256 and summarized in Table 257. The trial reported the success of the treatment as rated by the patient (global outcome). Steroids plus anesthetics were found to be more effective than steroids alone, but the difference did not reach statistical significance. The study was large enough to detect fairly small differences in outcomes between the groups. The trial also reported the number of work-days the patients missed due to their epicondylitis. There was insufficient data reported about work status to determine if the difference was statistically significant.

Table 256. Results of trials comparing steroids to steroids plus anesthetics as a treatment for epicondylitis

Study	Outcome measured	Number of patients	Reported data	Statistical signficance of the difference between groups
Kivi 1982 [604]	Success of treatment, at 12 months	47 Betamethasone and lidocaine 21 methylprednisolone	Steroid plus lidocaine: 36 excellent, 7 good, 3 same, 1 worse Steroid: 16 excellent, 3 good, 2 same, 0 worse	Chi-squared test p = 0.057
	Days off work, at 12 months	47 Betamethasone plus lidocaine 21 Methylprednisone	Steroid plus lidocaine: Mean 16.4 days off Steroid: Mean 12.2 days off	Cannot calculated from the reported data

NC = could not calculate from the reported data

Table 257. Effectiveness of steroids compared to steroids plus anesthetics as a treatment for epicondylitis

Study	Outcome measured	Number of patients	Which treatment was most effective?	Was the difference statistically significant?	What was the minimal difference between groups the study had the power to detect?	Effect size d (95% CI)[a]
Kivi 1982 [604]	Success of treatment	47 Betamethasone plus lidocaine 21 Methylprednisone	Betamethasone plus lidocaine	No	8%	0.13 (-0.39 to 0.64)
	Days off work	47 Betamethasone plus lidocaine 21 Methylprednisone	Methylprednisone	Not reported; cannot determine from reported data	Cannot calculated from the reported data	Cannot calculate from the reported data

[a] calculated by ECRI

Different combinations of glucocorticoids plus anesthetics

Two double-blinded randomized controlled trials of a total of 254 patients compared different combinations of steroids plus local anesthetics as a treatment for epicondylitis. One of the trials compared triamcinolone plus lidocaine to triamcinolone plus bupivacaine (Solveborn 1995). The other trial compared lignocaine alone to lignocaine plus hydrocortisone, lignocaine plus 10 mg of triamcinolone, and lignocaine plus 20 mg of triamcinolone (Price 1991). The trial by Solveborne 1995 did not report any data or statistics, but reported only that patients receiving bupivacaine had a better outcome two weeks after the injection than did patients receiving the lidocaine. The data reported by Price 1991 are shown in Table 258 and summarized in Table 259. Price 1991 reported that at one month, the group treated only with lignocaine had significantly less improvement than did the other groups, but that this difference was not statistically significant by 6 months. Price 1991 reported that some of the patients who received injections of triamcinolone experienced skin atrophy at the site of injection.

Table 258. Results of the study by Price 1991: patient-reported pain on VAS

Study	Treatment group	N patients	Months	Outcome mean (95% CI)	Effect size d (95% CI)[a]
Price 1991 [603]	Ligno	29	1	46 (37-55)	
	Ligno +hydro	29	1	28 (18-38)	3.66 (2.82 to 4.50)
	Ligno + triam	29	1	17 (10-25)	6.78 (5.44 to 8.12)
	Ligno + 10 triam	23	1	27 (18-37)	3.99 (3.05 to 4.93)
	Ligno + 20 triam	28	1	28 (19-37)	3.86 (2.98 to 4.74)
	Ligno	27	2	35 (26-43)	
	Ligno +hydro	27	2	30 (19-41)	0.99 (0.42 to 1.55)
	Ligno + triam	27	2	20 (10-30)	3.13 (2.34 to 3.93)
	Ligno + 10 triam	22	2	29 (17-40)	1.16 (0.55 to 1.77)
	Ligno + 20 triam	24	2	22 (14-31)	2.98 (2.18 to 3.77)
	Ligno	25	6	12 (8-17)	
	Ligno +hydro	26	6	24 (14-35)	-2.83 (-3.60 to -2.05)
	Ligno + triam	27	6	18 (7-28)	-1.40 (-2.01 to -0.80)
	Ligno + 10 triam	22	6	35 (21-48)	-4.52 (-5.60 to -3.44)
	Ligno + 20 triam	27	6	33 (22-45)	-4.55 (-5.58 to -3.52)

[a] calculated by ECRI, using lignocaine as the control group in each case. A positive effect size indicates the treatment group had less pain than the control group

Table 259. Summary of the study by Price 1991

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Relevant effect size d (95% CI)
Price 1991 [603]	29 Ligno 29 Ligno +hydro 30 Ligno + triam 27 Ligno + 10 triam 29 Ligno + 20 triam	1 month	Lignocaine plus triamcinolone	Yes	6.78 (5.44 to 8.12)
		2 months	Lignocaine plus triamcinolone	No	3.13 (2.34 to 3.93)
		6 months	Lignocaine	No	NA

Ligno = lignocaine
Hydro = hydrocortisone
Triam = triamcinolone

Conclusions

One randomized double-blinded study reported that injections of glucosamines are effective in treating the symptoms of epicondylitis in the short term (less than 6 months) as measured by global outcome and patient-reported pain. However, injections of glucosamines were found to have a high rate of side effects- 40% of patients experienced pain at the site of injection, and 6% developed hematomas at the site of injection.

One randomized double-blinded study reported that injections of methylprednisolone plus lidocaine were statistically significantly more effective at treating pain than were injections of lidocaine.

One randomized double-blinded study reported that injections of lignocaine plus triamcinolone were statistically significantly more effective at treating pain than were injections of lignocaine or injections of lignocaine plus hydrocortisone.

One randomized double-blinded study reported that injections of triamcinolone plus bupivacaine were more successful at treating epicondylitis than were injections of triamcinolone plus lidocaine.

One study reported a trend towards more successful treatment of epicondylitis after injections of methylprednisolone than after injections of hydrocortisone. However, this study was of less than optimal design, which makes it problematic to come to a definitive evidence-based conclusion on the basis of its results.

One study reported no difference in rates of successful treatment or number of work-days missed after treatment with injections of methylprednisolone as compared to injections of betamethasone plus lidocaine. This study had sufficient statistical power to have detected relatively small differences between-treatment groups. However, design flaws in this study make it problematic to come to a definitive evidence-based conclusion on the basis of its results.

What are the relative benefits and harms of ultrasound and phonophoresis therapy for persons with epicondylitis?

Ultrasound has been used as a therapy for the treatment of musculoskeletal pain. Ultrasound has been said to increase blood flow, membrane permeability, and to alter connective tissues and nerve conduction speed.[622,623] Phonophoresis refers to using ultrasound to drive a drug suspended in a coupling medium into the tissues.[623]

The relevant literature on this topic consists of three trials comparing ultrasound to sham or no treatment, and two trials comparing ultrasound to phonophoresis of hydrocortisone.

Internal validity

Two studies of 82 patients in total compared ultrasound alone to phonophoresis of hydrocortisone. Three studies of a total of 220 patients compared ultrasound treatment to sham or no treatment. Details of the study design are shown in Table 260. All of the studies were randomized controlled trials. All except for the study by Holdsworth 1993 were double-blinded; the study by Holdsworth 1993 blinded only the patients to the treatment administered. Lack of blinding of the evaluating physician is a design weakness. If the evaluating physician is aware of the treatment given, it is possible that he/she may unconsciously bias the patient's reponses by giving leading instructions.[474]

Two of the studies did not analyze their data according to the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results. However, we were unable to compensate for the attrition from these two studies due to incomplete data reporting.

Table 260. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Holdsworth 1993 [620]	42	1	NR	RCT	Yes	Patients	14.3	No	NA
Haker 1991 [619]	45	1	NR	RCT	Yes	Double	28.9	No	NA
Stratford 1989 [621]	40	1	No	RCT	Yes	Double	0	Yes	NA
Lundeberg 1988 [617]	99	1	NR	RCT	Yes	Double	0	Yes	NR
Binder 1985 [618]	76	1	NR	RCT	Yes	Double	0	Yes	NA

RCT = randomized controlled trial
NA = not applicable
NR = not reported

Generalizability

Details of the patient groups are shown in Table 261. Studies of the epidemiology of epicondylitis (see the Introduction) have found that the typical patient with epicondylitis is in the mid-forties and equally likely to be male or female. All of the patient groups enrolled in these trials are similar in mean age and gender composition to the typical patients.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 261 by a zero under that comorbidity. This limits the generalizability of these studies, as combordities are not usually an exclusion criterion for treatment with ultrasound or phonophoresis.

None of the studies reported any information on patient employment characteristics. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 261. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Holdsworth 1993 [620]	42	45.3 (22-62)	35.7	NR	NR	0	0	0	0	NR	NR	No	No
Haker 1991 [619]	45	49.3 (34-67)	44.4	8.5 (1-60)	NR	NR	NR	NR	NR	NR	NR	No	No
Stratford 1989 [621]	40	43.3	50.0	4.3	NR	NR	NR	0	NR	NR	NR	No	No
Lundeberg 1988 [617]	99	38 (21-68)	43.4	NR	NR	0	NR	0	0	NR	NR	No	No
Binder 1985 [618]	76	43.3 (29-65)	63.2	4.6 (1-12)	NR	0	NR	0	0	NR	NR	No	No

NR = not reported

Results

Success of Treatment

Two studies of a total of 59 patients measured the success of ultrasound treatment. One of these studies compared ultrasound to phonophoresis, while the other compared ultrasound to sham ultrasound. These data are shown in Table 262 and summarized in Table 263. One study measured treatment by asking the patients to rate their condition as excellent, improved, or the same/worse, while the other study asked the patients to rate their condition on a 10 cm visual analog scale (VAS). The studies reported no statistically significant difference between ultrasound treatment and sham treatment, and no statistically significant difference between ultrasound and phonophoresis treatment. Although the Holdsworth 1993 study was so small (n=16 patients) it could only have detected a 82.5% or larger difference, the Haker 1991 study could have detected a 20% or greater difference. Hence, this latter study suggests that that, if there is an effect of ultrasound on patient-rated treatment success, it is not large.

Table 262. Results of treating epicondylitis with ultrasound

Study	Number of patients	Reported outcome	Statistical significance of difference between groups
Holdsworth 1993 [620]	7 Phonophoresis 9 Ultrasound	At 1.5 months, mean (SE) patient-rated global outcome on VAS Phonophoresis: 49.6 (12.4) Ultrasound: 63 (12.2)	ANOVA p >0.05
Haker 1991 [619]	21 Ultrasound 22 Sham	At 3 months, patient-rated global outcome Ultrasound: 8 excellent, 8 improved, 5 same or worse Sham: 10 excellent, 7 improved, 5 same or worse	Mann-Whitney U-test NS

Table 263. Success of treating epicondylitis with ultrasound

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)
Holdsworth 1993 [620]	7 phonophoresis 9 ultrasound	1.5 months	Ultrasound	No	82.5%	0.33 (-0.55 to 1.20)
Haker 1991 [619]	22 sham 21 ultrasound	3 months	Sham	No	20%	-0.19 (-0.79 to 0.41)

Work Status

None of the studies reported data applicable to this outcome.

Pain

Three studies of a total of 161 patients reported pain after treating epicondylitis with ultrasound. One of these studies compared ultrasound alone to phonophoresis, while the other two studies compared ultrasound to sham or no treatment. The data from these studies are shown in Table 264 and summarized in Table 265. The study comparing ultrasound to phonophoresis reported no statistically significant difference in pain between the two treatment groups. It was, however, too small to detect differences between the treatment groups of less than 50%.

One of the studies comparing ultrasound to sham or no treatment reported no statistically significant difference in pain between treatment groups, while the other study reported a significant decrease in pain experienced by the group treated with ultrasound as compared to the untreated group. However, the effect sizes we calculated for both of these studies suggested a statistically significant effect of ultrasound as compared to no or sham treatment.

Table 264. Effect of ultrasound treatment on pain related to epicondylitis

Study	Number of patients	Reported outcome: patient-reported pain on VAS	Statistical signficance of difference between groups
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	At 2.5 months, mean (SD) Phonophoresis: 21.8 (30.4) Ultrasound: :28.3 (17)	ANCOVA P = 0.87
Lundeberg 1988 [617]	33 ultrasound 33 No treatment 33 sham	At 3 months, mean (SD) Ultrasound 2.8 (0.3) No treatment 2.1 (0.5) Sham 2.4 (0.3)	Wilcoxon's rank sum test NS
Binder 1985 [618]	38 Ultrasound 38 No treatment	0.5 months, mean Utlrasound 0.75 No treatment 2.2 1 months, mean Ultrasound 3.4 No treatment 1.5 2 months, mean Ultrasound 4 No treatment 1.7	Wilcoxon's rank sum test At 1 month p <0.01 At 2 months p <0.005

Table 265. Pain experienced by patients treated with ultrasound

Study	Number of patients	Time of followup	Which treatment resulted in less pain?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	2.5 months	Phonophoresis	No	54.3%	0.26 (-0.34 to 0.86)
Lundeberg 1988 [617]	33 ultrasound 33 No treatment 33 sham	3 months	Ultrasound	No	Could not calculate from the reported data	Vs. no: 1.68 (1.12 to 2.24) Vs. sham: 1.32 (0.79 to 1.85)
Binder 1985 [618]	38 Ultrasound 38 No treatment	1 and 2 months	Ultrasound	Yes at both times of followup	NA	1 month: 0.60 (0.14 to 1.06) 2 months: 0.66 (0.20 to 1.12)

[a] calculated by ECRI

Function and Activities

One study reported data on patient-reported function and activities of daily living. This study compared phonophoresis to ultrasound, and measured pain upon performing activities of daily living, function as rated by VAS, and the ability to perform recreational activities. No statistically significant difference for any of the outcomes was reported; however, the study could have detected only a 73.6% or larger difference between the groups, so it could have missed clinically important effects. The reported results are shown in Table 266 and summarized in Table 267.

Table 266. Effect of ultrasound on hand/arm function

Study	Number of patients	Patient-reported hand/arm function- VAS	Statistical signficance of the difference between groups
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	At 2.5 months, mean (SD) Phonophoresis 78.8 (23.7) Ultrasound 66 (25)	ANCOVA p >0.05

Table 267. Function after treatment with ultrasound

Study	Number of patients	Followup time	Which treatment resulted in more effective function?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Stratford 1989 [621]	10 phonophoresis 9 ultrasound	2.5 months	phonophoresis	No	73.6%	0.50 (-0.39 to 1.39)

a: calculated by ECRI

Quality of Life

None of the included studies reported on this outcome.

Morbidity and Complications

None of the included studies reported data applicable to this outcome.

Conclusions

Two randomized controlled trials of 82 patients in total compared ultrasound treatment to phonophoresis of hydrocortisone as a therapy for epicondylitis. Neither study reported statistically significant differences between-treatment groups for any of the outcomes. When interpreting these results, it is important to keep in mind that both studies may have been too small to be able to detect clinically relevant differences between-treatment groups.

Three randomized controlled trials of 220 patients in total compared ultrasound treatment to sham ultrasound treatment or no treatment as a therapy for epicondylitis. All three of the studies reported a trend towards better outcomes in the groups treated with ultrasound. However, this difference reached statistical significance in only one of the studies. Although low statistical power may explain the negative results of the two "nonsignificant" studies, further research is required to demonstrate this.

What are the relative benefits and harms of bracing, physiotherapy, and manipulation as therapy for persons with epicondylitis?

Splints, braces, and other supportive devices to be worn around the elbow are advocated by some as a therapy for epicondylitis. The devices are said to reduce the stresses to the forearm extensor muscle origin by providing a counterforce brace and thus allow the area to rest and heal while not interfering with normal activity.[78,624,625] Most braces used to treat epicondylitis consist of a band that straps tightly around the forearm just below the elbow. Physiotherapy for the treatment of epicondylitis refers to programs that generally aim gradually to stretch and strengthen the tendons and muscles of the forearm, in hopes that this will allow the affected area to resist stresses more effectively.[626] Manipulation refers to forced movements of the affected limb. Practitioners claim that manipulation returns out-of-place body parts to their original sites and releases adhesions.[75]

The relevant literature that addresses this question consists of one trial that compared manipulation to no treatment, and four trials that evaluated the relative effectiveness of different types of braces and physiotherapy.

Internal validity

Details of the designs of the trials are shown in Table 268. We identified one randomized double-blinded crossover study of 15 patients that evaluated a manipulative technique (contralateral glide) as compared to a placebo manipulation and no manipulation.

We included four studies that enrolled a total of 273 patients that evaluated braces as therapy for epicondylitis. Two crossover trials and one controlled trial compared braces to either a placebo brace or no treatment. A controlled trial of 185 patients compared a brace to physiotherapy. None of these four studies were blinded. Lack of blinding of the patient to the type of treatment, particularly when using subjective outcome measures, can alter measurements of treatment effect because patients might unconsciously rate their condition differently in order to please the clinician.[474] Lack of blinding of the evaluating physician may result in the physcian unconsciously biasing the patient's responses by giving leading instructions.[474]

Compliance was low in the two longer term trials. In the trial by Clements 1993, only 52.6% of the patients followed the prescribed regimen. In the trial by Solveborn 1997, compliance was initially high (88.1%), but at the longest followup time (3 months) compliance had dropped to 55%.

Statistical analysis was not intent-to-treat in the trials by Solveborn 1997 or Clements 1993. Both of these trials had attrition rates greater than 15%. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a

conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were not able to compensate for attrition in the trial Clements 1993 due to incomplete data reporting, but we were able to compensate for attrition in the trial by Solveborn 1997. Compensating for attrition did not change the conclusions of this trial.

Table 268. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Wuori 1998 [577]	50	1	No	RCT Xover	Yes	No	0	Yes	NA
Solveborn 1997 [579]	185	1	NR	CT	Yes	No	29.2	No	88.1
Vicenzino 1996 [592]	15	1	NR	RCT Xover	Yes	Double	0	Yes	NA
Clements 1993 [580]	19	1	NR	CT	Yes	No	15.8	No	52.6
Forbes 1990 [578]	19	1	Yes	Xover	Yes	No	0	Yes	NA

NR = not reported
RCT = randomized controlled trial
CT = controlled trial
Xover = crossover
NA = not applicable

Generalizability

Details of the patient characteristics are shown in Table 269. Studies of the epidemiology of epicondylitis (see the Introduction) have found that the typical patient is in the mid-forties and is equally likely to be male or female. Forbes 1990 did not report the ages of the patients. The mean ages of the patient groups in the other studies are all in the mid-forties. Solveborn 1997 did not report the sexes of the patients. The trial by Clements 1993 was predominantly male (73.7%), and the trial by Forbes 1990 was predominantly female (84.2%). It is possible these patient groups may be composed of atypical patients.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with some comorbidities, indicated in Table 269 by a zero under that comborbidity. This somewhat limits the generalizability of these studies, as comorbidities are not exclusion criteria for the treatments evaluated in this section.

The occupations and employment status of the patients are shown in Table 270. Only one study reported any information about the employment status of its patients. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis patient population cannot be determined from the information available.

Table 269. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Wuori 1998 [577]	50	44.5	46	7.5	NR	NR	NR	0	NR	NR	NR	No	No
Solveborn 1997 [579]	185	43.5 (19-71)	NR	12.3 (0-72)	NR	NR	NR	NR	NR	NR	NR	No	No
Vicenzino 1996 [592]	15	44 (22-62)	53.3	8 (2-36)	NR	NR	NR	NR	NR	NR	NR	No	No
Clements 1993 [580]	19	42.4 (33-54)	26.3	NR	NR	0	0	NR	NR	NR	NR	No	No
Forbes 1990 [578]	19	NR	84.2	NR	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Table 270. Generalizability: patient occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Wuori 1998 [577]	50	NR	NR	NR	NR	NR
Solveborn 1997 [579]	185	NR	NR	NR	NR	NR
Vicenzino 1996 [592]	15	NR	NR	NR	NR	NR
Clements 1993 [580]	19	NR	NR	NR	10.5	21.0% food services 15.7% mechanic/repairman 5.2% nurse 5.2% librarian 5.2% engineer 5.2% office worker
Forbes 1990 [578]	19	NR	NR	NR	NR	NR

NR = not reported

Results

Manipulation

One randomized controlled crossover trial of 15 patients compared a contralateral glide manipulation technique to no manipulation and to a placebo manipulation (Table 271). Patient-reported pain (VAS) and function (activities of daily living; ADL) were measured before treatment, and 24 hours after each treatment. Outcomes after each treatment were not directly compared. Instead, pre-post outcome measurements were compared. There were no statistically significant changes in these patient-oriented outcomes for any of the treatments. Statistical significance was defined as $p < 0.05$, but the test used was not described. The reported data were insufficient for effect size of power calculations.

Table 271. Effect of treatment with manipulation on epicondylitis

Study	Number of patients	Which treatment was more effective?	Was the difference statistically significant?	Was the effect size statistically significant?	Did the study have sufficient power to detect the observed difference?
Vicenzino 1996 [592]	15 manipulation 15 placebo	No difference	No	Could not calculate from the reported data	Could not calculate from reported data

Braces and physiotherapy

Success of Treatment

One trial that compared wearing a brace for several months to receiving regular physiotherapy reported on this outcome. The data are shown in Table 272 and summarized in Table 273. For both followup times, physiotherapy was statistically significantly more successful than was bracing.

Table 272. Results of treating epicondylitis with bracing or physiotherapy

Study	Number of patients	N patients treated successfully (%)	Statistical significance of difference between groups
Solveborn 1997 [579]	91 Bracing 85 Physiotherapy	At 1 month, Bracing 56 (61.5%) Physiotherapy 80 (95%) At 3 months, Bracing 23 (25.3%) Physiotherapy 38 (44.7%)	Chi-squared test At 1 month, p <0.0001 At 3 months, p <0.01

Table 273. Success of treating epicondylitis with bracing or physiotherapy

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Solveborn 1997 [579]	91 Bracing 84 Physiotherapy	1 and 3 months	Physiotherapy	Yes	At 1 month: -1.39 (-1.99 to -0.79) At 3 months: -0.44 (-0.79 to -0.08)

[a] calculated by ECRI

Work Status

The trial by Solveborn 1997 reported the number of days patients were unable to work due to their condition. These data are shown in Table 274 and summarized in Table 275. At three months and nine months of followup, the group treated with physiotherapy had statistically significantly fewer days of not working than did the group treated with bracing.

Table 274. Results of treating epicondylitis with bracing or physiotherapy on work status

Study	Number of patients	Mean number of days off work	Statistical significance of difference between groups
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	At 1 month: bracing 14 Physiotherapy 14 At 3 months: Bracing 20 Physiotherapy 13 At 9 months: Bracing 24 Physiotherapy 14	Chi-squared test At 1 month NS At 3 months $p < 0.01$ At 9 months $p < 0.01$

Table 275. Effect of treating epicondylitis with bracing or physiotherapy on work status

Study	Number of patients	Which treatment resulted in fewer days off work?	Was the difference statistically significant?	Effect size
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	Physiotherapy	No at 1 month Yes at 3 and 9 months	Could not calculate from the reported data

Pain

The crossover trial by Wuori 1998 asked the patients to rate their pain before, during, and after tests of grip strength while wearing various types of braces. There were no statistically significant differences in pain reported from tests wearing the different types of braces (data shown in Table 276 and summarized in Table 277). However, the trial by Wuori 1998 had insufficient power to detect differences between the groups of less than 64%.

The trial by Clements 1993 reported that patients who had been treated with a brace plus physiotherapy for a month had statistically significantly less self-reported pain than did patients treated only with physiotherapy (t-test; $p < 0.05$). The trial by Solveborn 1997 reported that all times of followup the patients treated with physiotherapy reported less pain than did the patients treated by bracing (data shown in Table 276 and summarized in Table 277).

Table 276. Results of treatment with bracing on pain related to epicondylitis

Study	Number of patients	Pain reported by patients	Statistical significance of difference between groups
Wuori 1998 [577]	50 Count'Rforce brace 50 Airprene brace 50 Placebo brace	Mean (SD) Before other tests CountRforce 1.3 (1.7) Airprene1.4 (1.9) Placebo 1.4 (1.8) During other tests CountRforce 3.4 (2.1) Airprene 3.3 (2.3) Placebo 3.4 (2.4) After other tests CountRforce1.5 (1.7) Airprene 1.7 (2.1) Placebo 1.4 (1.8)	ANOVA Before other tests NS During other tests NS After other tests NS
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	1 month Bracing 39 (22) Physiotherapy 27 (21) 3 months Bracing 32 (21) Physiotherapy 20 (22) 9 months Bracing 19 (19) Physiotherapy 13 (20)	Paired t-test 1 month p <0.0001 3 months p <0.0001 9 months p <0.045

Table 277. Effect of treatment with bracing on pain related to epicondylitis

Study	Number of patients	Which treatment resulted in less pain?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Wuori 1998 [577]	50 Count'Rforce brace 50 Airprene brace 50 Placebo brace	Airprene brace	No	64%	Before other tests: CountRforce -0.06 (-0.45 to 0.34) Airprene 0.00 (-0.39 to 0.39) During other tests: CountRforce 0.00 (-0.39 to 0.39) Airprene -0.04 (-0.43 to 0.35) After other tests: CountRforce 0.06 (-0.34 to 0.35) Airprene 0.15 (-0.24 to 0.54)
Clements 1993 [580]	10 bracing plus physiotherapy 9 physiotherapy	Bracing plus physiotherapy	Yes t-test	NA	Could not calculate from the reported data
Solveborn 1997 [579]	91 Bracing 94 Physiotherapy	Physiotherapy	Yes	NA	1 month:056 (0.26 to 0.85) 3 months: 0.56 (0.26 to 0.85) 9 months: 0.31 (0.02 to 0.60)

[a] calculated by ECRI

Function

Clements 1993 reported no statistically significant difference between patients treated with a brace plus physiotherapy and patients treated only with physiotherapy.[580] Although statistical power could not be calculated from the data provided, this study was small (n = 19), suggesting that only large differences could be detected.

Table 278. The Effect of Bracing plus Physiotherapy on Function

Study	Number of patients	Which treatment resulted in greater function?	Was the difference statistically significant?	Was the effect size statistically significant?	Did the study have sufficient power to detect the observed difference?
Clements 1993 [580]	10 bracing plus physiotherapy 9 physiotherapy	Bracing plus physiotherapy	No	Could not calculate from the reported data	Cannot calculate from the reported data

Quality of life

None of the studies reported on this outcome.

Morbidity and Complications

No morbidity or complications were reported by the studies.

Conclusions

Three crossover trials and two controlled trials evaluated the effectiveness of physiotherapy, elbow bracing, and manipulation as treatments for epicondylitis. Because only one study evaluated manipulation, only two evaluated short-term effects of braces, only one evaluated bracing vs. physiotherapy, and only one evaluated bracing plus physiotherapy, it is difficult to draw firm evidence-based conclusions from the available data.

Simply wearing an elbow brace is reported by two studies to have no effect on pain. One study reported that wearing a brace regularly over the course of several months is not as effective in treating epicondylitis as is physiotherapy, but a different study reported that wearing a brace regularly in addition to physiotherapy may be more effective than physiotherapy alone. One manipulative technique, the contralateral glide procedure, may have some benefit for the treatment of epicondylitis. These general trends are drawn from at most two studies per outcome. Confirmatory studies would strengthen confidence in these results.

What are the relative benefits and harms of acupuncture therapy for persons with epicondylitis?

Stimulation of acupuncture points is thought to induce the release of endorphins and thus induce an analgesic effect.[627] The relevant literature that addressed this question consists of two trials that compared acupuncture to sham acupuncture.

Internal validity

We identified two randomized controlled trials of a total of 134 patients that evaluated the effect of acupuncture on epicondylitis. Details of the designs of the trials are shown in Table 279. The trial by Molsberger 1994 was double-blinded. The trial by Haker 1990 was blinded as to rater only, and thus is susceptible to bias from a placebo effect.

One trial (Haker 1990) treated the control group with superficially inserted needles, while the other trial (Molsberger 1994) treated the control group with blunt probes at a different site. The appropriate control group to use in trials of acupuncture is unclear. Attempts at performing sham acupuncture, including inserting needles at other sites, inserting needles only superficially, and only stimulating the skin with a blunt probe, have been reported to have similar physiological effects as true acupuncture.[627] Therefore any comparison of acupuncture to placebo may yield a greater apparent effect than any comparison of acupuncture and sham acupuncture. However, comparing acupuncture to no treatment does not control for any placebo effect.

Table 279. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Molsberger 1994 [575]	48	1	NR	RCT	Yes	Double	0	Yes	NA
Haker 1990 [576]	86	1	NR	RCT	Yes	Rater	4.7[a]	Yes	NA

[a]: Attrition at longest follow up time (12 months)

Generalizability

Details of the patient characteristics are shown in Table 280. Studies of the epidemiology of epicondylitis (see the Introduction) have found that the typical patient is in the mid-forties and that approximately equal proportions of men and women are affected. The patients in both studies are similar to this profile.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Both studies excluded patients with certain comorbidities, indicated in Table 280 by a zero under that comorbidity. This somewhat limits the

generalizability of these studies, as comborbiditie s are not generally exclusion criteria for treatment with acupuncture.

Neither study reported employment characteristics of their patient groups. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis patient population cannot be determined from the information available.

Table 280. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Molsberger 1994 [575]	48	47.9	54.2	15.4	NR	0		NR	NR	NR	NR	No	No
Haker 1990 [576]	86	46.9 (25-70)	34.9	9 (1-120)	NR	0	NR	0	0	NR	NR	No	No

Results

Success of Treatment

Both studies reported on the global outcome success of treatment. The data reported by the studies are shown in Table 281 and summarized in Table 282. Both studies reported that acupuncture was statistically significantly more successful than control treatment at early followup times (two to four weeks). Only one of the trials followed the patients for longer than two weeks, and it reported that at longer followup times the difference between the groups was not statistically significant. The results of the shorter followup times of the studies are shown graphically in Figure 71. We calculated an effect size (Hedges' d) for each study. At all followup times, the effect sizes indicated that patients treated with acupuncture had statistically significantly better outcomes. Figure 72 displays the effect sizes for the shorter followup times.

Table 281. Results of global assessment of acupuncture

Study	Number of patients	Global assessment patient-reported	Statistical significance of difference between groups
Haker 1990 [576]	44 acupuncture 38 control	Acupuncture- 1 month: 7 excellent, 15 good, 17 well improved, 4 improved, 1 same or worse 3 months: 14 excellent, 19 good, 3 well improved, 4 improved, 3 same or worse 12 months: 26 excellent, 8 good, 3 well improved, 1 improved, 2 same or worse Control- 1 month: 2 excellent, 6 good, 17 well-improved, 3 improved, 10 same or worse 3 months: 7 excellent, 14 good, 9 well improved, 3 improved, 2 same or worse 12 months: 13 excellent, 16 good, 2 well improved, 2 improved, 2 same or worse	Mann-Whitney U test P<0.01 at 1 month, NS at 3 and 12 months
Molsberger 1994 [575]	24 acupuncture 24 control	At 2 weeks Acupuncture- 19 treated successfully Control- 6 treated successfully	Chi-squared p <0.01

Table 282. Success of treating epicondylitis with acupuncture

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Haker 1990 [576]	44 Acupuncture 38 Control	1 month	Acupuncture	Yes	0.84 (0.39 to 1.29)
		3 months	Acupuncture	No	0.44 (0.00 to 0.88)
		12 months	Acupuncture	No	0.75 (0.30 to 1.20)
Molsberger 1994 [575]	24 Acupuncture 24 Control	2 weeks	Acupuncture	Yes	1.32 (0.58 to 2.06)

[a] calculated by ECRI

Figure 71. Success of acupuncture: statistical tests

The results of Haker were statistically significant at 1 month only.

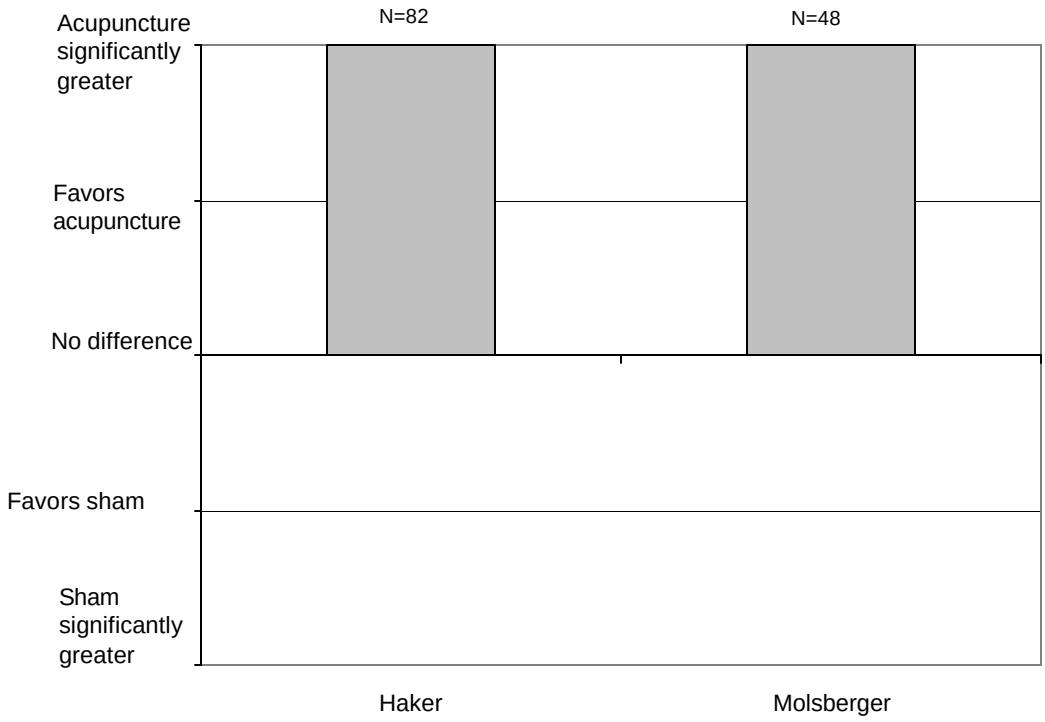
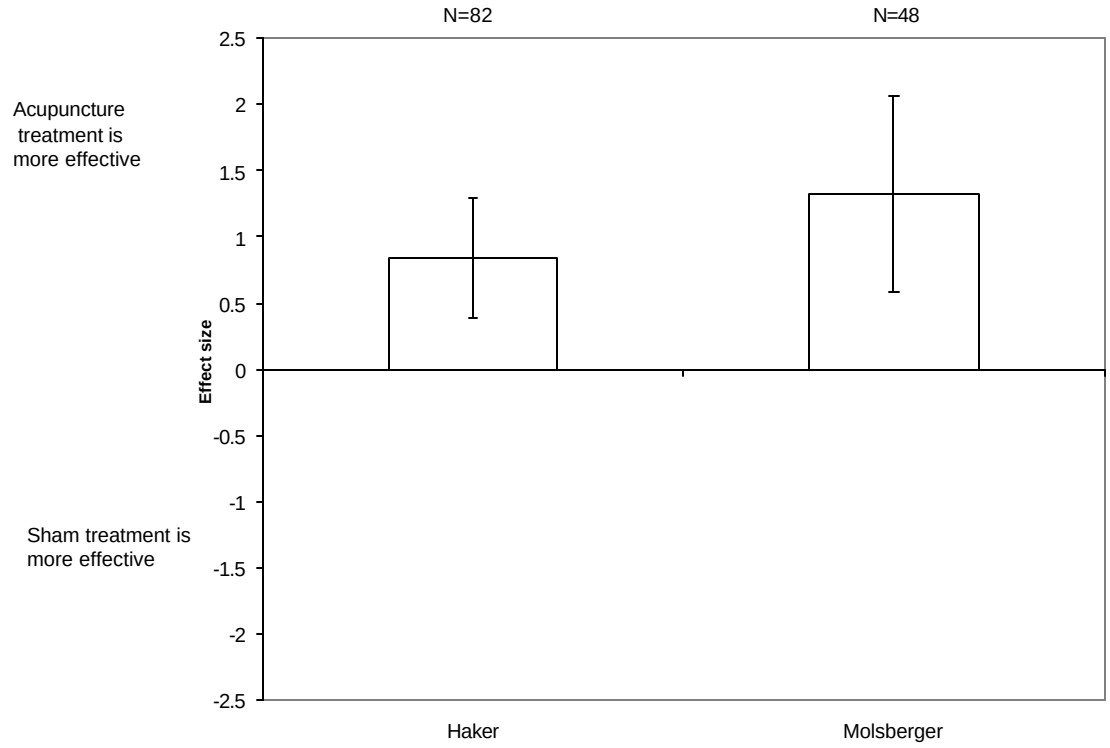


Figure 72. Success of acupuncture: effect sizes



The results of Haker are presented for the 1 month time point only.

Work Status

Neither of the included studies reported on this outcome.

Pain

The study by Molsberger 1994 reported on the degree of relief the patients had from their pain and on how long the relief lasted after the treatment. The group treated with acupuncture had significantly greater pain relief and the pain relief lasted significantly longer than it did in the control group. The data reported for this outcome are shown in Table 283 and summarized in Table 284.

Table 283. Results of the effect of acupuncture treatment on pain related to epicondylitis

Study	Pain measured by	Number of patients	Reported outcome	Statistical significance of difference between groups
Molsberger et al. 1994 [575]	Patient-rated relief of pain	24 Acupuncture 24 Control	Acupuncture- mean 55.8 SD 2.95 Control- mean 15 SD 2.77	t-test p <0.01 for both outcomes
	Patient-rated duration of the relief of pain	24 Acupuncture 24 Control	Acupuncture- mean 20.2 SD 21.54 Control- mean 1.4 SD 3.5	

SD = standard deviation

Table 284. Effect of acupuncture treatment on pain related to epicondylitis

Study	Number of patients	Time of followup	Which treatment resulted in less pain?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Molsberger 1994 [575]	24 Acupuncture 24 Control	2 weeks	Acupuncture	Yes	Relief of pain: 14.02 (11.16 to 16.89) Duration of pain relief: 1.20 (0.58 to 1.81)

[a] calculated by ECRI

Function and Activities

Neither of the studies reported either of these outcomes.

Quality of life

Neither of the studies reported this outcome.

Morbidity and Complications

No complications or morbidity were reported by either study.

Conclusions

Two randomized controlled trials of a total of 134 patients evaluated the effect of acupuncture on epicondylitis. Both studies reported patients treated with acupuncture had better global outcomes and greater pain relief than did patients treated with sham acupuncture at relatively short (2-4 weeks) followup times. The effect seemed to diminish at longer followup times. However, this latter observation was based on only one study so additional data are needed to confirm it.

What are the relative benefits and harms of surgical treatment for persons with epicondylitis?

Surgical techniques used to treat epicondylitis can be divided into four broad categories: denervation, nerve decompression, excision of tissues, and lengthening of the extensor tendon (ERCB).[83] Further information about these categories is provided in the Introduction. The relevant literature addressing this question consists of two studies evaluating the relative merits of different surgical procedures. Neither study compared surgical treatment to no or sham treatment, and neither study compared surgical treatment to nonsurgical treatments, so the absolute effectiveness of surgical treatment cannot be determined.

Internal validity

We identified two controlled trials of surgical techniques for the treatment of epicondylitis. These trials enrolled a total of 227 patients. Details of the study designs are shown in Table 285. The study by Almquist 1998 is a retrospective case-controlled trial. Patients treated with limited surgical resection of the lateral extensor aponeurosis (limited fasciectomy) were compared to patients treated with either limited resections or wide resections plus rotation of the vascular pedicle of the anconeus muscle into the defect created by the excision of tissue. Patients were chosen consecutively from the records of one clinic. A major difficulty with this study is that the group of patients treated with limited fasciectomy plus anconeous transfer had all been previously treated with fasciectomy only, with poor results, while the other two groups had not had previous surgical treatments. Hence, the patients in these two groups were different prior to the study.

The study by Wilhem 1996 was a historically controlled study that compared three different surgical techniques. The groups in this study were not treated at the same time, i.e., all of the denervation surgeries were performed from 1970 to 1990, all of the denervation plus decompression surgeries were performed from 1980 to 1990, and all of the denervation plus disinsertion surgeries were performed after 1991. Because the different groups were not treated during the same time periods, other factors aside from the surgical techniques, such as improvements in general post-operative care, could have affected the results.

The study by Wilhelm 1996 did not use intent-to-treat analysis. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle for the trial

by Wilhelm 1996, and found that the conclusions of the study did not change after compensation.

Neither study blinded the patients or the evaluating physician to the type of treatment, which can bias the results.

Table 285. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Almquist 1998 [83]	61	1	No	CT	No	No	0	Yes	NA
Wilhelm 1996 [84]	166	1	NR	CT	No	No	11.4	No	NA

CT = controlled trial
NR = not reported
NA = not applicable

Generalizability

Characteristics of the patient groups are shown in Table 286. Our analysis of patients treated with surgery for epicondylitis (see the answer to Question 2) found that the typical patient was of either sex and in their mid-forties. The patients in both studies fit this profile.

Neither study reported on the presence of comorbidities or employment characteristics. Therefore, the extent to which these patient groups can be generalized to the overall epicondylitis population cannot be determined from the information available.

Table 286. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Almquist 1998 [83]	61	43.9 (27-63)	39.3	27.3 (6-72)	NR	NR	NR	NR	NR	NR	NR	No	No
Wilhelm 1996 [84]	166	44.5 (21-62)	57.8	NR	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Success of Treatment

The study by Wilhem 1996 reported that patients treated with denervation alone rated their outcomes more positively than did patients treated with denervation plus decompression or with denervation plus disinsertion. These data are reported in Table 287 and summarized in Table 288. The difference in outcomes was statistically significant between the denervation and denervation plus decompression groups, but was not statistically significant between the denervation and the denervation plus disinsertion groups. The denervation plus decompression group rated their outcomes statistically significantly more positively than did the denervation plus disinsertion group.

Table 287. Results of the success of surgery at treating epicondylitis

Study	Number of patients	Success of treatment	Statistical significance of difference between groups
Wilhem 1996 [84]	39 denervation 46 denervation and disinsertion 81 denervation and decompression	Denervation: 29 excellent, 4 good, 2 fair, 1 poor Disinsertion: 30 excellent, 7 good, 3 fair, 2 poor Decompression: 36 excellent, 13 good, 16 fair, 10 poor	Chi-squared test Denervation vs. disinsertion p = 0.159 Denervation vs. decompression P = 0.0071 Disinsertion vs. decompression p = 0.033

Table 288. Success of surgery at treating picondylitis

Study	Number of patients	Which treatment was most successful?	Was the difference significant?	Effect size d (95% CI)[a]
Wilhem 1996 [84]	39 denervation 46 denervation and disinsertion 81 denervation and decompression	Denervation	Yes, between denervation and decompression Yes, between decompression and disinsertion No, between denervation and disinsertion	Disinsertion: 1.13 (0.71 to 1.55) Denvervation: 0.75 (0.36 to 1.14)

[a] calculated by ECRI using decompression plus denervation as the control group

Work Status

Almquist 1998 reported on the number of patients able to resume normal work after treatment. These data are reported in Table 289 and summarized in Table 290. Wide fasciectomy plus anconeus transfer was reported to have a better outcome than did fasciectomy alone or limited fasciectomy plus anconeus transfer. The difference, however, was not statistically significant, despite the fact that the study

had sufficient power to detect a difference between groups as small as 3%. Hence, this negative finding is probably not the consequence of a small sample size.

Table 289. Results of surgical treatment on work status

Study	N patients	Percentage of patients able to return to normal work	Statistical significance of the difference between groups
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Fasciectomy - 81% Wide fasciectomy plus anconeus transfer - 96% Limited fasciectomy - 86%	Chi-squared test P>0.05

Table 290. Effect of surgical treatment on work status

Study	N patients	Which treatment resulted in more patients returning to work?	Was the difference significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Wide fasciectomy plus anconeus transfer	No	3%	Wide fasciectomy: 1.05 (-0.25 to 2.35) limited fasciectomy: 0.17 (-0.90 to 1.25)

[a] calculated by ECRI with fasciectomy alone as the control group

Pain

Almquist 1998 reported that patients treated with wide fasciectomy plus anconeus transfer had more pain relief than did patients treated with fasciectomy. This difference was reported to be statistically significant. Patients treated with wide fasciectomy plus anconeus transfer were reported to have more pain relief than patients treated with limited fasciectomy plus anconeus transfer, but the difference in outcomes between these two groups was not statistically significant. These data are reported in Table 291 and summarized in Table 292.

Table 291. Results of surgical treatment on pain

Study	N patients	Percentage of patients with pain relief	Statistical significance of the difference between groups
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Fasciectomy - 62% Wide fasciectomy plus anconeus transfer- 87% Limited fasciectomy - 86%	Chi-squared test P<0.05 between wide plus transfer and fasciectomy only

Table 292. Effect of surgical treatment on pain

Study	N patients	Which treatment resulted in more pain relief?	Was the difference significant?	Effect size d (95% CI)[a]
Almquist 1998 [83]	16 fasciectomy 31 wide fasciectomy plus anconeus transfer 14 limited fasciectomy plus anconeus transfer	Wide fasciectomy plus anconeus transfer	Yes, between wide plus transfer and fasciectomy; No, between wide plus transfer and limited	Wide fasciectomy: 0.76 (-0.05 to 1.56) Limited fasciectomy: 0.69 (-0.31 to 1.68)

[a] calculated by ECRI with fasciectomy alone as the control group

Function and Activities

Neither of the included studies reported patient-oriented measurements of these outcomes.

Quality of Life

Neither of the included studies reported on this outcome.

Morbidity and Complications

Morbidity and complications related to the surgery were not reported by either study. Wilhem 1996 did describe the length of time required to recover from surgery. Denervation required only 2.7 weeks of recovery, as compared to 5.7 weeks to recover from denervation plus disinsertion and 11.7 weeks to recover form denervation plus decompression. These differences were reported to be statistically significant. These data are summarized in Table 293.

Table 293. Length of time after surgery before returning to work

Study	Number of patients	Which treatment had the shortest recovery time?	Was the difference significant?
Wilhem 1996 [84]	39 denervation 46 denervation and disinsertion 81 denervation and decompression	Denervation	Yes

Conclusions

One retrospective case-controlled study of 61 patients compared fasciectomy, wide fasciectomy plus anconeus transfer, and re-operation of failed fasciectomy to include an anconeus transfer. This study reported that patients treated with wide fasciectomy plus anconeus transfer had better outcomes than did patients treated with either fasciectomy or re-operation of failed fasciectomy to include an anconeus transfer. However, the design of this study was not optimal, and precludes one from making a firm evidence-based conclusion.

One non-parallel historically controlled trial of 166 patients reported that simple denervation lead to statistically significantly better global outcome and greater pain relief than did denervation plus decompression. Simple denervation was also reported to lead to better global outcome, and greater pain relief, than did denervation plus disinsertion, but the difference was not statistically significant. However, design difficulties with this study preclude one from using its results to make a firm evidence-based conclusion.

What are the relative benefits and harms of transcutaneous electrical nerve stimulation therapy for persons with epicondylitis?

Transcutaneous electrical nerve stimulation therapy (TENS) refers to applying an electrical current across the skin. TENS has been reported to relieve pain and stimulate wound healing. The scope of our answer to this question is determined by the scope of the published literature. The relevant literature consists of one study that compared TENS to sham TENS treatment.

Internal validity

One double-blinded randomized crosover trial was identified that employed transcutaneous electrical nerve stimulation therapy (TENS) for treating epicondylitis. Details of this study are shown in Table 294. The study treated one patient group with a Rebox device, which delivers a low-current voltage to the patient. The control group received sham treatment with a disabled Rebox device. After ten treatments, the groups spent a week receiving no treatment, then they received the opposite treatment.

Analysis and reported data are for only those who completed the entire trial (not intent-to-treat). Ignoring attrition when analyzing the data can create a bias in the results. However, attrition in this trial was not substantial (8.6%).

Table 294. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Johannsen 1993 [612]	35	1	NR	RCT	Yes	Double	8.6	No	NA

Generalizability

The characteristics of the patients are shown in Table 295. The mean age of the patients was 43, which is similar to that reported in studies of the epidemiology of epicondylitis (see the Introduction). However, the patients were predominantly male (82.9% male). Studies of the epidemiology of epicondylitis (see the Introduction) have indicated that patients with epicondylitis are equally likely to be of either sex. Thus, this may be an atypical group of patients. No information as to the occupations or employment status of the patients was reported. The study excluded patients with various comorbidities. This limits the generalizability of the study, as comorbidities are not generally exclusion criteria for treatment with TENS.

Table 295. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Johannsen 1993 [612]	35	43 (36-58)	17.1	6 (3-12)	NR	0	0	0	0	NR	NR	No	No

Results

Three outcomes were reported by this study; none were patient-oriented. Because no patient-oriented outcomes were reported, we have not shown any tables of data or performed any analysis. We will, however, briefly discuss the outcomes and results reported by this study. Grip strength was measured using a dynamometer with both the elbow extended and flexed. Mean improvements were reported. The amount of pain the patient experienced while lifting a 2 kg weight with the elbow extended and the forearm pronated was also measured and reported as mean improvements. For all three outcomes, differences between the treatment groups were statistically insignificant until the complete course of ten treatments had been administered, at which time a statistically significantly better outcome was found for the patients receiving TENS.

Conclusions

One randomized controlled crossover trial of 35 patients reported that patients treated with TENS had statistically significantly better outcomes than did patients receiving sham treatment. However, none of the reported outcomes were patient-oriented, and reaching definitive evidence-based conclusions from the results of a single trial is problematic. Further research into this treatment is necessary.

What are the relative benefits and harms of pulsed electromagnetic field therapy for persons with epicondylitis?

Pulsed electromagnetic fields (PEMF) have been said to speed healing, alleviate pain, and reduce inflammation. The scope of our answer to this question is determined by the scope of the published literature. The relevant literature consists of one trial that compared PEMF therapy to sham PEMF therapy.

Internal validity

One double-blinded randomized controlled trial of 30 patients that evaluated pulsed electromagnetic fields (PEMF) as a therapy for epicondylitis was identified. The study design is summarized in Table 296. The gender compositions of the two groups appears to be different, but chi-squared tests calculated by ECRI indicate the difference is of borderline statistical significance ($p = 0.06$).

Table 296. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Devereaux 1985 [598]	30	1	NR	RCT	Yes	Double	0	Yes	NA

Generalizability

Only patients diagnosed with epicondylitis who had a positive thermographic pattern with a hot area near the lateral epicondyle were included in the trial. Data on what percentage of epicondylitis patients in general who have such a thermographic pattern are not available. Thus, it is unclear whether these patients are typical epicondylitis patients. Other characteristics of these patients are shown in Table 297. The mean age (43.3 years) and percent female (43.3%) are similar to those found in studies of the epidemiology of epicondylitis (see the Introduction). No information as to the occupations or employment status of the patients was reported. The study did exclude patients with some comorbidities, which further limits the generalizability of the trial as comorbidities are not exclusion criteria for treatment with PEMF.

Table 297. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Devereaux 1985 [598]	30	43.8	43.3	10.0	NR	0	NR	0	0	0	NR	No	No

Results

The patients were evaluated every two weeks for the ability to lift weight, pain upon wrist dorisflexion, effect on work, pain during common activities of daily living (ADL), tenderness over the elbow, and grip strength. Data were only reported for grip strength, not for any of the patient-oriented outcomes. Grip strength was statistically significantly more effective at 6 weeks evaluation in the group given PEMF as compared to the group given sham treatment. However, examination of the data indicates that this difference is primarily the result of a mean decrease in grip strength at 6 weeks in the sham-treated group. For all of the other outcomes, at all time points, there were no reported statistically significant differences between the treatment groups. However, this study was small (n = 30), so it is possible that it lacked sufficient power to detect a statistically significant difference between the treatment groups. Because data reporting was incomplete, power calculations cannot be performed for this study.

Table 298. Success of treating epicondylitis with PEMF

Study	Number of patients	Which treatment was more effective?	Was the difference statistically significant?	Was the effect size statistically significant?	Did the study have sufficient power to detect the observed difference?
Devereaux 1985 [598]	15 PEMF 15 Sham	PEMF	No Wilcoxon rank sum test	Cannot calculate from the reported data	Cannot calculate from the reported data

PEMF = pulsed electrical magnetic field

Conclusions

A single double-blinded randomized controlled trial of 30 patients reported that there were no statistically significant differences in the signs and symptoms of epicondylitis between patients treated with PEMF and patients receiving sham treatment. When interpreting the results of this trial, it must be kept in mind that the small size of the trial may have prevented the results from reaching statistical significance.

What are the relative benefits and harms of extracorporal shock-wave therapy for persons with epicondylitis?

Extracorporal shock wave therapy (ESWT) refers to passing a shock wave through a localized area of the body. It has been reported to relieve pain.[581] The relevant literature consists of one published study that compared ESWT to a sham ESWT procedure.

Internal validity

Two manuscripts by the same group have been published evaluating ESWT as a treatment for epicondylitis. Both manuscripts refer to the same study; the earlier manuscript includes fewer patients.[582] Therefore, only the later manuscript is discussed in this report.[581] Details of the study design are shown in Table 299. The study was a randomized controlled trial. Neither the patients nor the evaluating physicians were blinded to the type of treatment received. Lack of blinding of the patient to the type of treatment, in particular when using subjective outcome measures, can alter measurements of treatment effect because patients might unconsciously rate their condition differently in order to please the clinician.[474] If the evaluating physician is aware of the treatment given, it is possible that he/she may unconsciously bias the patient's responses by giving leading instructions.[474]

The trial did not analyze the data by the intent-to-treat principle. Ignoring attrition when analyzing the data can create a bias in the results. For this particular trial, we were unable to compensate for the failure to follow the intent-to-treat principle. The attrition rate from this trial was substantial (13.0%) and thus may have biased the results.

Table 299. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Rompe 1996 [581]	115	1	NR	RCT	Yes	No	13.0	No	NA

NR = not reported
NA = not applicable
RCT = randomized controlled trial

Generalizability

Characteristics of the patient groups enrolled in the trial are shown in Table 300. All of the patients had been diagnosed with lateral epicondylitis. The mean age of the patients was 42.9, and the patient group was 50.4% female. These patient characteristics match those reported in published studies of the epidemiology of epicondylitis (see the Introduction), suggesting that the results of the study are generalizable beyond this particular patient group. The study did not report any

information as to the occupations or employment status of the patients. The study excluded patients with arthritic changes of the elbow, which may limit its generalizability to the overall epicondylitis patient population.

Table 300. Generalizability information: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Rompe 1996 [581]	115	42.9 (26-61)	50.4	22.9 (10-120)	NR	0	NR	NR	NR	NR	NR	No	No

Results

The reported patient-oriented results are shown in Table 301 and summarized in Table 302. The patients were asked to rate their improvement in pain and function. There is a statistically significant better outcome for patients treated with ESWT as compared to sham therapy at all followup times. We calculated an effect size for each time point and outcome and this is shown in Table 301.

Table 301. Results of treating epicondylitis with ESWT

Study	Outcome	Treatment group	N	Time of followup months	Reported outcome				Statistical test	Hedges' d (95% CI)[a]
					Excellent	Good	Acceptable	Poor		
Rompe 1996 [581]	Patient-rated improvement in pain and function								Chi-squared test[a] P<0.000001 at all time points	
		ESWT	50	1	11	16	18	5		2.76 (2.22 to 3.31)
		Sham	50	1	0	10	16	24		
		ESWT	50	1.5	10	16	18	6		3.05 (2.48 to 3.62)
		Sham	50	1.5	0	6	10	34		
		ESWT	50	6	6	11	13	21		1.20 (0.78 to 1.62)
		Sham	50	6	0	3	12	35		
	Pain at night, patient-rated	ESWT	50	0	34.6 (15.8)				Fisher's exact test p >0.05 at time 0, p <0.001 at all other times	-0.21 (-0.61 to 0.18)
		Sham	50	0	31.2 (16)					
		ESWT	50	1	13.2 (9.9)					1.49 (1.04 to 1.93)
		Sham	50	1	34.6 (17.6)					
		ESWT	50	1.5	7.7 (8.8)					1.91 (1.44 to 2.38)
		Sham	50	1.5	35.1 (18.1)					
		ESWT	50	6	7.3 (8.7)					1.48 (1.04 to 1.93)
		Sham	50	6	27.3 (16.8)					

[a] calculated by ECRI

Table 302. Effect of ESWT on epicondylitis

Study	Number of patients	Which treatment resulted in the greatest improvement?	Was the difference statistically significant?	Was the effect size statistically significant?
Rompe 1996 [581]	50 ESWT 50 Sham	ESWT, at 1, 1.5, and 6 months	Yes	Yes

ESWT = extracorporal shock wave therapy

Conclusions

One randomized controlled trial of 100 patients reported that patients treated with ESWT had statistically significantly greater improvements in pain and arm function than did patients given sham treatment. However, it is difficult to reach firm evidence-based conclusions from the results of this trial because the lack of blinding and lack of intent-to-treat analysis of this trial may have affected its results.

What are the relative benefits and harms of various combinations of therapy for persons with epicondylitis?

Internal validity

Five studies that compared combinations of therapies are discussed in this section. The therapies used are summarized in Table 303. Some of the data from the trials by Holdsworth 1993 and Straford 1989 were also included in the section on ultrasound therapy. Details of the study designs are summarized in Table 304.

All of the trials are randomized controlled trials. Three of the five trials were not blinded. The trial by Stratford 1989 was double-blinded as to whether patients received ultrasound or phonophoresis, but the patients were aware of their status as regards massage therapy or not. Likewise, the trial by Holdsworth 1993 blinded the patients as to whether they received ultrasound or phonophoresis, but the patients were aware of their status as regards being assigned an elbow brace or not. None of the studies reported on compliance with the prescribed treatments.

The study Holdsworth 1993 did not use intent-to-treat analysis. This study had a high attrition rate (14.3%). Ignoring attrition when analyzing the data can create a bias in the results. We were not able to compensate for not following the intent-to-treat principle for this trial because of the nature of the data reported.

Table 303. Summary of trials of mixed therapies for epicondylitis

Study	Treatments compared
Drechsler 1997 [593]	Manipulations plus home exercise
	Ultrasound plus physiotherapy plus home exercise
Holdsworth 1993 [620]	Ultrasound
	Ultrasound plus brace
	phonophoresis
	Phonophoresis plus brace
Vasseljen 1992 [591]	Laser
	Ultrasound plus deep friction massage
Stratford 1989 [621]	Ultrasound
	Ultrasound plus deep friction massage
	Phonophoresis
	Phonophoresis plus deep friction massage
Burton 1988 [594]	Manipulation
	Manipulation plus brace
	Manipulation plus cream
	Manipulation plus cream plus brace

Table 304. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Drechsler 1997 [593]	18	1	NR	RCT	Yes	No	0	Yes	NR
Holdsworth 1993 [620]	42	1	NR	RCT	Yes	Patients	14.3	No	NA
Vasseljen 1992 [591]	30	1	NR	RCT	Yes	No	0	Yes	NA
Stratford 1989 [621]	40	1	No	RCT	Yes	Double	0	Yes	NA
Burton 1988 [594]	33	1	Yes	RCT	Yes	No	0	Yes	NR

RCT = randomized controlled trial
NR = not reported
NA = not applicable

Generalizability

Details of the patient characteristics are shown in Table 305. Epidemiology studies of epicondylitis (see the Introduction) have found that the typical patient is in the mid-forties and of either sex. All of the patient groups of these studies fit this profile.

The presence of various comorbidities associated with epicondylitis is incompletely reported in these studies. Some studies excluded patients with various comorbidities, indicated in Table 305 with a zero under that comorbidity. This

limits the generalizability of the studies, as comorbidities are not usually exclusion criteria for the treatments discussed in this section.

None of studies reported any information as to patient occupations or employment status. Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall population of epicondylitis patients cannot be determined from the available data.

Table 305. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Drechsler 1997 [593]	18	45.9 (30-57)	55.6	NR	0	0	NR	0	0	NR	0	No	No
Holdsworth 1993 [620]	42	45.3 (22-62)	35.7	NR	NR	0	0	0	0	NR	NR	No	No
Vasseljen 1992 [591]	30	45.5 (25-70)	56.7	2.1 (1-12)	NR	0	NR	NR	NR	NR	NR	No	No
Stratford 1989 [621]	40	43.3	50.0	4.3	NR	NR	NR	0	NR	NR	NR	No	No
Burton 1988 [594]	33	45.1	48.5	1.2	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Manipulations plus exercise compared to ultrasound plus physiotherapy

The study by Drechsler 1997 compared a combination of manipulations designed to increase mobility of the elbow plus a regimen of home exercises to a combination of ultrasound, physiotherapy, and home exercises. This study measured grip strength, self-reported difficulties in performing activities, and measurements of upper limb tension. The data recorded for the patient-oriented outcome difficulties in performing activities are shown in Table 306 and summarized in Table 307. The authors performed an analysis of variance (ANOVA) on their data and found that patients treated with manipulations plus home exercises had fewer difficulties in performing activities of daily living than patients treated with ultrasound, physiotherapy, and home exercises. The difference in outcomes was statistically non-significant at 1.5 months of followup, but was statistically significant by 3 months of followup.

Table 306. Treating epicondylitis with ultrasound plus physiotherapy compared to manipulations

Study	Number of patients	Patient-reported difficulties in performing ADL	Statistical significance of difference between groups
Drechsler 1997 [593]	10 US, physiotherapy 8 Manipulations	Mean (SD) At 1.5 months US + physio: 1.9 (0.233) Manipulations: 1.875 (0.295) At 3 months US + physio: 2.1 (0.0314) Manipulations: 1.5 (0.189)	ANOVA At 1.5 months, NS At 3 months, p <0.05

US = ultrasound
Physio = physiotherapy

Table 307. Treating epicondylitis with ultrasound plus physiotherapy compared to manipulations

Study	Number of patients	Which treatment was most successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Drechsler 1997 [593]	10 US, physiotherapy 8 Manipulations	Manipulation	At 1.5 months, No At 3 months, Yes	At 1.5 months, 0.11 (-0.77 to 0.99) At 3 months, 4.24 (2.66 to 5.82)

[a] calculated by ECRI
US = ultrasound

Ultrasound with or without bracing

Holdsworth 1993 compared groups treated with ultrasound combined with elbow bracing therapy to groups treated with ultrasound only. The data reported by Holdsworth 1993 are shown in Table 308 and summarized in Table 309. Holdsworth 1993 reported that the addition of bracing to either ultrasound or phonophoresis had no statistically significant effect on patient-rated success of the treatment. However, this trial could have detected only an 83% or larger difference between groups. Therefore, its small size may have caused it to miss clinically important effects.

Table 308. Results of treating epicondylitis with ultrasound plus bracing

Study	Number of patients	Patient-rated success of treatment on VAS	Statistical significance of difference between groups
Holdsworth 1993 [620]	7 Phonophoresis 10 Phonophoresis plus bracing 9 ultrasound 8 Ultrasound plus bracing	1.5 months mean (SE) Phonophoresis: 49.6 (12.4) Phonophoresis + bracing: 55.9 (16.1) Ultrasound: 63 (12.2) Ultrasound + bracing: 62.6 (11.3)	ANOVA NS

Table 309. Treating epicondylitis with ultrasound plus bracing

Study	Number of patients	Which treatment was more successful?	Was the difference statistically significant ?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Holdsworth 1993 [620]	7 Phonophoresis 10 Phonophoresis plus bracing 9 Ultrasound 8 Ultrasound plus bracing	Phonophoresis	No	83.5%	Phonophoresis: 0.33 (-0.55 to 1.21) 0.15 (-0.73 to 1.03) 0.01 (-0.87 to 0.89)

[a] calculated by ECRI using ultrasound as the comparison group

Ultrasound plus massage compared to laser

Vasseljen 1992 compared laser therapy to a mixture of ultrasound and deep friction massage. Each patient received eight treatments. Pain (physician-rated) was measured after all the treatments had been administered, and four weeks later. The group treated with ultrasound plus massage had significantly less pain ($p < 0.01$; ANOVA) after treatment than did the group treated with laser therapy.

Ultrasound plus massage compared to ultrasound

Stratford 1989 compared ultrasound plus deep friction massage to ultrasound alone. Each patient received nine treatments over the course of five weeks. The results are shown in Table 310 and summarized in Table 311. The study did not find a statistically significant difference between any of the treatment combinations. However, the study could have only detected a 42% or larger difference between the groups. Therefore, it was too small to detect a small to moderate clinically important effect.

Table 310. Results of treating epicondylitis with ultrasound plus massage as compared to ultrasound

Study	Type of Treatment	Number of patients with successful treatment	Statistical significance of difference between groups
Stratford 1989 [621]	10 Phonophoresis 10 Phonophoresis plus massage 9 Ultrasound 11 Ultrasound plus massage	3 phonophoresis 2 phonophoresis plus massage 1 ultrasound 4 ultrasound plus massage	Chi-squared test[a] Phonophoresis with or without massage P = 0.61 Ultrasound with or withour massage P = 0.19

[a] calculated by ECRI

Table 311. Success of treating epicondylitis with ultrasound plus massage as compared to ultrasound

Study	Number of patients	Which treatment was most successful?	Was the difference statistically significant ?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Stratford 1989 [621]	10 Phonophoresis 10 Phonophoresis plus massage 9 Ultrasound 11 Ultrasound plus massage	Ultrasound plus massage	No	42%	Phonophoresis: 0.71 (-0.65 to 2.07) Phonophoresis plus massage: 0.43 (-1.0 to 1.85) Ultrasound plus massage: 0.95 (-0.39 to 2.28)

[a] calculated by ECRI with ultrasound as the comparison group

Manipulation plus bracing

Burton 1988 compared manipulations to improve mobility of the elbow to manipulations plus bracing, manipulations plus a topical anti-inflammatory cream, and a combination of all three therapies. Burton 1988 measured patient-rated hand-arm function. The data are shown in Table 312 and summarized in Table 313. No statistically significant differences between groups were found. However, this study lacks the statistical power to detect less than a 67% difference between the therapies, and thus could not have detected small to moderate clinically important effects.

Table 312. Results of treatment of epicondylitis with combinations of manipulation, bracing, and topical anti-inflammatories

Study	Number of patients	Mean (SD) of patient-rated function VAS			Effect size d (95% CI)[a]
Burton 1988 [594]	8 Bracing plus manipulation 8 Bracing plus cream plus manipulation 9 Cream plus manipulation 8 Manipulation	Initial measure	Bracing plus manipulation	3.2 (0.4)	0.0 (-0.88 to 0.88)
			Bracing plus cream plus manipulation	3.6 (1.0)	0.35 (-0.54 to 1.23)
			Cream plus manipulation	3 (0.7)	-0.19 (-1.07 to 0.68)
			Manipulation	3.2 (1.2)	
		1 week	Bracing plus manipulation	2.8 (0.8)	0.00 (-0.88 to 0.88)
			Bracing plus cream plus manipulation	2.8 (1.4)	0.00 (-0.88 to 0.88)
			Cream plus manipulation	2.5 (0.7)	-0.29 (-1.17 to 0.59)
			Manipulation	2.8 (1.2)	
		2 weeks	Bracing plus manipulation	2.5 (1.1)	0.00 (-0.88 to 0.88)
			Bracing plus cream plus manipulation	2.5 (1.7)	0.00 (-0.88 to 0.88)
			Cream plus manipulation	1.7 (0.6)	-0.63 (-1.53 to 0.26)
			Manipulation	2.5 (1.6)	
		4 weeks	Bracing plus manipulation	1.6 (1.0)	0.08 (-0.79 to 0.96)
			Bracing plus cream plus manipulation	1.5 (1.6)	0.00 (-0.88 to 0.88)
			Cream plus manipulation	1 (0.8)	-0.44 (-1.33 to 0.44)
			Manipulation	1.5 (1.3)	

[a] calculated by ECRI with manipulation as the comparision group

Table 313. Treatment of epicondylitis with combinations of manipulation, bracing, and topical anti-inflammatories

Study	N patients	Which treatment resulted in greater function?	Was the difference statistically significant?	Minimal difference the study had the power to detect	Where any of the effect sizes statistically significant?
Burton 1988[594]	8 Bracing plus manipulation 8 Bracing plus cream plus manipulation 9 Cream plus manipulation 8 Manipulation	Bracing plus cream plus manipulation	No for all followup times ANOVA test p >0.05	67%	No

Morbidities and complications

None of the included studies reported any complications or morbidities.

Conclusions

Five randomized controlled trials evaluated various combinations of therapies for the treatment of epicondylitis. Because no two trials evaluated the same combinations, no meta-analysis could be performed. One trial of 18 patients found that patients treated with manipulation plus a home exercise program had fewer difficulties in performing activities of daily living than did patients treated with a combination of ultrasound, physiotherapy, and home exercise. The other four trials did not find statistically significant differences between-treatment groups. However, these studies were small, which may have prevented them from detecting clinically important differences between the treatment groups. One of these studies reported a trend towards phonophoresis being rated as more successful than ultrasound, phonophoresis plus bracing, or ultrasound plus bracing. One of these studies reported a trend towards ultrasound plus deep friction massage being rated as more successful than ultrasound, phonophoresis, or phonophoresis plus deep friction massage. One of these studies reported no statistically significant functional differences after treatment with various combinations of bracing, manipulation, and topical anti-inflammatory cream. One of these studies reported a trend towards less pain experienced by patients treated with ultrasound plus deep friction massage than those treated with laser therapy.

No firm evidence-based conclusions as to the effectiveness of these combinations of therapies can be reached from the results presented by these trials. Four of the studies included too few patients to be able to have detected small but clinically meaningful effects of the therapies. Although the fifth study did find a statistically significant difference between groups for one outcome, it was a small study (n = 18)

that did not blind either the patients or the evaluating physicians to treatments. Further studies are required to corroborate this study's results.

What are the relative benefits and harms of different therapies for persons with epicondylitis?

Internal validity

Seven studies were identified that directly compared the efficacy of different therapies for treating epicondylitis. Details of the therapies compared by these studies are summarized in Table 314. One of the trials (Brattberg 1983) was not randomized; the rest of the trials are randomized controlled trials. Three of the trials did not use blinding, and two blinded only the evaluating physician, not the patients.

Only two of the studies (Hay 1999 and Halle 1986) used intent-to-treat analysis. Attrition rates were fairly low (less than 10%) in four out of the five studies that did not use intent-to-treat analysis. However, in the study by Saartok 1986 attrition rates were greater than 10%. Ignoring attrition when analyzing the data can create a bias in the results. Where possible, we have tried to compensate for this by attempting to gauge the maximum possible effect of not following this principle. Thus, we assumed that all patients who were not followed until the end of the study received unsuccessful treatment. This is a conservative assumption. However, if statistical significance is obtained under this assumption, one can be more confident that the magnitude of this design weakness is not large enough to overturn the results of a statistically significant trial. We were able to compensate for not following the intent-to-treat principle in all of the trials included in this section. This compensation suggests that failure to follow the intent-to-treat principle did not alter the conclusions of any of these trials.

The trial by Hay 1999 is a multi-center trial that may be potentially confounded by co-interventions. By 12 months of followup, approximately 35-38% of the patients in all groups had received some unspecified treatment in addition to their assigned treatment. Because approximately equal numbers of patients in each group received additional treatments, it is possible that these interventions did not affect the results of the trial. However, the types of interventions are not specified. Thus, it is theoretically possible that patients in one group received different co-interventions than did patients in other groups, and thus the co-interventions could affect the results of the trial.

Table 314. Summary of the trials comparing different therapies for epicondylitis

Study	Treatments compared	
	Group 1	Group 2
Hay 1999 [609]	Injection of methylprednisolone and lidocaine	Naproxen, 500 mg 2X/day
		Placebo pills
Pienimaki 1996 [599]	Physical therapy	Ultrasound
Verhaar 1995 [607]	Injection of triamcinolone and lidocaine	Deep friction massage and manipulations, 12 times over 4 weeks
Haker 1993 [611]	Injection of bupivacaine and triamcinolone	Epicondylitis clasp, worn daily for 3 months
		Elbow immobilized in splint, worn daily for 3 months
Halle 1986 [606]	Injection of hydrocortisone and lidocaine	Ultrasound
	TENS	Phonophoresis of hydrocortisone
Saartok 1986 [610]	Injection of betamethasone	Naproxen, 250 mg/day for 2 weeks
Brattberg 1983 [608]	Injection of steroids, unspecified type, unspecified number of injections	Acupuncture at five points in the region of the elbow. One to two treatments per week for four weeks

TENS = transcutaneous electrical nerve stimulation therapy
NSAID = non steroidal anti-inflammatory drug

Table 315. Internal validity

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective?	Blinding	%Attrition	Intent to treat analysis	Compliance
Hay 1999 [609]	182	Multiple	NR	RCT	Yes	Rater	0.55	Yes	NR
Pienimaki 1996 [599]	42	1	NR	RCT	Yes	Rater	7.1	No	NA
Verhaar 1995 [607]	106	1	No	RCT	Yes	No	2.8	No	NA
Haker 1993 [611]	76	1	NR	RCT	Yes	Double	6.6	No	NA
Halle 1986 [606]	48	1	NR	RCT	Yes	No	0	Yes	NR
Saartok 1986 [610]	21	1	NR	RCT	Yes	Double	14.2	No	NR
Brattberg 1983 [608]	63	1	NR	CT	Yes	No	4.8	No	NA

RCT = randomized controlled trial
CT = controlled trial
NR = not reported
NA = not applicable

Generalizability

Details of the patient characteristics are shown in Table 316. The patients in all of the trials appear to be fairly typical of epicondylitis patients in general (see the epidemiology subsection in the Introduction). However, the Saartok trial appears to be predominantly male (19.0% female), and the Haker trial is also predominantly male (25.0% female); studies of the epidemiology of epicondylitis suggest that the general population is approximately 50% female. Thus, these two trials may be drawn from special subpopulations and their results may not be generalizable.

Some of the studies excluded patients with various comorbidities, indicated by a zero under that comorbidity. This limits the generalizability of the studies, as comorbidities are not usually exclusion criteria for the treatments discussed in this section.

Patient employment characteristics are incompletely reported in these studies (Table 317). Therefore, the extent to which the employment characteristics of these patients may be generalized to the overall epicondylitis patient population cannot be determined from the information available.

Table 316. Generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of condition mean and range	% Patients with diabetes	% Patients with arthritis	% Patients with previous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Hay 1999 [609]	182	NR	42.8	NR	NR	0	NR	NR	NR	0	NR	No	No
Pienimaki 1996 [599]	42	42 (31-53)	59.5	NR	NR	0	0	0	0	NR	NR	No	No
Verhaar 1995 [607]	106	43	47	8	NR	0	NR	0	0	NR	NR	No	No
Haker 1993 [611]	76	47.8	25	5 (1-36)	NR	0	NR	0	0	NR	NR	No	No
Halle 1986 [606]	48	(20-59)	54.1	NR	NR	NR	NR	0	0	NR	NR	No	No
Saartok 1986 [610]	21	45	19.0	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Brattberg 1983 [608]	63	(30-60)	36.5	NR	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Table 317. Generalizability: occupations

Study	Number of patients	% Patients employed	% Patients on Workers' compensatio	% Patients retired	% Patients homemakers	Reported occupations
Hay 1999 [609]	182	62.6	NR	NR	NR	NR
Pienimaki 1996 [599]	42	30.9	NR	NR	NR	NR
Verhaar 1995 [607]	106	NR	NR	NR	NR	NR
Haker 1993 [611]	76	NR	NR	NR	NR	NR
Halle 1986 [606]	48	NR	NR	6.3	29.1	33.3% blue collar workers 31.3% white collar workers
Saartok 1986 [610]	21	NR	NR	NR	NR	NR
Brattberg 1983 [608]	63	NR	NR	NR	NR	NR

NR = not reported

Results

NSAIDs compared to corticosteroid injections

Two randomized controlled trials of a total of 203 patients compared oral NSAIDs (naproxen) to corticosteroid injections (methylprednisolone and betamethasone). Both studies measured pain and function. In addition, they rated the overall success of the treatments. One of the studies reported no statistically significant difference in outcomes between the study groups, while the other study reported that the patients treated with corticosteroid injections had statistically statistically significantly better outcomes than did patients treated with oral NSAIDs or with placebo. The patient-oriented outcomes reported by these two studies are shown in Table 318 and summarized in Table 319. The study that reported no significant difference in outcomes (Saartok 1986) only had a total of 21 patients, and thus may have been too small for the difference in outcomes between its patient groups to reach statistical significance. We calculated that this study could have detected a 36% or greater difference between its groups. The fact that the Hay trial found a larger difference than this suggests that the results of these two trials are truly different, and not simply the result of a lack of statistical power on the part of the Saartok trial. As discussed previously, it is possible that the Hay trial was confounded by co-interventions.

Table 318. Results of treating epicondylitis with NSAIDs as compared to steroid injections

Study	Number of patients	Global assessment-patient rated categories	Statistical significance of difference between groups
Hay 1999 [609]	52 corticosteroid injection 53 NSAIDS 56 placebo	Corticosteroid injections: 22 complete recovery, 26 improvement, 3 no change, 1 worse, 0 much worse NSAIDs: 3 complete recovery, 27 improvement, 16 no change, 7 worse, 0 much worse Placebo: 2 complete recovery, 26 improvement, 23 no change, 4 worse, 1 much worse	Mann-Whitney U test p <0.05 injections compared to NSAID and injections compared to placebo
Saartok 1986 [610]	11Corticosteroid injection 10 NSAIDs	Corticosteroid injections: 1 much improved, 5 improved, 2 no change, 4 worse, 0 much worse NSAIDs: 0 much improved, 6 improved, 3 no change, 1 worse, 0 much worse	Mann-Whitney U test NS

Table 319. Success of treating epicondylitis with NSAIDs as compared to steroid injections

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Minimal difference the study had the power to detect	Effect size d (95% CI)[a]
Hay 1999 [609]	52 steroid injection 53 oral NSAIDs 56 placebo	One month	Injection of corticosteroids	Yes	NA	Steroids vs. placebo: 0.57 (0.18 to 0.95) NSAIDs vs. placebo: -0.08 (-0.46 to 0.30) Steroids vs. NSAIDs: 1.31 (0.88 to 1.73)
Saartok 1986 [610]	11 steroid injection 10 oral NSAIDs	2 weeks	No difference	No	36%	0.54 (-0.33 to 1.42)

[a] calculated by ECRI
NSAID = non steroidal anti-inflammatory drug

Acupuncture compared to corticosteroid injections

One controlled trial of 63 patients compared acupuncture treatment to injections of corticosteroids. This trial reported only patient-rated pain. Patients were followed for different times after the treatment, with a mean followup time of 5.8 months, and a range of 2 to 9 months. Statistical tests performed by the authors indicated that acupunture treatment was statistically significantly more successful at relieving pain than was corticosteroid treatment. The data are summarized in Table 320. The calculated effect size agrees with the statistical tests performed by the authors. However, when interpreting the results of this trial it must be kept in mind that all of the patients had been found to be unresponsive to treatment with corticosteroid injections before being enrolled in the trial.

Table 320. Success of treating epicondylitis with acupuncture as compared to steroid injections

Study	Number of patients	Pain-patient rated categories	Statistical significance of difference between groups	Effect size d (95% CI)[a]
Brattberg 1983 [608]	34 acupuncture 26 corticosteroid injection	Acupuncture: 8 no pain, 9 slight pain, 4 better, 3 improved, 10 unchanged, 0 worse Injections: 2 no pain, 6 slight pain, 0 better, 8 improved, 6 unchanged, 4 worse	Chi-squared test P<0.05 Statistically significant	-0.59 (-1.09 to -0.08)

[a] calculated by ECRI

Physiotherapy compared to corticosteroid injections

One randomized controlled trial of 106 patients compared a combination of exercises and deep friction massage designed to improve mobility of the elbow to injections of corticosteroids. The reported results for the other patient-oriented outcomes are shown in Table 321 and summarized in Table 322. Manipulation and massage were found to be statistically significantly less effective than are injections of corticosteroids at treating pain and are rated as less effective by patients. Statistically significantly more patients treated with corticosteroid injections returned to work, but the effect size calculated for this outcome did not reach statistical significance.

Table 321. Results of treating epicondylitis with physiotherapy as compared to steroid injections

Study	Number of patients	Outcome measured	Outcome measurement At 1.5 months	Statistical significance of difference between groups
Verhaar 1995 [607]	52 corticosteroid injection 51 Manipulations and massage	Global assessment - patient rated categories	corticosteroid injection: 18 excellent, 18 good, 10 moderate, 6 poor Manipulations and massage: 1 excellent, 12 good, 15 moderate, 23 poor	Chi-squared test P<0.001
		Pain - patient rated categories	Injection: 22 absent, 20 slight, 9 moderate,1 severe Manipulations and massage: 3 absent, 19 slight, 22 moderate, 7 poor	Chi-squared test p <0.001
		Return to work	Injection: 9 resumed work, 15 still working, 9 unable to work, 19 did not work and still do not Manipulations and massage: 4 resumed work, 14 still working, 13 unable to work, 20 did not work and still do not	Chi-squared test p <0.05

Table 322. Success of treating epicondylitis with manipulations compared to injections of steroids

Study	Number of patients	Time of followup	Which treatment was more successful?	Was the difference statistically significant?	Effect size d (95% CI)[a]
Verhaar 1995 [607]	52 steroid injection 51 manipulation	1.5 months	Injections of corticosteroids	Yes (Chi-squared test)	Global assessment: 1.15 (0.74 to 1.56) Pain:1.02 (0.61 to 1.43) Return to work: 0.10 (-0.29 to 0.48)

[a] calculated by ECRI

Bracing or immobilization compared to corticosteroid injections

One randomized controlled trial of 76 patients compared forearm elbow bracing, immobilization of the elbow, and corticosteroid injections. The authors report that after two weeks, the group treated with the corticosteroid injections had a statistically significantly better result for the outcome patient-rated pain than did the other two treatment groups. At longer followup times, however, the authors report there was no statistically significant difference between the treatment groups. The

data from the longer followup times were not reported. The calculated effect size agrees with the statistical tests performed by the authors. The data are summarized in Table 323.

Table 323. Results of bracing, injections, and splinting compared

Study	Number of patients	Patient-rated improvement in pain	Statistical signficance of the difference between groups	Effect size d (95% CI)[a]
Haker 1993 [611]	17 bracing 19 corticosteroid injection 19 immobilization / splinting	At 0.5 months, bracing 1 excellent, 1 good, 4 improved, 3 somewhat improved, 8 no change injections 3 excellent, 10 good, 2 improved, 3 somewhat improved, 1 no change splinting 0 excellent, 1 good, 6 improved, 6 somewhat improved, 6 no change	Chi-squared test Injections vs. bracing p = 0.000055 Injections vs. splinting p = 0.000427 Splinting vs. bracing p = 0.000001 Injections are most effective	Bracing: 1.04 (0.36 to 1.71) Splinting: 1.19 (0.51 to 1.86)

[a] calculated by ECRI using corticosteroid injections as the comparison group

TENS, ultrasound, phonophoresis, and injections of corticosteroids compared

One randomized controlled trial of 48 patients compared four different treatments for epicondylitis: TENS, ultrasound, phonophoresis of hydrocortisone, and injections of corticosteroids. This study measured patient-reported pain in several ways, and combined the results into a summary percentage. The authors report that there was no statistically significant difference in outcomes between any of the treatment groups. The calculated effect sizes agree with the results of the authors' statistical tests. However, the study was small and this may be the reason why the difference in outcomes between the groups did not reach statistical significance. The data reported by this study are shown in Table 324 and summarized in Table 325.

Table 324. Results of comparing injections, TENS, phonophoresis, and ultrasound

Study	Number of patients	Global outcome	Statistical significance of difference between groups
Halle1986 [606]	12 Corticosteroid injection 12 phonphoresis 12 TENS 12 ultrasound	Corticosteroid injection: 63% improved, 25% unchanged, 12% worse phonophoresis: 65% improved, 12% unchanged, 23% worse TENS: 56% improved, 23% unchanged, 21% worse ultrasound: 69% improved, 12% unchanged, 19% worse	Kruskal-Wallas ANOVA test NS

Table 325. The study by Halle 1986 lacks statistical power

Study	Number of patients	Followup time	Which treatment was most effective?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Halle 1986 [606]	12 injections 12 phonophoresis 12 ultrasound 12TENS	0.13 month	Corticosteroid injections	No	31%	Phonophoresis: -0.67 (-1.49 to 0.15) TENS: -0.02 (-0.82 to 0.78) Ultrasound: -0.53 (-1.35 to 0.28)

[a] calculated by ECRI using injections as the control group

Physiotherapy compared to ultrasound

One randomized controlled trial of 42 patients compared ultrasound treatment to a regimen of stretching, strengthening, and conditioning exercises. This study reported only one patient-oriented outcome, return to work. The reported results for this outcome are shown in Table 326 and summarized in Table 327. The study may be too small (n = 39) for its results on patients returning to work to have reached statistical significance.

Table 326. Results of physiotherapy compared to ultrasound

Study	Number of patients	Number of patients not working	Statistical significance of difference between groups
Pienimaki 1996 [599]	19 ultrasound 20 Physiotherapy	6 ultrasound 2 physiotherapy	Chi-squared test p = 0.355

Table 327. Physiotherapy compared to ultrasound

Study	Number of patients	Followup time	Which treatment resulted in more patients returning to work?	Was the difference statistically significant?	Minimal difference between groups the study had the power to detect	Effect size d (95% CI)[a]
Pienimaki 1996 [599]	19 ultrasound 20 physiotherapy	2 months	Physiotherapy	No	31%	0.77 (-0.20 to 1.74)

[a] calculated by ECRI

Conclusions

One randomized controlled trial of 106 patients reported that patients treated with injections of corticosteroids had better outcomes than did patients treated with manipulations and deep friction massage. One randomized controlled trial of 76 patients reported that patients treated with injections of corticosteroids had better outcomes than did patients treated with braces or immobilization.

Two randomized controlled trials of a total of 203 patients compared oral NSAIDs to injections of corticosteroids. One study did not find a statistically significant difference between the groups. The other study reported that patients treated with injections of corticosteroids had better outcomes than did the patients treated with oral NSAIDs. This study may have been confounded by co-interventions administered to the patients in addition to their allocated treatment.

One randomized controlled trial of 63 patients reported that patients treated with acupuncture had better outcomes than patients treated with corticosteroid injections. However, this study included only patients previously found to be unresponsive to injections of corticosteroids.

Two randomized controlled trials, one comparing TENS, ultrasound, phonophoresis, and injections of steroids, the other comparing physical therapy to ultrasound, reported no statistically significant differences between-treatment

groups. However, both trials may have been too small to be able to have detected clinically meaningful differences between-treatment groups.

Thirty-eight randomized controlled trials, four randomized crossover trials, and eight controlled trials of a total of 3147 patients evaluated eighteen different types of treatments for epicondylitis and reported 73 different outcomes. The studies tend to be small, and there are too few studies addressing each treatment to allow any definitive evidence-based conclusions to be made. Two tentative conclusions can be reached: Laser therapy does not appear to be an effective treatment for epicondylitis, and patients with epicondylitis who were treated with acupuncture had better global outcomes and greater pain relief than patients given sham acupuncture.

Question #4. Is there a correlation between specific clinical findings and specific treatment outcomes among patients with epicondylitis?

In addressing this question, we consider whether published literature suggests that there are clinical findings that predict positive or negative outcomes after treatment for epicondylitis. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 328.

Table 328. Excluded studies

Author	Reason for exclusion
Seegenschmiedt et al. 1998 [628]	Incomplete description of multivariate analysis (did not describe all variables and unclear description of some variables)
Gabel and Morrey 1995 [555]	Stratified study that did not examine any correlations that were also examined by at least two other studies
Verhaar et al. 1993 [559]	Stratified study that did not examine any correlations that were also examined by at least two other studies

Evidence base

After these exclusions, there remained three studies with a total of 160 patients.

Study quality

The criteria used to evaluate study quality were identical to those described in Question 4 for carpal tunnel syndrome. Table 329 shows relevant quality characteristics of studies that met the inclusion criteria for this question. All studies performed some type of multiple regression analysis. Two were prospective and one was retrospective.

Table 329. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Kurvers et al. 1995 [556]	No	Multiple regression
Stratford et al. 1989 [621]	Yes	Multiple regression
Gerberich et al. 1985 [629]	Yes	Multiple logistic regression

Results

Table 330 shows the relationship of specific clinical findings to treatment outcomes in those studies that used regression to identify predictor variables. There are three such studies with a total of 160 patients. Also presented in this table are non-clinical variables (e.g. age, gender) to show all of the variables used in each multiple regression (the variables relevant to the present question are bolded in Table 330).

Only one study reported on each combination of outcome and clinical finding. All three studies reported correlations between variables and global assessment of the success of the treatment. None of the studies reported correlation coefficients or p-values.

Stratford et al. included only two clinical findings in their multiple regression analysis: grip strength and site of pain.[621] They found that grip strength did not correlate with treatment outcome, but site of pain did. Patients with pain over the origin of the extensor carpi radialis longus (ECRL) had better outcomes than did patients with pain elsewhere. Patients with pain over the origin of the extensor carpi radialis brevis (ECRB) had poorer outcomes than did patients with pain elsewhere.

Gerberich et al. incorporated only two clinical findings into their analysis: severity of pain before treatment, and degree of functional limitations before treatment.[629] They reported no statistically significant correlation between the degree of functional limitations and success of the treatment, but found a correlation between severity of pain and success of the treatment. Patients with severe pain had poorer outcomes than patients with milder pain.

Kurvers et al. included only one clinical finding in their analysis: timing of the onset of symptoms (acute or gradual).[556] They found no statistically significant correlation between the timing of the onset of symptoms and the success of the treatment.

Table 330. Relationship between specific clinical findings and treatment outcomes among patients with Epicondylitis (multiple regression analysis)

Author/year	N	Treatment	Outcomes	Variables used in multiple regression												
				Age	Gender	Hobbies	Comorbidity (ulnar neuritis)	Duration of symptoms	**Functional limitations**	**Site of pain**	**Severity of pain**	**Grip strength**	**Timing of onset (acute or gradual)**	Compliance with rest	Use of hydrocortisone cream	Number of treatments
Kurvers et al. 1995 [556]	38 (ME)	Surgery	Global outcome (level of symptoms)	NS	NS	NS	Sig	–	–	–	–	–	NS	–	–	–
Stratford et al. 1989 [621]	40 (LE)	Ultrasound	Global outcome (success/failure)	NS	NS	–	–	NS	–	Sig	–	NS	–	NS	–	–
Gerberich et al. 1985 [629]	82 (LE)	Ultrasound	Global outcome (improvement)	NS	NS	–	–	NS	NS	–	Sig	–	–	–	NS	Sig (males) NS (females)

LE – Lateral epicondylitis
ME – Medial epicondylitis
aVariables in boldface indicate clinical findings

Conclusions

None of the three studies that addressed this question evaluated the relationship between the same combination of clinical findings, outcomes, and treatment type. One study reported that the site of pain could be used to predict response to treatment, one reported that the severity of pain could be used to predict response to treatment, and one reported that the timing of onset of symptoms (acute vs. gradual) did not correlate with the response to treatment. Because only one study addressed each outcome, it is difficult to reach firm evidence-based conclusions from the available data.

Question #5. Is there a correlation between duration of symptoms and specific treatment outcomes among patients with epicondylitis?

In addressing this question, we consider whether published literature suggests that duration of symptoms predicts positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different duration of symptoms.

Excluded studies

No studies were excluded due to failure to meet the question-specific criteria.

Evidence base

Seven studies with a total of 319 patients addressed this question.

Study quality

The criteria used to evaluate study quality were identical to those described in Question 4 for carpal tunnel syndrome. Seven studies were identified that reported treatment outcomes stratified or analyzed by duration of symptoms. These studies are listed in Table 331. Four studies (two prospective and two retrospective) performed multiple regression to identify predictor variables. The remaining three studies (one prospective and two retrospective) used stratification or alternative statistical comparisons.

Table 331. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Bankes and Jessop1998 [553]	No	Not described
Seegenschmiedt 1998 [628]	No	Multiple regression
Kurvers 1995 [556]	No	Multiple regression
Newey and Pattterson1994 [558]	No	Stratification
Verhaar 1993 [559]	Yes	chi-square test for linear trends
Stratford 1989 [621]	Yes	Multiple regression
Gerberich 1985 [629]	Yes	Multiple logistic regression

Results

The treatments and outcomes used in studies that performed a multiple regression are shown inTable 332. Two studies using ultrasound therapy found no statistically significant correlation between duration of symptoms before treatment and response to treatment with ultrasound. One surgical trial also found no statistically significant correlation between duration of symptoms and treatment outcome. The remaining trial was the largest trial and the only trial using radiotherapy, and this trial found a significant correlation between shorter duration of symptoms and a better treatment outcome.

Three studies used stratification or statistical techniques that did not control for the effects of other predictor variables (Table 333) All three studies evaluated surgical treatments. Two studies (one prospective, one retrospective) reported no statistically significant correlation between duration of symptoms and success of surgical treatment, while one retrospective study reported a significant correlation between shorter duration of symptoms and a better treatment outcome.

Table 332. Relationship between duration of symptoms and treatment outcomes among patients with Epicondylitis (multiple regression analysis)

Author/year	N	Treatment	Outcomes	Mean duration of symptoms (range)	Statistical significance (duration associated with better outcome)	Other variables examined
Seegenschmiedt and Keilholz 1998 [628]	104 (LE and ME)	Radiotherapy	Global outcome (Response to treatment)	15 months (6-86 months)	Sig (shorter duration - <12 months)	Immobilization in plaster (sig), other variables not reported
Kurvers et al. 1995 [556]	38 (ME)	Surgery	Global outcome (level of symptoms)	12 months (6-30 months)	NS	Age, gender, timing of symptom onset, comorbid conditions, hobbies
Stratford et al. 1989 [621]	40 (LE)	Ultrasound	Global outcome (success/failure)	NR	NS	Age, gender, compliance, grip strength, site of pain
Gerberich et al. 1985 [629]	82 (LE)	Ultrasound	Global outcome (improvement)	9.8 months	NS	Age, gender, severity of pain, degree of functional limitations, use of hydrocortisone cream, number of treatments

LE – Lateral epicondylitis
ME – Medial epicondylitis
NS – Not signficant

Table 333. The relationship between duration of symptoms and treatment outcomes among patients with Epicondylitis (stratification or univariate statistical comparisons)

Author/ year	N	Treatment	Outcomes	Mean duration of symptoms (range)	Statistical significance (duration associated with better outcome)
Bankes and Jessop 1998 [553]	20	Surgery	Global outcome (patient improvement)	32.2 (11-126)	NS
Newey and Pattterson 1994 [558]	27	Surgery	Global outcome (pain relief)	32.5 (8-108)	Sig (shorter duration)
Verhaar 1993 [559]	57	Surgery	Global outcome (patient satisfaction)	NR	NS

LE – Lateral epicondylitis
ME – Medial epicondylitis
NS – Not signficant

Conclusions

Seven studies examined whether duration of symptoms correlated with treatment outcomes. These studies employed three different treatments, so this correlation might be altered if these treatments have differential success rates. Only one of the four studies that employed multiple regression found a statistically significant relationship between symptom duration and outcomes, and this study was retrospective. One of three studies that stratified patients according to their duration of symptoms found a statistically significant correlation with treatment outcomes. This study was also retrospective. Consequently, although there is some evidence to suggest a relationship, it is contradictory and not strong. Two prospective studies that employed multiple regression did not find such a relationship. Both were of patients who had received ultrasound. These latter data seem to suggest that there is not a strong correlation between symptom duration and treatment outcome. However, currently available evidence about use of ultrasound in patients with epicondylitis or de Quervain's disease does not allow firm evidence-base conclusions, and the effectiveness of ultrasound for carpal tunnel is suspect. Thus, lack of treatment effectiveness could obscure potential relationships between symptom duration and treatment-related outcomes. Therefore, one cannot draw firm evidence-based conclusions from currently available data.

Question #6. Is there a relationship between patient characteristics and specific treatment outcomes among patients with epicondylitis?

In addressing this question, we consider whether published literature suggests that there are demographic variables that predict positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment demographic characteristics.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 334.

Table 334. Excluded studies

Author	Reason for exclusion
Seegenschmiedt et al. 1998 [628]	Study did not report whether demographic variables were included in the multiple regression analysis
O'Neil 1980 [567]	Stratified study that conducted a demographic variable/outcome comparison not performed by any other study

Evidence base

After these exclusions, there remained six studies with 277 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4 for carpal tunnel syndrome. Table 335 shows the studies that met the inclusion criteria for this question. Three studies (two prospective and one retrospective) performed multiple regression to identify predictor variables. The remaining three studies (one prospective and two retrospective) performed stratification or alternative statistical comparisons.

Table 335. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Gabel and Morrey1995 [555]	No	Statistical analysis (method not described)
Kurvers 1995 [556]	No	Multiple regression
Newey and Pattterson1994 [558]	No	Stratification
Verhaar 1993 [559]	Yes	chi-square test for linear trends
Stratford 1989 [621]	Yes	Multiple regression
Gerberich 1985 [629]	Yes	Multiple logistic regression

Results

Three studies that addressed this question performed multiple regression to identify predictor variables (Table 336). Two of the studies treated patients with ultrasound and one used surgical treatment. None of the three studies found a statistically significant correlation between age and outcome, or gender and outcome. One study reported that there was no statistically significant correlation between patients with hobbies involving knitting or needlework and outcomes. The only study that examined co-morbidities reported that patients with coexistent ulnar neuritis had a poorer outcome after surgery than did patients without ulnar neuritis.

Three other studies performed stratification or statistical comparisons that did not control for the effects of other predictor variables (Table 337). All studies evaluated surgical treatments. Age was the only relevant variable reported by all of these studies, and none found a statistically significant correlation between age and treatment outcome.

Table 336. Relationship between patient characteristics and treatment outcomes among patients with Epicondylitis (multiple regression analysis)

Author/ year	N	Treatment	Outcomes	Variables used in multiple regression											
				Age[a]	**Gender**	**Hobbies**	**Comorbidity (ulnar neuritis)**	Duration of symptoms	Functional limitations	Site of pain	Severity of pain	Grip strength	Timing of onset (acute or gradual)	Compliance with rest	Use of hydrocortisone cream	Number of treatments
Kurvers et al. 1995 [556]	38 (ME)	Surgery	Global outcome (response to treatment)	NS	NS	NS	Sig	–	–	–	–	–	NS	–	–	–
Stratford et al. 1989 [621]	40 (LE)	Ultrasound	Global outcome (success/failure)	NS	NS	–	–	NS	–	Sig	–	NS	–	NS	–	–
Gerberich et al. 1985 [629]	82 (LE)	Ultrasound	Global outcome (improvement)	NS	NS	–	–	NS	NS	–	Sig	–	–	–	NS	Sig (males) NS (females)

LE – Lateral epicondylitis
ME – Medial epicondylitis
NS – Not significant

[a]Variable in boldface indicate patient characteristics

Table 337. The relationship between duration of symptoms and treatment outcomes among patients with Epicondylitis (stratification or univariate statistical comparisons)

Author/year	N	Treatment	Outcome	Age
Gabel and Morrey1995 [555]	26 (LE)	Surgery	Global outcome (Excellent to poor)	NS
Newey and Patterson1994 [558]	28 (LE)	Surgery	Global outcome (Pain relief)	NS
Verhaar 1993 [559]	63 (LE)	Surgery	Global outcome (Level of satisfaction)	NS

LE – Lateral epicondylitis
NS – Not significant

Conclusions

Six studies reported data that addressed this question. Three of them used multiple regression to identify predictor variables. All three studies found no statistically significant correlation between gender or age and response to treatment. One study found no such correlation between certain hobbies and response to treatment. The only study that examined co-morbidities reported that patients with co-existant ulnar neuropathy had significantly poorer outcomes than patients without ulnar neuropathy. However, it is difficult to reach evidence-based conclusions from the results of a single study.

Question #7: What are the surgical and nonsurgical costs or charges for treatment of epicondylitis?

According to Medicare Provider Analysis and Review (MEDPAR), average total charges per patient for the DRG (diagnosis-related group) of major shoulder/elbow procedures with comorbidities or complications are $9,008.94 (calculated by dividing total charges by number of discharges). For the DRG shoulder, elbow or forearm procedures, except major joint procedures, without comorbidities or complications, average total charges per patient are $7729.16. The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for strapping of the elbow or wrist is $62.61 (cost of open release was not reported by this database).

Question #8. For persons who have had surgery to treat epicondylitis, what are the appropriate methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

This question distinguishes between symptom recurrence and continued symptoms after failed treatment. Rates of recurrence, possible reasons for recurrence, and recommended strategies to avoid recurrence have not been addressed by the available literature. In the absence of controlled trials, no analysis may be performed and no conclusions may be drawn

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with epicondylitis?

We address this question in the same manner that we addressed Question 9, Carpal Tunnel Syndrome. The reader is referred to that section of this evidence report for detail. Briefly, we define an instrument that can accurately assess functional limitations in an individual with epicondylitis as one that has test-retest reliability, internal reliability, content validity, concurrent validity, predictive validity, and responds to treatment.

Evidence base

Three studies with a total of 122 patients met the inclusion criteria (see the section Inclusion Criteria). These studies are listed in Table 338. The functional assessment instruments evaluated by them are listed in Table 339.

Table 338. Trials of functional assessment instruments that met the inclusion criteria

Study	Instruments evaluated[a]	N subjects	Outcome measurements
Overend 1999 [315]	PRFEQ	50	Validity Test-retest reliability
Stratford 1993 [630]	F-VAS	40	Validity Response to treatment
Stratford 1987 [631]	F-VAS	32	Validity Response to treatment Test-retest reliability

a The full names of the instruments and descriptions of the instruments are given in Table 339.

Table 339. Instruments evaluated to measure functional limitations associated with epicondylitis

Instrument	Abbreviation	First described by	Scoring system	Subjects covered	Extent of use[a]
Patient-rated forearm evaluation questionnaire	PREFQ	Overend 1999 [632]	Functional categories	Common activities of daily living	Not widely used
Functional visual analog scale	F-VAS	Stratford 1987 [631]	VAS	Not described	Not widely used

a a search of Medline for the assessment instrument found that there were fewer than 3 studies reporting the use of each of the instruments

Study quality

Internal validity

Studies evaluating instruments need not include a separate control group, because each patient acts as his/her own control. All of the studies included in this section are single-arm prospective cohort studies. Factors relating to the quality of the studies are shown in Table 340. None of the studies administered and scored the instruments with evaluators who were blinded to the identity, history, and other test scores of the patients. Studies that did not use blinded evaluators may be subject to bias.

Table 340. Details of study design

Study	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Overend 1999 [632]	50	1	No	Cohort	Yes	No	6	No	NA
Stratford 1993 [630]	40	1	NR	Cohort	Yes	No	0	Yes	NA
Stratford 1987 [631]	32	1	No	Cohort	Yes	No	0	Yes	NA

NA = not applicable

Generalizability

An important factor in evaluating assessment instruments is the patient group. In order to accurately evaluate the instrument, it is important that the test group be similar to the patients that the instrument will be used to evaluate in clinical practice. Details of the patient groups are shown in Table 341. The mean ages and gender composition of the patient groups are similar to that reported in epidemiology studies of epicondylitis (see the Introduction). None of the studies reported on the presence of co-morbid conditions that may have contributed to functional limitations. None of the studies reported any information as to the occupations or employment status of the patients.

Table 341.Study generalizability: patient characteristics

Study	Number of patients	Mean age and range	% female	Duration of conditon mean and range months	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditons	% Patients with peripheral neruopathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Overend 1999 [632]	50	45	48.9	NR	NR	NR	NR	NR	NR	NR	NR	No	No
Stratford 1993 [630]	40	43	50	4.2	NR	NR	NR	0	NR	NR	NR	No	No
Stratford 1987 [631]	32	44.9 (32-61)	NR	3.7 (0-12)	NR	NR	NR	NR	NR	NR	NR	No	No

NR = not reported

Results

Test-retest reliability

Both instruments (F-VAS and PRFEQ) are reported to give consistent results when administered to the same subjects on different days (Table 342).

Table 342. Results of test-retest reliability tests

Study	Number of patients	Tests evaluated	Time between test administrations	Type of statistical comparison being made	Was the instrument reliable?
Overend 1999 [632]	50	PRFEQ	NR	Correlation coefficient r = 0.89	Yes
Stratford 1987 [631]	32	F-VAS	4 days	Correlation coefficient r = 0.85	Yes

NR = not reported

Internal reliability

None of the included studies reported data relevant to this aspect of instrument evaluation.

Content validity

None of the included studies reported data that addressed this aspect of validity.

Response to treatment

Stratford reported that scores on the F-VAS increase as patients are successfully treated for epicondylitis (Table 343).

Table 343. Results of response to treatment tests

Study	Number of patients	Test evaluated	Treatment	Time of testing months	Effect size Hedges' d (95% CI)[a]	Was the instrument responsive to treatment?
Stratford 1993 [630]	40	F-VAS	Not reported	1	0.97 (0.22 to 1.72)	Yes
Stratford 1987 [631]	32	F-VAS	Ultrasound	1.5	1.60 (1.04 to 2.16)	Yes

a calculated by ECRI

Concurrent validity

All three trials compared the scores on the assessment instruments to pain-free hand grip strength, as is shown in Table 344. A moderate correlationm ($r = 0.36$) between hand grip strength and the results of the PRFEQ was reported. Stratford 1993 and Stratford 1987 reported the scores on the F-VAS correlated well with hand grip strength.

The instruments were not validated against any other measurements of hand/arm function.

Table 344. Results of validity tests

Study	Number of patients	Test evaluated	Type of statistical comparison being made	Validated against	Was the instrument valid by this measurement ?
Overend 1999 [632]	50	PRFEQ	Intraclass correlation coefficient r = -0.36	Hand grip strength	Yes, but r is low
Stratford 1993 [630]	40	F-VAS	Interclass correlation coefficient r = 0.53	Hand grip strength	Yes
Stratford 1987 [631]	32	F-VAS	Interclass correlation coefficient r = 0.66	Hand grip strength	Yes

Predictive validity

None of the included studies reported data relevant to this aspect of instrument evaluation.

Conclusion

Three studies evaluated two different instruments as ways to measure functional limitations of patients with epicondylitis. The results of the studies are summarized in Table 345. Neither assessment instrument was shown to be a useful instrument for evaluating functional limitations in persons with epicondylitis. However, it is difficult to reach firm evidence-based conclusions about the instruments evaluated in this report due to the limited evidence base.

Table 345. Utility of assessment instruments for evaluating functional limitations associated with epicondylitis

Instrument	Is the instrument			Strength of Evidence
	Valid?	Responsive to treatment?	Reliable?	
Patient-rated forearm evaluation questionnaire	No	NR	Yes	One study of 50 patients
Functional visual analog scale	Yes	Yes	Yes	Two studies of 72 patients by the same group

NR = not reported

Question #10: What are the functional limitations for an individual with epicondylitis before treatment?

This question addresses the functional limitations of individuals before receiving conservative or surgical treatment for epicondylitis. Our objective is to catalogue these limitations, and not to address the effectiveness of these treatments. We address the effectiveness of conservative and surgical treatments in Question 3.
The available literature governs our approach to the present question. Hence, we consider functional status rather than functional limitations, because no published studies specifically addressed the latter. In addition, the only available data operationally defines functional status in terms of scores on certain written tests. Therefore, we also address functional status in these terms. The validity and reliability of these written tests is discussed in Question 9. Study inclusion criteria are described under Methods.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 346.

Table 346. Excluded studies

Author	Reason for exclusion
Pienimaki and Vanharanta 1998 [544]	Study reported that patients received prior treatment

Evidence base

Two studies (with a total of 82 patients) remained that addressed this question after the above exclusion.

Internal validity

Aspects of study quality that are most relevant to the present question are shown in Table 347. Because we are cataloging functional status rather than using it to determine treatment effectiveness, randomization and the use of control groups are not of paramount importance here. Therefore, Table 347 does not depict these aspects of study design. However, the following variables are important: attrition rates, whether the trial was prospective, and whether the raters of functional status (in this case the patients) were blinded to the treatment the patient received. Attrition was low (6%) or non-existent in the two included studies. Both were unblinded prospective case series. Because it is difficult to blind patients to the treatment received, we are considering unblinded studies to be of acceptable quality for this question.

Table 347. Study quality

Author	Number of patients	Number of centers	Funded by a for-profit agency?	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Overend 1999 [632]	50	1	No	Yes	No	6	No	NA
Stratford 1987 [631]	32	1	No	Yes	No	0	Yes	NA

NA – Not applicable

Generalizability

Selected patient characteristics are presented in Table 348. Both studies reported mean age of patients and percent female, one study reported duration of symptoms, and no studies reported comorbidities or severity of disease. Mean age and percent female patients were consistent with the numbers reported by epidemiologic studies (see Introduction section, epicondylitis, subheading epidemiology).

No study reported information concerning patient employment or occupation (Table 349). Therefore, one cannot determine the generalizability of these studies in terms of occupational variables.

Table 348. Patient characteristics

Author	Number of patients	Mean age (range)	% female	Duration of condition (range)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe	Did the study exclude patients with mild
Overend 1999 [632]	50	45	48.9	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Stratford 1987 [631]	32	44.9 (32-61)	50	Mean: 111 days (3-364)	NR	NR	NR	NR	NR	NR	NR	NR	NR

NR – Not reported

Table 349. Patient occupation

Author	Year	ID#	Number of patients	% Patients employed	% Patients on Workers Compensation	% Patients retired	% Patients homemakers	Reported Occupations
Overend	1999	[632]	50	NR	NR	NR	NR	NR
Stratford	1987	[631]	32	NR	NR	NR	NR	NR

NR – Not reported

Results

Table 350 shows the results of the two studies that addressed this question. Overend (1999) excluded patients with prior surgery or elbow injection (within the last 30 days), but there is still uncertainty about whether some patients received prior treatment.[632] Stratford (1987) did not report whether patients had received prior treatment. Both studies used different functional status scales, so their results are not directly comparable. They found similar mean or median values in their pre-treatment study groups (between 30-40% of the maximum score).

Table 350. Studies with pre-treatment functional limitation data for patients with lateral epicondylitis

Study	N	Study Design	Stratified subgroups	n	Scale	Overall mean pre-treatment functional status score (SD)	% of maximum score
Overend (1999) [632]	50	Stratified case series	Male Female	24 23	PRFEQ (0-10 scale)	2.8 (1.9) 4.1 (2.1) p = 0.033[a]	28 41
			Subacute LE Chronic LE	35 12		3.6 (2.0) 3.1 (2.2) p = 0.475[a]	36 31
			Work-related LE Non-work-related LE	21 26		4.2 (2.3) 2.8 (1.7) p = 0.022[a]	42 28
			Total group	47		3.4 (2.1)	34
Stratford (1987) [631]	32	Prospective case series	NA	NA	PFF (0-8)	Median: 3	37.5

[a]Calculated by ECRI
PFF – Pain-Free Function Index
PRFEQ – Patient Rated Forearm Evaluation Scale

Conclusions

This question is addressed by only two studies comprised of a total of 82 patients. Although these studies suggest that the functional difficulties experienced by patients with epicondylitis are increased by 30% to 40%, the low number of studies and patients makes it difficult to arrive at an evidence-based answer to this question.

Question #11: What are the functional limitations of an individual with epicondylitis after treatment?

This question considers the functional limitations of an individual after they have received conservative or surgical treatment for epicondylitis. In addressing it, our objective is to catalogue these limitations, and not to address the effectiveness of these treatments. We address the effectiveness of conservative and surgical treatments in Question 3.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, one of the retrieved studies did not meet our more specific inclusion criteria for this question. This study, and the reason we did not consider it for this question is shown in Table 351.

Table 351. Excluded studies

Author	Reason for exclusion
Stratford et al., 1987[631]	Study reports median value for successes and failures but does not report the number or percentage of successes and failures.

Evidence base

After this exclusion, there were no studies that met the general or question-specific inclusion criteria.

Conclusion

There were no studies that met the inclusion criteria for this question. Therefore, it cannot be answered in an evidence-based fashion.

Chapter. 3 DeQuervain's Disease (continued)

Question #1: What are the appropriate methods and approaches for the early identification and diagnosis of de Quervain's disease?

Inclusion Criteria

We included articles for this question if they reported data that could be used for evaluation of the test in diagnosing de Quervain's disease, and they included ten or more patients.

Evidence Base

We found no diagnostic studies that met the inclusion criteria.

Results

Three review articles stated that diagnosis of de Quervain's disease is made by the Finkelstein's test.[53,85,87] In this test, the patient makes a fist around the thumb, and the examiner deviates the wrist in an ulnar direction (away from the base of the thumb). If the patient experiences intense pain on the radial side of the wrist, the test is positive. All included treatment studies of de Quervain's disease (see question 3, below) listed Finkelstein's test among the inclusion criteria.[88,633-635] This suggests that Finkelstein's test is routinely used in diagnosis of this condition.

Conclusion

There is no published evidence by which one can assess the effectiveness of any test for DeQuervain's disease. Therefore it is not possible to reach evidence-based conclusions about these tests.

Question #2: What Are The Specific Indications For Surgery For de Quervain's Disease?

Published evidence does not directly address the specific indications for surgery for de Quervain's disease. Therefore, we describe the reported characteristics of patients who have received surgery for de Quervain's disease in published studies. The extent to which these patients represent typical surgical candidates is unclear. Patients included in published studies of a procedure are frequently a subset of patients who are candidates for that procedure. They may represent an unusual group of interest, or an optimized group most likely to benefit from the procedure. Therefore, the data presented here, while informative, may not accurately reflect the overall patient population. They do, however, represent the best data available, and is the most comprehensive compilation of de Quervain's disease patient characteristics compiled to date.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, one of the retrieved studies did not meet our more specific inclusion criteria for this question. This study, and the reason we did not consider it for this question are shown in
Table 352.

Table 352. Excluded studies

Author and year	Reason for exclusion
Kay 2000[86]	Demographic information not reported separately for surgical and non-surgical patients

Evidence base

Three studies with a total of 160 patients contained information relevant to this question for patients with de Quervain's disease. Table 353 shows selected patient characteristics and reported surgical indications. Information not reported by these studies included race, extent of disease, pregnancy, menopause, oral contraceptive use, alcohol use, smoking status, whether patients were overweight, workers' compensation status, and whether the patient retained a lawyer.

Table 353. Specific indications for surgery for de Quervain's disease

Author/year	N	Mean age (range)	% female	Study design	Signs and symptoms	Occupations (n)	Specific indications for surgery
Ta et al. (1999) [88]	43	48 (24-73)	79.1	Retrospective stratified case series	Pain over radial aspect of wrist aggravated by excessive use of thumb, a positive Finkelstein test	Packer (10), domestic (9), secretary (7), machine operator (6), computer engineer (3), teacher (2), hospital orderly (2), salesperson (2), carpenter (1), and business executive (1)	Specific indications not reported
Witt et al. (1991) [633]	95	44 (16-75)	77	Prospective stratified case series	Pain radiating from radial styloid process to thumb and forearm, increased pain on passive movement of thumb and wrist, swelling and tenderness over first dorsal compartment, and positive result on Finkelstein testing	Housekeeping (26), Secretarial and clerical work (17), light manual labor (16), managerial or professional work (16), strenuous manual labor (4), music (2), education (2)	Failure of non-operative treatment
Yuasa et al. (1998) [634]	22	47 (21-67)	95.5	Retrospective case series	Radial wrist pain, tenderness over first extensor compartment, and positive Finkelstein's test results	NR	Failure of non-operative treatment

NR – Not reported

Conclusions

Two of the three studies that addressed this question reported that surgery was performed only on patients who did not benefit from conservative (non-operative) treatment.[633,634] However, with so few studies and so many unreported patient characteristics, one cannot assume that the present data are representative of the larger patient population with de Quervain's disease.

Question #3: What are the relative benefits and harms of various surgical and nonsurgical interventions for persons with de Quervain's disease?

For this question, we included any controlled trials (even retrospective) as long as at least two groups (treated or otherwise) were comparable. Study inclusion criteria for this question are listed under Methods (section).

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, not all of the retrieved studies met our more specific inclusion criteria for this question. These latter studies, and the reason we did not consider them for this question are shown in Table 354.

Table 354. Excluded studies

Author	Reason for exclusion
Kay 2000 [86]	Uncontrolled study
Ta et al. 1999 [88]	Uncontrolled study
Yuasa et al. 1998 [634]	Uncontrolled study
Witt et al. 1991 [633]	Uncontrolled study

Evidence base

After these exclusions, one trial describing 87 patients remained.

Internal validity

The criteria used to evaluate study quality were identical to those described for Question 3 under carpal tunnel syndrome. Table 355 shows the internal validity of the only study that met the inclusion criteria. Because this study was non-randomized, retrospective and unblinded, it is particularly susceptible to bias. The extent of such bias, if any, and its impact on interpretation of the results, can not be determined.

Table 355. Study quality

Author	Number of patients	Number of centers	Funded by a for-profit agency?	Study design	Prospective	Blinding	% Attrition	Intent to treat analysis	% Compliance
Weiss 1994 [635]	87	1	No	Non-randomized controlled trial	No	No	0	Yes	NR

NR – Not reported

Generalizability

Selected patient characteristics are presented in Table 356. Because there were so few studies (even counting excluded studies) evaluating treatment of de Quervain's disease, the generalizability of the study by Weiss et al. to the larger patient population cannot be determined. However, the study appears to be consistent with the epidemiological information reported in review articles of de Quervain's disease (see Introduction, de Quervain's disease, subheading epidemiology).

Weiss et al. presented little specific information related to occupation (Table 357), but as already noted, there are too few studies to determine the generalizability of this study to the larger patient population.

Table 356. Patient characteristics

Author	Number of patients	Mean age (range)	% female	Duration of condition mean and range (months)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Weiss 1994 [635]	87	38 (17-72)	85.1	7 (0.25-36)	5.7	1.1	10.3	5.7	0	1.1	0	NR	NR

Table 357. Patient occupation

Author	Number of patients	% Patients employed	% Patients on Workers Compensation	% Patients retired	% Patients homemakers	Reported Occupations
Weiss 1994 [635]	87	NR	39.1	NR	NR	Heavy manual labor, lightlabor, keyboard or typing activities

Results

Weiss et al. found a statistically significant increase in the number of treatment successes after corticosteroid plus lidocaine (CS) injection compared to immobilization splints or splints plus injection (Table 358 and Table 359). Treatment successes were defined as patients with no or minimal symptoms who did not subsequently require surgery.

Table 358. Results of global assessment

Study	Number of wrists[a]	Global assessment patient-reported categories	Statistical significance of difference between groups
Weiss 1994 [635]	42 CS injection 37 immobilization splint 14 CS injection plus immobilization splint	29 successes, 13 failures 11 successes, 26 failures 8 successes, 6 failures	Fisher's exact test P <0.001

aResults were reported based on number of wrists, rather than patients, that received treatment.
CS – Corticosteroid plus lidocaine

Table 359. Success of nonsurgical treatments for de Quervain's disease

Study	Number of wrists[a]	Length of followup (months)	Which treatment was more successful?	Was the difference statistically significant?	Effect size Hedges' d (95% CI)
Weiss 1994 [635]	42 CS injection 37 immobilization splint 14 CS injection plus immobilization splint	Mean (range)[b] 13 (6-14)	CS injection	Yes	Injection vs splint: 0.91 (0.38 to1.44) Injection plus splint vs splint: 0.62 (-0.08 to 1.32)

aResults were reported based on number of wrists, rather than patients, that received treatment
bLength of followup only reported for patients who did not undergo eventual surgery (treatment successes)
CS – Corticosteroid plus lidocaine

Conclusions

Although one study found that corticosteroid plus lidocaine injection produced more treatment successes than immobilization splints among de Quervain's patients, there were design problems with this study. Because of these problems and the fact that only one study addressed this question, it is difficult to reach firm evidence-based conclusions

concerning the effectiveness of any treatment for de Quervain's disease. However, lack of evidence of an effect does not constitute evidence of lack of effect.

Question #4: Is there a relationship between specific clinical findings and specific treatment outcomes among patients with de Quervain's disease?

In addressing this question, we consider whether published literature suggests that there are clinical findings that predict positive or negative outcomes after treatment for de Quervain's disease. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment clinical findings.

Excluded studies

We did not exclude any study that addressed this question.

Evidence base

Evidence that addresses this question is derived from one study of 43 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4 under carpal tunnel syndrome. One retrospective study (Ta et al., 1999) addressed this question for patients with de Quervain's disease (Table 360).[88] Of 43 patients who received surgery, 31 had a septated first dorsal compartment. The authors attempted to identify predictor variables by performing a multiple logistic regression with descending stepwise variable selection.

Table 360. Study quality

Author	Prospective?	Methods used to identify predictor variables
Ta et al. (1999) [88]	No	Multiple logistic regression

Results

The results of the only study that addressed this question are shown in Table 361. Odds ratios for non-septated and septated patients were not significantly different for a global outcome (patient satisfaction) or complications.

Table 361. Relationship between clinical findings and treatment outcomes

Author	Treatment	Variables examined	Comparison groups	Outcomes	Results
Ta et al. (1999) [88]	Surgery (n = 43)	Age, gender, steroid treatment, septation, duration of symptoms, occupational status	Septation No (12) Yes (31)	Global outcome (patient satisfaction -yes/no) Complications (yes/no)	Odds Ratio (95% CI) 1.0 (referent) 0.53 (0.07-3.68) p = 0.61 1.0 (referent) 1.25 (0.79-9.66) p = 1.00

Conclusions

This question was addressed by only one relatively small retrospective study. This precludes a firm evidence-based answer to this question.

Question #5: Is there a relationship between duration of symptoms and specific treatment outcomes among patients with de Quervain's disease?

In addressing this question, we consider whether published literature suggests that duration of symptoms predicts positive or negative outcomes after treatment for de Quervain's disease. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different duration of symptoms.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, one study did not meet our more specific inclusion criteria for this question. This study, and the reason we did not consider it for this question are shown in Table 362.

Table 362. Excluded Studies

Author	Reason for exclusion
Witt et al. (1991) [633]	Stratified study with no duration of symptoms stratifications/outcome comparisons reported by other studies

Evidence base

After the above exclusion, there remained one study with 43 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4 under carpal tunnel syndrome. Only one study addressed this question for patients with de Quervain's disease (Table 363). Ta et al. (1999) conducted a retrospective study that attempted to identify predictor variables with a multiple logistic regression in descending stepwise order.

Table 363. Study quality

Author/year	Prospective?	Methods used to identify predictor variables
Ta et al. (1999) [88]	No	Multiple logistic regression

Results

Table 364 shows the results of the study by Ta et al. Patients with a longer duration of symptoms were more likely to experience satisfaction after surgery.[88]

Table 364. Relationship between duration of symptoms and treatment outcomes among patients with de Quervain's disease

Author/ year	Treatment(s)	Variables examined	Comparison groups	Outcomes	Results
Ta et al. (1999) [88]	Surgery (n = 43)	Age, gender, steroid treatment, septation, duration of symptoms, occupational status	Duration of symptoms 1-3 months (n = 2) 4-6 months (n = 8) 7-9 months (n = 14) 10-12 months (n = 2) 13-15 months (n = 16) >15 months (n = 1)	Global outcome (patient satisfaction - yes/no)	Odds Ratio (95% CI) 1.0 (referent) 1.21 (0.75-2.36) 1.16 (0.91-2.03) 1.42 (1.12-2.78) 1.74 (1.08-2.24) 1.62 (1.04-3.12) p = 0.034
				Complications (yes/no)	1.0 (referent) 0.82 (0.54-1.71) 1.15 (0.72-1.86) 1.79 (0.46-2.53) 1.21 (0.63-1.85) 1.72 (0.89-2.65) p = 0.24

Conclusions

This question was addressed by only one relatively small retrospective study. This precludes a firm evidence-based answer to this question.

Question #6: Is there a relationship between factors such as patients' age, gender, socioeconomic status and/or racial or ethnic grouping and specific treatment outcomes among patients with de Quervains's disease?

In addressing this question, we consider whether published literature suggests that there are demographic variables that predict positive or negative outcomes after treatment for carpal tunnel syndrome. The studies we considered all attempted to identify predictors by using regression techniques or by comparing outcomes in different groups of patients with different pre-treatment demographic characteristics.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. However, one of the retrieved studies did not meet our more specific inclusion criteria for this question. This study, and the reason we did not consider it for this question are shown in Table 365.

Table 365. Excluded studies

Author	Reason for exclusion
Witt et al. (1991) [633]	Stratified study with no demographic variable stratifications/outcome comparisons reported by other studies

Evidence base

After the above exclusion, there remained one study with 43 patients.

Study quality

The criteria used to evaluate study quality were identical to those described for Question 4. One study addressed this question for patients with de Quervain's disease (Table 366). Ta et al. (1999) conducted a retrospective study that attempted to identify predictor variables with a multiple logistic regression in descending stepwise order.

Table 366. Study quality

Author/year	Prospective?	Methods used to minimize differences between stratified groups	Is the stratification confounded?
Ta et al. (1999) [88]	No	Multiple logistic regression	No

Results

Table 367 shows the results of the study by Ta et al. They found that there was no statistically significant relationship between occupational status, age, or gender and patient satisfaction or complications.[88]

Table 367. Relationship between patient demographics and treatment outcomes

Author	Treatment(s)	Variables examined	Comparison groups	Outcomes	Results
Ta et al. (1999) [88]	Surgery (n = 43)	Age, gender, steroid treatment, septation, duration of symptoms, occupational status	Occupational status Unemployed (n = 12) Employed (n = 31)	Global outcome (patient satisfaction -yes/no) Complications (yes/no)	Odds Ratio (95% CI) 1.0 (referent) 3.60 (0.36-5.26) p = 0.36 1.0 (referent) 0.32 (0.12-3.78) p = 0.62
			Age (years) 21-30 (n = 3) 31-40 (n = 9) 41-50 (n = 14) 51-60 (n = 9) >60 (n = 8)	Global outcome (patient satisfaction-yes/no) Complications (yes/no)	Odds Ratio (95% CI) 0.92 (0.57-1.36) 0.80 (0.43-1.21) 1.06 (0.82-1.16) 1.02 (0.64-1.47) (referent) p = 0.16 1.06 (0.76-1.53) 0.72 (0.52-1.27) 0.94 (0.85-1.33) 0.88 (0.72-1.10) p = 0.41
			Gender Female (n = 34) Male (n = 9)	Global outcome (patient satisfaction-yes/no) Complications (yes/no)	Odds Ratio (95% CI) (referent) 0.40 (0.11-1.42) p = 0.54 (referent) 4.15 (0.54-35.10) p = 0.16

Conclusions

This question was addressed by only one relatively small retrospective study. This precludes a firm evidence-based answer to this question.

Question #7: What are the surgical and nonsurgical costs or charges for treatment of de Quervain's disease?

According to the Medicare Provider Analysis and Review (MEDPAR) database, which covers hospital inpatient services, average total charges per patient for the DRG (diagnosis-related group) of hand or wrist procedures (excepting major joint procedures) without complications or comorbidities are $7,408.14 (calculated by dividing total charges by number of discharges). The Median Costs for Hospital Outpatient Services Dataset contains median costs for services that are reimbursed under Medicare for the hospital outpatient prospective payment system. The reported median cost for application of a short arm static splint is $72.69.

Question #8: For persons who have had surgery for de Quervain's disease, what are the most effective methods for preventing the recurrence of symptoms, and how does this vary depending on subject characteristics or other underlying health problems?

There were no published studies that addressed this question.

Question #9: What instruments, if any, can accurately assess functional limitations in an individual with de Quervain's disease?

There were no published studies that addressed this question.

Question #10: What are the functional limitations for an individual with de Quervain's disease before treatment?

There were no published studies that addressed this question.

Question #11: What are the functional limitations of an individual with de Quervain's disease after treatment?

There were no published studies that addressed this question.

Chapter 3. Results (continued)

Non-Treatment-Specific Questions

Question#12. What are the cumulative effects on functional abilities among individuals with more than one worker-related musculoskeletal disorder of the upper extremity in the same limb?

In this question, we address studies of patients with more than one worker-related, upper extremity musculoskeletal disorder in the same limb, including patients reported to suffer from "double crush" syndrome. We acknowledge that the existence of "double crush" syndrome is controversial.[14,636-638] However, we include it because these patients are experiencing symptoms, and it is important to determine whether these symptoms can be relieved.

Excluded studies

As discussed in the Methods section, we retrieved articles identified by our literature searches according to certain *a priori* criteria. Of the 23 publications that were retrieved as possibly addressing this question, none met our criteria for inclusion (Table 368). Twenty-one studies were excluded for not containing functional ability data. The remaining two reported information indirectly related to functional abilities, but neither measured functional abilities using validated functional status scales or attempted to determine a patient's ability to perform individual functional activities.[639,640] One of these studies evaluated outcomes such as grip strength, pinch strength, and range of motion,[639] while the other study reported the number of patients with grip weakness or pinch weakness.[640] None of these outcomes is a direct measure of the ability of patients to perform daily or work-related activities.

Table 368. Excluded studies reporting patients with more than one work-related musculoskeletal disorder of the upper extremity in the same limb.

Study	Reason for exclusion
Bursell 1999 [641]	No functional activity outcomes
Chung 1999 [642]	No functional activity outcomes
Richardson 1999 [638]	No functional activity outcomes
Baba 1998 [643]	No functional activity outcomes
Morgan 1998 [644]	No functional activity outcomes
Chaudhry 1997 [637]	No functional activity outcomes
Guzel 1997 [645]	No functional activity outcomes
Moore 1996 [646]	No functional activity outcomes
Golovchinsky 1995 [258]	No functional activity outcomes
Lanzetta 1995 [647]	No functional activity outcomes
Nemchausky 1995 [648]	No functional activity outcomes
Sie 1992 [649]	No functional activity outcomes
Gonzalez 1991 [650]	No functional activity outcomes
Grundberg and Reagan 1991 [639]	No functional activity measures using validated functional status scales or assessing ability to perform specific functional activities.
Narakas 1990 [640]	No relevant functional activity measures
Wood 1990 [651]	No functional activity outcomes
Kerrigan 1988 [652]	No functional activity outcomes
Osterman 1988 [653]	No functional activity outcomes
Eason 1985 [654]	No functional activity outcomes
Hurst 1985 [655]	No functional activity outcomes
Bryar 1984 [656]	No functional activity outcomes
Massey 1981 [657]	No functional activity outcomes
Nissenbaum 1980 [658]	No functional activity outcomes

Evidence base

After the above exclusions, no studies remained that met the general or question-specific inclusion criteria.

Conclusions

There were no studies that met the inclusion criteria for this question. Therefore, it cannot be answered in an evidence-based fashion.

Question#13. What level of function can patients achieve in what period of time when required to change hand dominance as they are a result of injury to their dominant hand?

In this question, we address studies of patients that were forced to change hand dominance. Workers may be required to perform tasks with the non-dominant hand because of severe injury or amputation prevents the use of the dominant hand. Workers may also wish to switch tasks to the non-dominant had to give relief to the dominant hand.

Excluded studies

We did not exclude any study from consideration for this question.

Evidence base

We found two studies with a total of 89 patients that addressed the use of the non-dominant hand in work activities and the effect of training programs or learning on this transfer. The two studies differed in the type of patients they examined. Mitchell-Krever and Lacroix, 1998[659] looked at extensive skill training in patients who could not use their dominant arm, while Salazar and Knapp, 1996[660] used volunteer subjects to evaluate differences between dominant and non-dominant hands and the effect of learning.

Internal Validity

Both studies examined for this section were prospective observational studies in which issues of randomization, blinding, and compliance are not relevant (Table 369). These issues are applicable for questions comparing the outcomes of different treatments or treatment and placebo. The present question does not relate to treatment, and neither of the included studies had more than one patient group. There was no attrition for the outcomes evaluated up to two to six months of followup. However, Mitchel-Krever et al. reported an 80% loss to followup at their 1.5 to two year evaluation of outcomes.

Table 369. Internal Validity

Author	Number of patients	Number of centers	Funded by a for-profit agency?	Prospective	% Attrition	Intent to treat analysis
Mitchell-Krever and Lacroix 1998 [659]	53	1	NR	Yes	At 2-6 months: 0 At 1.5-2 years: 80	Yes
Salazar and Knapp 1996 [660]	36	1	NR	Yes	0	Yes

NR – Not reported

Generalizability

Patient ages were similar in the two studies, they fall within the typical range reported in epidemiologic studies (see Introduction section for the individual disorders), and roughly half of the patients in each study were female (Table 370). Other patient characteristics were incompletely reported.

Table 370. Generalizability

Author	Number of patients	Mean age (range)	% female	Duration of condition mean and range (months)	% Patients with diabetes	% Patients with arthritis	% Patients with prevous relevant injuries	% Patients with other relevant nerve impingement conditions	% Patients with peripheral neuropathy	% Patients pregnant	% Patients on kidney dialysis	Did the study exclude patients with severe disease?	Did the study exclude patients with mild disease?
Mitchell-Krever and Lacroix 1998 [659]	53	Range: 20-59	41.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Salazar and Knapp 1996 [660]	36	Range: 20-55	66.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NR – Not reported

Results

Both studies used measures of individual functional activities to determine level of function in non-dominant hands. The results are shown in Table 371. In the study by Mitchell-Krever and Lacroix, higher scores indicate better function. Three of the tests in this study (finger dexterity, Purdue pegboard test, and the O'Connor tweezer dexterity test) were particularly informative because the reported scores represent percentile ranking compared to the same sex dominant hand. Because Salazar and Knapp measured the time it took to perform specific tasks, lower scores indicate better functional ability in their study. Both studies showed statistically significant improvement over time in the functional ability of non-dominant hands.

Mitchell-Krever and Lacroix found that almost every task improved after their training program as assessed during a two to six month followup period. Gross motor skills, fine motor skills, combined fine and gross motor skills, writing skills, and grip strength all showed statistically significant improvement. Typing and keypadding speed also increased, but accuracy for both skills was unchanged perhaps because accuracy was already high (>95%). Age was not related to post-

test performance except for manuscript writing (no data reported) and sex had no effect on any of the pre- and post-tests except for the strength measurement where men were stronger than women (no data reported). A questionnaire was sent to participants one-and-a-half to two years following program completion to assess the long-term effects of the program. However, only 20% of the participants returned the questionnaire, and this attrition rate may be too high to allow a meaningful conclusion about the long-term outcomes of this training program. The results assessed at two to six months do not suffer from this difficulty.

Salazar and Knapp reported their results separately for men and women. Both men and women showed an increase in the dexterity test using tweezers and in the drilling task. However the bolt task and nail-driving test showed no improvement after one week. The lack of improvement in the bolt task may have been due to a ceiling effect, as the participants were already performing as fast as possible on the first day. The lack of improvement in nail-driving may have been related to the physical nature of the task and more time may be needed to learn how to use the non-dominant hand in this task.

Table 371. Results of outcomes measured in publications that reported information on changing hand dominance.

Author	Length of followup	Outcome	Pretest Mean	Pretest SD	Post-test Mean	Post-test SD
Mitchell-Krever and Lacroix, 1998[659]	Mean: 5 months (range 2-6 months)	Peg transfer [a]	53.68	10.97	87.43	11.10
		Peg turn [a]	49.53	12.21	89.06	10.63
		Rivets and washers [a]	41.85	11.76	77.30	13.66
		Finger dexterity [a]	26.11	24.43	61.97	29.74
		Purdue pegboard test [a]	13.77	17.53	42.93	26.10
		O'Connor Tweezers Dexterity test [a]	10.40	17.61	38.55	29.71
		Writing – manuscript [a]	7.27	2.68	15.42	4.95
		Writing – cursive [a]	7.44	3.26	14.82	6.05
		Typing speed [a]	8.21	4.79	17.83	8.05
		Typing accuracy	94.92	4.78	95.00	4.75
		Keypadding speed [a]	10.73	5.26	30.71	13.85
		Keypadding accuracy	95.21	9.41	96.17	3.45
		Grip strength [a]	32.57	14.36	36.97	13.68
Salazar and Knapp, 1996[660b]	One week after first test	Bolts task				
		Men	36.9	10.2	33.0	8.3
		Women	46.5	13.4	42.9	12.7
		O'Connor Tweezers Dexterity test [c]				
		Men	33.7	11.4	24.4	6.0
		Women	34.2	13.5	31.2	15.0
		Drilling task [c]				
		Men	36.4	10.9	20.0	6.8
		Women	63.1	27.9	34.4	22.1
		Nail-driving task				
		Men	15.9	5.8	15.2	4.0
		Women	58.3	35.8	48.4	28.0

a Significant improvement between pre- and post-test scores, *t*-test with P<0.001 as reported in Mitchell-Krever and Lacroix, 1998[659]

b Only data for non-preferred hand is presented

c Significant improvement between pre- and post-test scores, F-test with P<0.05 as reported in Salazar and Knapp, 1996[660]

Conclusions

The evidence presented in these two studies suggests that learning and training in the use of the non-dominant hand is possible and statistically significant improvement can be accomplished in 2 to 6 months of training. For some activities, statistically significant improvement can be accomplished within one week. However, these studies lack long-term followup data to determine how well the interventions work towards providing the patient with employment opportunities and if the improvement of the non-dominant hand is sufficient to allow resumption of normal activities.

Chapter 4. Conclusions

Carpal Tunnel Syndrome

There is a great diversity of diagnostic tests for carpal tunnel syndrome. As a result, the available evidence in support of any given test is limited, making it difficult to draw firm evidence-based conclusions. Because all of the studies of diagnostics that were included in this evidence report used healthy asymptomatic persons as controls, their results may overestimate the specificity of nerve conduction measurements in typical practice.

ECRI's meta-analyses of distal motor latency studies found the sensitivity of the test to be 57% to 66% and the specificity to be 98%. Meta-analysis of palmar sensory latency studies found a sensitivity of 76% and a specificity of 98%. No other electrodiagnostic tests provided sufficient evidence for meta-analysis to be conducted. As implied above, the estimate of specificity derived from this meta-analysis may be an overestimate.

The sensitivity of Phalen's maneuver was lower than its specificity, and two trials reported sensitivity of 80% to 90%. All of the studies of Tinel's sign found that its sensitivity was lower than its specificity, and none found a sensitivity of 75 percent or greater. There was too much heterogeneity in the results for us to conclude that one test was superior to the other, or to compare these tests to nerve conduction testing.

One well-designed study suggests that nerve conduction measurement may be able to identify some workers at risk of developing CTS in the future. By itself, this evidence is not sufficient for us to conclude that nerve conduction screening for CTS is effective, but there could be sufficient unpublished results from this study to confirm the findings of the one reported test.

Patients who have undergone surgery for carpal tunnel syndrome are predominantly middle aged and female. Because of underreporting, no firm evidence-based conclusions can be drawn regarding the signs, symptoms, neuroelectrical characteristics and comorbidities of these patients.

No controlled trials have been published testing whether surgical transection of the transverse carpal ligament is an effective treatment for carpal tunnel syndrome. However, lack of evidence for a treatment does not constitute evidence against a treatment. The existence of studies comparing the effects of different types of surgery suggests that surgery does exert an effect.

Meta-analysis of studies comparing global treatment outcome among patients receiving open and endoscopic carpal tunnel release show a small but statistically significant advantage to endoscopic release. In addition, the data show a trend toward faster return to work and to activities of daily living among patients receiving endoscopic release. The results of this analysis are suggestive rather than not definitive. This is because four of the five studies included in this were neither randomized nor blinded. Endoscopic release may have a higher complication rate as well as a higher rate of reoperation compared to open release because of incomplete transection of the transverse carpal ligament. The exact complication rates cannot be determined from presently available data. Presently available data do not allow one to reach firm

evidence-based conclusions about the relative effects of open and endoscopic surgery on function.

Meta-analysis of global outcomes demonstrates a benefit from not performing neurolysis following open carpal tunnel surgery that was not apparent from examination of the individual studies. As above, the results of this analysis are suggestive rather than definitive. This is because this analysis included studies that were neither randomized nor blinded. Available return to work data also shows a trend toward an advantage of not performing neurolysis. There is insufficient data to determine the effect of neurolysis on pain and function. The available evidence suggest there is little or no benefit from performing neurolysis along with surgical release of the carpal tunnel. The possibility remains that neurolysis may be helpful is special cases, such as in the presence of marked scarring or neural adhesion, but no available evidence specifically documents the benefits and harms of neurolysis among such patients.

Injection of steroid into the carpal tunnel yields superior global outcomes compared to no treatment, placebo or oral steroids. Carpal tunnel injection was significantly better than intramuscular injection at a one month followup time. Because no further time points were reported, we are unable to determine whether this difference persists beyond this time. There are no data available that indicate whether any type of steroid may be superior to any other, or whether any particular dose is optimum. Although the effects of steroid injection may wear off over time, there is no information indicating the expected duration of relief for the average patient, or whether any patients can expect to experience permanent relief.

Two double-blinded randomized controlled trials suggest that oral steroids may lead to a reduction in symptoms of CTS. However, the effects of oral steroids are short-lived and may not be sufficient for patient satisfaction. The effects of higher steroid doses or longer treatment regimens have not been examined in published controlled trials

A single published randomized controlled trial indicates that oral tenoxicam (an NSAID) and trichlormethiazide (a diuretic) do not reduce the symptoms of CTS under the dosing regimens described. Further trials are needed to confirm this observation, and to test the effects of additional drugs and dosing regimens.

Some forms of physical therapy may have some use in the treatment of carpal tunnel syndrome, but because of a lack of blinding and low statistical power one cannot conclude that this trend is real. A large, blinded, randomized controlled trial is necessary to confirm these results.

Other treatments were addressed only by single studies of suboptimal design, making it difficult to come to an evidence-based conclusion as to whether they are effective. These treatments include:

- Ultrasound
- Splinting after surgery
- Ligament reconstruction

- Vitamin B_6 therapy.

Although no firm evidence-based conclusion can be reached, tendencies in the available evidence do not support the use of these treatments.

There is only limited evidence of any relationship between patient characteristics and treatment outcome. The only clinical finding variable shown by more than one study to significantly predict treatment outcomes was electrodiagnostic testing. Patients with mildly impaired or normal results of electrodiagnostic tests had longer sick leave and were less likely to be satisfied with the results of treatment. This finding was statistically significant in three of the four studies that examined it.

This apparent lack of consistency of results could indicate that, although the relationship between electrodiagnostic tests and treatment outcomes is statistically significant, it may not be substantial. The possibility that this relationship is small is supported by the results of stratified studies that examined the relationship between electrodiagnostic test results and global outcomes. Six of seven studies did not find a statistically significant relationship.

There is some disagreement in the available evidence concerning a relationship between duration of symptoms and global treatment outcome. The highest quality study (prospective with multiple regression analysis) suggested that there was no statistically significant correlation between duration of symptoms and global outcome after surgery. One prospective and two retrospective stratified studies found similar results. Two retrospective studies (one performing multiple regressions, one stratified) found a statistically significant relationship between shorter duration of symptoms and symptom resolution or patient satisfaction after surgery. The retrospective nature of these trials could have created bias that influenced these findings. Additional high quality studies would provide a better evidence base for determining whether there is a relationship between symptom duration and treatment outcome.

The available evidence suggests that patients who are not receiving workers' compensation tend to return to work faster than those receiving such compensation. This is suggested by one of two "multiple regression" studies of this relationship and by a combination of 10 prospective and retrospective stratified studies. These are correlational studies, so the possibility that there may be a relationship does not imply that workers compensation status causes slower return to work..

Some evidence also suggests that patients who are not receiving workers' compensation have better global outcomes, but this evidence is derived exclusively from retrospective studies. Therefore, these latter findings require confirmation.

Available evidence suggests that there is no strong relationship between gender, employment status, or hand dominance and return to work or global outcomes.

There is insufficient evidence to arrive at a firm evidence-based conclusion on the relationship between type of work, presence of diabetes, or age and patient outcomes.

Three prospective cohort trials have indicated that the SF-36 is not a useful instrument for assessing functional limitations in individuals with carpal tunnel syndrome. The SF-36 was reported to be unresponsive to treatment and to be unable to predict ability to work. In contrast, four prospective cohort trials have indicated that the Levine CTS-I may be a useful instrument for assessing functional limitations in individuals with carpal tunnel syndrome. This instrument was reported to be responsive to treatment, and to have concurrent validity as measured by grip and pinch strength. However, none of the studies included in this evidence report evaluated the Levine CTS-I's content validity, or prediction of the ability to perform activities of daily living. In addition, the Levine CTS-I has been reported by one study to not be able to predict ability to work.

No other instruments were evaluated by more than one study. This limited evidence base makes it difficult to reach an evidence-based conclusion about the usefulness of these other instruments evaluated in this report due to the limited evidence base.

There is some evidence to suggest that most untreated patients with carpal tunnel syndrome have mild to moderate functional difficulties before treatment. However, this evidence is derived from only two studies comprised of a total of 51 patients. This is too few patients and too few studies to allow one to reach a firm evidence-based conclusion. Although studies of non-surgical therapies suggested that most patients experience only mild difficulty with functional activities after treatment, it is unclear whether the results of these two studies are generalizable to the larger patient population. Studies with surgical outcomes suggested that most patients report no-to-moderate difficulty with functional activities (mean 1.4-2.6 on the Levine CTS-I) after surgery. The available data are insufficient to determine a cutoff point on measuring scales above which patients are unable to work.

Cubital Tunnel Syndrome

The evidence base of literature about cubital tunnel syndrome is limited in both quantity and quality, which makes it difficult to come to any definitive conclusions about the disorder and how to diagnose or treat it.

A survey of 32 studies indicates that the typical patient who has been enrolled in a clinical trial of surgery for cubital tunnel syndrome is middle-aged and likely to be male. No further typical characteristics could be gleaned from the limited evidence available.

There are no controlled trials available addressing the effectiveness of non-surgical treatment. Three controlled trials addressed the effectiveness of various types of surgical treatment, but no conclusion can be reached from the available data as to whether any type of surgical treatment is superior.

A survey of 17 studies indicates that age, sex, workers' compensation status, and duration of symptoms before treatment are not well correlated with the success of surgical treatment. However, patients who present with milder symptoms and patients whose cubital tunnel syndrome was precipitated by trauma had better outcomes after surgery than did other patients.

Epicondylitis

Due to limited data, one cannot determine, in an evidence-based fashion, the optimal method for diagnosing epicondylitis. Thirty-eight randomized controlled trials, four randomized crossover trials, and eight controlled trials of a total of 3147 patients evaluated eighteen different types of treatments for epicondylitis and reported 73 different outcomes. Only two of these trials included patients with medial epicondylitis; the rest reported exclusively on lateral epicondylitis. The studies tended to be small, and there are too few studies addressing each treatment to allow any definitive conclusions to be made. The only treatment for which a sufficient number of studies had been published to allow a meta-analysis was laser therapy. A meta-analysis of these data suggests that laser therapy is no more effective than sham laser therapy for treating epicondylitis.

Five studies did not find a statistically significant correlation between the duration of symptoms and the success of treatment. Three studies reported that a patient's age and sex have no correlation with the success of treatment for epicondylitis. One study each reported that grip strength and timing of symptom onset (acute vs. chronic) had no correlation with the success of treatment. One study each reported that the presence of ulnar neuritis or severe pain were correlated with a poorer outcome.

A survey of nineteen studies indicated that the typical patient who received surgery for epicondylitis was middle-aged (mean 44.3 years of age), and almost equally likely to be male or female. Due to a lack of reported data, no other trends or characteristics of surgical patients could be derived. It must be kept in mind that because patients enrolled in clinical trials often differ from the general population of patients.

DeQuervain's Disease

There is limited evidence that addresses some of the questions about de Quervain's disease, but not enough to allow any firm evidence-based conclusions about either its diagnosis or treatment. For indications for surgery, two of three studies reported that surgery was performed only on patients who did not benefit from conservative treatment. However, many patient characteristics were unreported, so one cannot assume that these patients are representative of the larger patient population. Only one non-randomized controlled trial addressed the question of relative benefits and harms of various treatments. Although the study found that corticosteroid plus lidocaine injection produced more treatment successes than immobilization splints, no conclusion can be reached based on one study of suboptimal design. One retrospective study addressed the questions of relationships between specific clinical findings and treatment outcomes, duration of symptoms and treatment outcomes, and patient demographic variables and treatment outcomes. No firm evidence-based conclusions can be reached from one retrospective study.

There were no studies that met our inclusion criteria for the questions involving early identification and diagnosis of de Quervain's disease, effectiveness of methods to prevent recurrence of disease, instruments to assess functional limitations, or functional limitations before and after treatment of de Quervain's disease.

Chapter 5. Future Research

In this section, we discuss particular shortcomings of study design and research in the available literature. By inference, these shortcomings point the way towards future research. We then discuss the optimal designs of trials that could answer many outstanding questions. While these are optimal design characteristics, they may not always be practical. It is impossible, for example, to blind patients to the fact that they have received surgery. However, to the extent that it is possible to adopt optimal procedures, they should be adopted.

Gaps in Current Research

Lack of adequate statistical power

A consistent theme observed throughout the literature on WRUEDs is a lack of statistical power. Studies that do not contain adequate numbers of patients cannot detect clinically meaningful differences in outcomes between treatment groups. When designing clinical trials, *a priori* power analysis calculations can be used as a guide to ensure that sufficient numbers of patients are enrolled so that the proposed trial can answer the questions it is investigating.

Inclusion of hands, rather than patients

It is tempting, in bilateral cases of WRUEDs, to count the number of arms/hands treated rather than the number of treated patients. However, when one does so, the data are not independent. Therefore, statistical procedures that take this lack of independence into account must be used for data analysis.

Outcomes

The primary outcome measures in trials of WRUEDs are often physiological measurements such as nerve conduction velocity and grip strength. Although such outcomes are of interest, the correlation between the effect of WRUEDs on physiology and their effect on patients' lives is not well established. Outcomes of greater applicability include measurements of the effect of the disorder on the patient's quality of life and on the patient's ability to work and perform common activities of daily living. An additional shortcoming of the available literature is the incomplete reporting of harms, morbidities, and complications of treatment.

Sufficient length of time of followup

WRUEDs are often chronic conditions that affect patients for many years. Studies that evaluate the effect of a treatment for only a few weeks are unlikely to have followed patients for a long enough period of time to allow for definitive conclusions about the effectiveness of a treatment.

Intent-to-treat statistical analysis

Intent-to-treat statistical analysis is the accepted method of handling attrition from clinical trials. Trials that do not use intent-to-treat statistical analysis may come to incorrect conclusions.

Diagnostics

It is difficult to evaluate the usefulness of a diagnostic test without first establishing a "gold standard" diagnostic method. This difficulty appears likely to remain because there currently appears to be no test that is widely accepted as a gold standard. Nevertheless, improvements in studies of diagnostic tests are possible. Thus, although it is appropriate to perform pilot studies of diagnostic methods on groups pre-selected to contain only definite "normals" and "diseased", the specificities derived from such studies will be inaccurate. Therefore, these specificities may not reflect those one will obtain in actual clinical practice. The relevance of diagnostic studies to this practice can be increased by evaluating a diagnostic test in a population like the one in which it will be used in clinical practice. The accepted method of analyzing diagnostic data, ROC analysis, has been rarely used in this literature. Most of the published articles on diagnostic tests for WRUEDs reported results at only one diagnostic threshold, and usually selected thresholds based on arbitrary criteria rather than on an objective analysis of the consequences of false positive and false negative results.

Optimal Study Designs

Prospective, randomized double-blinded controlled trials are widely considered to provide the highest quality of evidence for treatment effectiveness. Non-randomized trials may have differences in outcomes between patient groups because of differences in the characteristics of the patient groups, rather than the treatment applied. Trials without a control group are unable to examine the potential for recovery in the absence of treatment, and they do not allow one to accurately gauge the magnitude of any change that occurs after treatment. Blinding of patients and evaluators to treatments avoids the potential for placebo effects and previously held beliefs about the effectiveness of treatments to impact on the results of trials.

Studies of diagnostic tests need not be randomized or contain concurrent control groups. In the absence of a "gold standard" test, longitudinal studies that employ clinical outcomes as the gold standard are desirable for assessing diagnostic tests for WRUEDs. In these studies, patients are first given the diagnostic test, and then they are followed for a period of time to see if they develop symptoms of a WRUED. Repeating the tests at regular intervals during the trial could yield insights into the etiology of the conditions as well as measure test-retest variability. Controlled studies designed to gather epidemiological data and identify risk factors are often not possible. Thus, well-designed observational cohort studies are accepted as the optimal design to gather this sort of information. In order to generate generalizable data, it is important that cohort studies enroll sufficient numbers of patients and follow the patients for sufficient periods of time.

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Appendix A. Search Strategies

PubMed/Medline syntax

#1 cumulative trauma disorders[mh] OR (repetitive AND (motion OR strain)) OR "cumulative trauma" OR "work-related musculoskeletal disorders" OR "occupation-related syndromes" OR "occupational disorders" OR "overuse syndrome"

#2 #1 AND (arm[mh] OR bones of upper extremity[mh] OR "upper extremity" OR arm injuries[mh] OR arm* OR shoulder* OR elbow* OR wrist* OR hand* OR finger* OR digit*).

#3 ("De Quervain" OR "de Quervain" OR "DeQuervain") OR ((tenosynovitis OR tenovaginitis) AND stenos*) OR "trigger wrist"

#4 "trigger finger" OR "trigger digit" OR ((tenosynovitis OR tenovaginitis) AND (finger* OR digit OR digits OR thumb*) AND stenos*)

#5 Cubital tunnel syndrome OR (ulnar AND entrap* AND elbow*)

#6 Carpal tunnel syndrome OR (median AND entrap* AND wrist)

#7 Epicondylitis OR "tennis elbow" OR "golfer's elbow

#8 #2 or #3 or #4 or #5 or #6 or #7

To restrict retrieval of articles identified by the above-described searches to clinical trials we employed the following:

(clinical trials[mh] OR clinical trial[pt] OR controls[ab] OR randomized controlled trials[mh] OR random allocation[mh] OR randomized controlled trial[pt] OR random* OR double-blind method[mh] OR single-blind method[mh] OR "single-dummy" OR "double-dummy" OR sham OR controls[ab] OR controlled clinical trials[mh] OR controlled clinical trial [pt] OR multicenter study[pt] OR meta-analysis OR meta-analysis[pt] OR placebo* OR outcomes research[mh] OR prospective studies[mh] OR "evidence-based medicine" OR "systematic review")

To retrieve articles related to diagnostic concepts we employed the following syntax:

(diagnosis OR diagnose OR diagnostic OR di[sh] OR "gold standard" OR "ROC" OR "receiver operating characteristic" OR sensitivity OR specificity OR sensitivity and specificity[mh] OR likelihood OR "false positive" OR "false negative" OR "true positive" OR "true negative" OR "predictive value")

To retrieve articles on therapeutic concepts we employed the following syntax:

(th[sh] OR su[sh] OR dt[sh] OR effectiveness OR efficacy OR "intention to treat" OR treat OR treatment OR therapy OR therapeutic OR "outcome assessment" OR "relative risk")

HCUPnet

We searched the HCUPnet database for the following ICD-9 procedure codes:

ICD-9 Procedure Codes

80.14	82.09	82.36	82.52	82.92	80.92	83.72	83.77
80.24	82.11	82.39	82.53	82.93	81.85	83.73	83.79
80.34	82.12	82.41	82.54	82.94	88.22	83.75	83.85
80.44	82.19	82.42	82.57	82.95	83.01	83.76	84.99
80.74	82.21	82.43	82.59	80.12	83.31	83.83	88.84
80.94	82.22	82.44	82.71	80.22	83.61	83.88	93.04
82.01	82.31	82.45	82.85	80.32	83.62	83.97	93.12
82.02	82.33	82.46	82.86	80.42	83.64	83.65	93.17
82.03	82.35	82.51	82.91	80.72	83.71	83.74	93.27

Datasets CPT Codes

The HCUPnet database was searched for the following CPT:

9991 ANESTHESIA ACUPUNCTURE

9992 OTHER ACUPUNCTURE

053 SYMPATH NERVE INJECTION*

0539 SYMPATH NERVE INJECT NEC

8294 INJECT BURSA OF HAND

8295 INJECT TENDON OF HAND

923 INJECT STEROID

9929 INJECT/INFUSE NEC

9354 APPLIC ATION OF SPLINT

9927 IONTOPHORESIS

932 OTH PT MUSCULOSKEL MANIP*

936 OSTEOPATHIC MANIPULATION*

9367 OSTEOPATH MANIPULAT NEC

8392 INSERT SKEL MUSC STIMULA

8393 REMOV SKEL MUSC STIMULAT

9327 MUSC OR TEND STRETCHING

9308 ELECTROMYOGRAPHY

9314 JOINT MOVEMENT TRAINING

9383 OCCUPATIONAL THERAPY

9361 OMT FOR GEN'L MOBILIZAT

8211 TENOTOMY OF HAND

8313 OTHER TENOTOMY

8092 EXCISION OF ELBOW NEC

8093 EXCISION OF WRIST NEC

8235 HAND FASCIECTOMY NEC

8344 OTHER FASCIECTOMY

82 HAND MUSCL/TEND/FASC OPS*

8201 EXPLOR TEND SHEATH-HAND

821 DIV HAND MUSC/TEND/FASC*

8221 EXC LES TEND SHEATH HAND

8232 EXCIS HAND TEND FOR GRFT

8241 SUTURE TENDN SHEATH HAND

8242 DELAY SUT FLEX TEND HAND

8243 DELAY SUT HAND TEND NEC

8244 SUTUR FLEX TEND HAND NEC

8245 SUTURE HAND TENDON NEC

830 INCIS MUS/TEND/FASC/BURS*

8301 TENDON SHEATH EXPLORAT

831 MUSCL/TEND/FASC DIVISION*

8331 EXCIS LES TENDON SHEATH

836 SUTURE MUSCL/TENDON/FASC*

8361 TENDON SHEATH SUTURE

8362 DELAYED TENDON SUTURE

8364 OTHER SUTURE OF TENDON

837 MUSCLE/TENDON RECONSTRUC*

8371 TENDON ADVANCEMENT

8372 TENDON RECESSION

8373 TENDON REATTACHMENT

8375 TENDON TRNSFR/TRANSPLANT

8376 OTHER TENDON TRANSPOSIT

8383 TENDON PULLEY RECONSTRUC

8385 MUSC/TEND LNG CHANGE NEC

807 SYNOVECTOMY*

8070 SYNOVECTOMY-SITE NOS

8073 WRIST SYNOVECTOMY

8074 HAND SYNOVECTOMY

8079 SYNOVECTOMY-SITE NEC

82 HAND MUSCL/TEND/FASC OPS*

8201 EXPLOR TEND SHEATH-HAND

821 DIV HAND MUSC/TEND/FASC*

8221 EXC LES TEND SHEATH HAND

8241 SUTURE TENDN SHEATH HAND

8242 DELAY SUT FLEX TEND HAND

8243 DELAY SUT HAND TEND NEC

8244 SUTUR FLEX TEND HAND NEC

8245 SUTURE HAND TENDON NEC

825 HAND MUSC/TEND TRANSPLAN*

8251 HAND TENDON ADVANCEMENT

8252 HAND TENDON RECESSION

8253 HAND TENDON REATTACHMENT

0443 CARPAL TUNNEL RELEASE

8174 ARTHROPLASTY CARPAL WIT

8175 ARTHROPLASTY CARPAL W/O

8257 TRANSPOSIT HAND TEND NEC

8259 TRANSPOSIT HAND MUSC NEC

8376 OTHER TENDON TRANSPOSIT

8379 OTHER MUSCLE TRANSPOSIT

0532 NEUROLYT INJEC-SYMP NRV

047 OTHER PERIPH NEUROPLASTY*

0479 OTHER NEUROPLASTY

8022 ELBOW ARTHROSCOPY

8822 SKEL XRAY-ELBOW/FOREARM

8023 WRIST ARTHROSCOPY

8823 SKEL XRAY-WRIST & HAND

Diagnostic Related Groups (DRGs)

The HCUPnet database was searched for the following:

006	SURG	CARPAL TUNNEL RELEASE
007	SURG	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W CC
008	SURG	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC
216	SURG	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE
223	SURG	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC
224	SURG	SHOULDER, ELBOW OR FOREARM PROC, EXC MAJOR JOINT PROC, W/O CC
226	SURG	SOFT TISSUE PROCEDURES W CC
227	SURG	SOFT TISSUE PROCEDURES W/O CC
228	SURG	MAJOR THUMB OR JOINT PROC, OR OTH HAND OR WRIST PROC W CC
229	SURG	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC
232	SURG	ARTHROSCOPY
233	SURG	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W CC
234	SURG	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC
240	MED	CONNECTIVE TISSUE DISORDERS W CC
241	MED	CONNECTIVE TISSUE DISORDERS W/O CC
246	MED	NON-SPECIFIC ARTHROPATHIES
247	MED	SIGNS & SYMPTOMS OF MUSCULOSKELETAL SYSTEM & CONN TISSUE
248	MED	TENDONITIS, MYOSITIS & BURSITIS
249	MED	AFTERCARE, MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE

250	MED	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC
251	MED	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC
252	MED	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE 0-17
256	MED	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES
462	MED	REHABILITATION

Ambulatory Payment Classifications (APCs)

The HCUPnet database was searched for the following APCs:

0041 Arthroscopy

0042 Arthroscopically-Aided Procedures

0047 Arthroplasty without Prosthesis

0049 Level I Musculoskeletal Procedures Except Hand and Foot

0050 Level II Musculoskeletal Procedures Except Hand and Foot

0051 Level III Musculoskeletal Procedures Except Hand and Foot

0053 Level I Hand Musculoskeletal Procedures

0054 Level II Hand Musculoskeletal Procedures

HCPCS Codes

The HCUPnet database was searched for the following HCPCS codes:

25000 Incision of tendon sheath

25020 Decompression of forearm

25023 Decompression of forearm

24000 Exploratory elbow surgery

24006 Release elbow joint

24100 Biopsy elbow joint lining

24101 Explore/treat elbow joint

24102 Remove elbow joint lining

24301 Muscle/tendon transfer

24305 Arm tendon lengthening

24310 Revision of arm tendon

24320 Repair of arm tendon

24330 Revision of arm muscles

24331 Revision of arm muscles

24341 Repair arm tendon/muscle

24350 Repair of tennis elbow

24351 Repair of tennis elbow

24352 Repair of tennis elbow

24354 Repair of tennis elbow

24356 Revision of tennis elbow

25260 Repair forearm tendon/muscle

25263 Repair forearm tendon/muscle

25265 Repair forearm tendon/muscle

25270 Repair forearm tendon/muscle

25272 Repair forearm tendon/muscle

25274 Repair forearm tendon/muscle

25280 Revise wrist/forearm tendon

25290 Incise wrist/forearm tendon

25295 Release wrist/forearm tendon

25310 Transplant forearm tendon

25320 Repair/revise wrist joint

25332 Revise wrist joint

26035 Decompress fingers/hand

26037 Decompress fingers/hand

26040 Release palm contracture

26055 Incise finger tendon sheath

26060 Incision of finger tendon

26121 Release palm contracture

26123 Release palm contracture

26125 Release palm contracture

26130 Remove wrist joint lining

26135 Revise finger joint, each

26140 Revise finger joint, each

26145 Tendon excision, palm/finger

26170 Removal of palm tendon, each

26180 Removal of finger tendon

26350 Repair finger/hand tendon

26356 Repair finger/hand tendon

26418 Repair finger tendon

26525 Release finger contracture

26591 Repair muscles of hand

26593 Release muscles of hand

26596 Excision constricting tissue

26989 Hand/finger surgery

29830 Elbow arthroscopy

29835 Elbow arthroscopy/surgery

29836 Elbow arthroscopy/surgery

29837 Elbow arthroscopy/surgery

29838 Elbow arthroscopy/surgery

29840 Wrist arthroscopy

29843 Wrist arthroscopy/surgery

29844 Wrist arthroscopy/surgery

29845 Wrist arthroscopy/surgery

29846 Wrist arthroscopy/surgery

29848 Wrist arthroscopy/surgery

64702 Revise finger/toe nerve

64704 Revise hand/foot nerve

64718 Revise ulnar nerve at elbow

64719 Revise ulnar nerve at wrist

64721 Carpal tunnel surgery

95831 Limb muscle testing, manual

95832 Hand muscle testing, manual

95851 Range of motion measurements

95852 Range of motion measurements

95857 Tensilon test

95858 Tensilon test & myogram

95860 Muscle test, one limb

95861 Muscle test, two limbs

95872 Muscle test, one fiber

95875 Limb exercise test

95900 Motor nerve conduction test

95903 Motor nerve conduction test

95904 Sense/mixed n conduction test

95925 Somatosensory testing

95937 Neuromuscular junction test

Appendix B: Data Abstraction Forms

Clinical Trial Information Form

Standard Input Form for Clinical Trial Information Table

A separate record (row in the table) is entered for each published clinical trial to be entered in the database.

First column: What appears on the form **Second column: What should be entered in the form**

Record Entry Information

Person Extracting Record:	*Enter name of analyst extracting and entering data*
Date When Record Was Entered:	*00/00/00 Date format*
Person Reviewing Record:	*Enter name of analyst reviewing data entry. Not all entries will be reviewed.*
Date When Record Was Reviewed:	*00/00/00 Date format*

Trial Identification

Unique ID Number for Trial Publication:	*Enter the Alex number given to the publication, this number links all of the information from this trial entered in other data tables*
First Author	*Enter name of first author only (used for identification purposes)*
Year of Publication	*Enter the year of publication (used for sorting purposes)*

Author Names and Year (PROCITED)	*This entry will be generated from the Procite number after the database is completed. The analyst does not enter anything in this box.*
Years in Which Trial was Conducted	*If not presented attempt to calculate the years based on the year of publication and the longest follow up time for outcome measurement*
Country(s) Where Trial Was Performed	
Clinical Setting Where Trial Was Performed	Drop-down box: *Outpatient; Inpatient; Outpatient and inpatient, Not reported*
Number of Centers in which Trial was conducted	Drop-down box: *Single, less than 5, more than 5*
Institution of First Author:	*Enter name of the institution or Not reported*
Was trial funded by a for-profit pharmaceutical company or medical device manufacturer?	Drop-down box: *Yes; No; Not reported*
Prior publication or followup, provide reference number to prior publication or followup publication for same clinical trial:	*Provide the reference(s) (author and year) and the database number(s) (Procite #) to any prior publications or followup publications involving the patients in this trial*
Type of Study	Drop-down box: *Diagnostic; Treatment; Epidemiology; Natural History*
General Intervention Examined in Trial:	Drop-down box: *Surgical; Pharmaceutical; Implanted Device; Non-implanted device (includes orthopedic devices); Behavioral (including psychological and psychiatric); Education/Training; Natural History/Study course of disease; and combinations of these general interventions.*
Brief description of the purpose for conducting this trial:	*One or two sentences about the intended purpose of the trial*

Type of Disorder: Drop-down box: *See attached Sub-table of Disorder Names.*

Within the context of a broad type of disease or medical condition there are usually specifically defined disorders. This box is intended to provide a general category for the disorder or condition being examined. The form for Patient Groups – Treatments and Characteristics provides a drop-down box with more specific names of conditions or sub-classifications within a disorder. If the general disorder name is not sufficient to describe the patient groups in a trial use the drop-down box in the Patient Groups – Treatments and Characteristics form to describe the group.

Analyst Comment

Comments on Trial Design, flaws in reporting or analysis by the authors, etc.: *Enter analyst's comments*

Comment on the quality of the trial design and its usefulness in a meta-analysis. These comments can be extensive and used when writing the final report. This section should be used to clarify entries for which there are no description and definition boxes, such as indicating that not all outcome measurements were blinded, or that the data as reported are flawed due to inaccurate calculations etc. List threats to validity and potential biases. Were outdated methods used?

Was this trial included in the report? Check box: *Yes or No.*

Very often the abstract to a clinical trial publication may indicate that it contains useful information that applies to one or more of the key questions being assessed, but after reading the article a major flaw prevents the use of this publication when formulating an answer to any of the proposed questions. Therefore the trial will not be used in the report. If this is the case, not check this box. Fill in the box below with the reasons for rejecting this publication. ***No further information is to be entered in any of the Forms in the database.***

If this trial was excluded from the report, explain why. *Provide a brief explanation in the text box.*

Possible explanations include but are not limited to: Insufficient details about intervention; Insufficient details about study protocols; Mixture of patients with various disorders; Intervention not applied in intended-use manner; Confounded by concurrent intervention applied inconsistently; Single-arm or single-group trial with no baseline measures reported; Does not answer a key question; Statistical analysis invalid and cannot be recalculated; Methods used were outdated and inaccurate; Demonstrable differences between patient groups in controlled trial AND one group cannot be retained for pre-post analysis.

Application to Key Questions

Does this publication provide data that may help to answer any of the following key questions?

Question 1: Check box: *Yes or No*

Continued for as many questions as needed

Patient Selection Criteria

Were patient inclusion and exclusion criteria explicitly described? Quality Assessment Question	Check box: *Yes or No. Define explicit*
Was the study's source of patients adequately described and generalizable to broader clinical practice? Quality Assessment Question	Check box: *Yes or No. A definition of adequate must be decided on.*
Trial's Patient Inclusion Criteria	*Describe the inclusion criteria as presented in the publication. Remember to include that fact that all patients failed previous conservative or surgical treatment if this is a requirement for entry in the trial.*
Trial's Patient Exclusion Criteria	*Describe the exclusion criteria*
Method of Diagnosis:	*Described the method of diagnosis used to determine patient condition. Only a brief description of a few sentences are needed. If this is a diagnostic trial or extensive information on the diagnostic procedures is reported, that information should be entered in the Diagnostic Trial Information Form.*
Were the diagnostic tests adequately described? Quality Assessment Question	Check box: *Yes or No. A definition of adequate must be decided on.*
Select which special population was examined	Drop-down box: *See the attached sub-Table for list of Name of Special Population.*
Did all patients have previous conservative treatment?	Check box: *Yes or No*
Did any patients have previous surgical treatment?	Check box: *Yes or No*

Trial Design and Patient Allocation

Is this a randomized controlled trial? Quality Assessment Question	Check box: *Yes or No*
What type of trial design was used?	Drop-down box: *Randomized controlled trial; Other longitudinal controlled trial; Other parallel controlled trial; Not controlled.*
Longitudinal refers to trials in which the pretreatment measurements act as the controls for the posttreatment measurements within the same patient group. Parallel refers to trials in which a specific patient group acts as the control for any time point in the study, but this group was selected in a non-randomized manner.	
Was patient selection prospective or retrospective?	Drop-down box: *Prospective or Retrospective*
Was a two-arm crossover design used in this study?	Check box: *Yes or No*
Method of Patient Allocation	Drop-down box: *Stochastic randomization; Non-stochastic randomization; Random with method not described; Matched controls; Historical controls; Consecutive cases; Cases between specific dates; Not reported*
Is a parallel control group (treated or otherwise) included in the trial?	Check box: *Yes or No*
What type of parallel control group was included?	Drop-down box: *Placebo control; Passive control (waitlist or untreated); Treated control (as when comparing two drugs or drug to surgery); No control*
Was blinding of patients possible?	Check box: *Yes or No*
Were patients blinded? Quality Assessment Question	Check box: *Yes or No*

Was blinding of second or third party raters possible?	Check box: *Yes or No*
Were second or third party raters blinded? Quality Assessment Question	Check box: *Yes or No*

Patients Enrolled

Total Patients Enrolled in Trial:	*Enter number. The number of patients enrolled in a study refers to patients considered for the study but not allocated to treatment.*

Many studies do not report this number and present only the number of patients allocated to treatment. In a retrospective trial, this is the number of patients from which data could have been obtained, such as all patients within a set period of time who received a particular treatment.

Total Patients Allocated to Trial:	*Enter number. This is the number of patients who receive treatment and for which pretreatment data was collected. In a retrospective trial, this is the number of patients for which data were collected.*

Attrition Reported. Quality Assessment Question	Check box: *Yes or No.*

Attrition refers only to patients in a prospective trial who drop-out of the trial and do not appear again at any time during the completion of the trial. Specific reasons for attrition are contained in the Patient Groups – Treatments and Characteristics Form. The publication must specifically state that these patients dropped-out. Patients who are not evaluated for all outcomes or at all time periods are not considered part of the trial attrition.

Did trial report attrition for entire study only?	Check box: *Yes or No; separate patient group attrition was not reported*

Total Patient Attrition (all patient groups):	*Enter number*

Trial Treatment Arms, Patient Stratification, and Sub-grouping

Number of Treatment Arms:	*This is the number of treatment arms in the trial, not the total number of patient groupings for which data is reported*
Data reported for stratified patient groups or subgroups	Check box: *Yes or No*
How were the stratifications planned?	Drop-down box: *A priori; Post hoc; Not reported*
Number of stratified patient groups or subgroups	*The number of patient groupings based on group characteristics or other sub-groupings for which data is reported; does not include the number of treatment arms*
Description of patient stratification or sub-grouping:	*To enter data for a stratified group or subgroup that is not a treatment arm, enter additional patient groups in the Patient Characteristics Input Form.*

Data may be reported according to specific patient characteristics such as male or female gender; the data may be presented as a single group across treatments, or subdivided by treatment and other patient characteristics.

Trial Reporting

Reported number of male and female patients	Check box: *Yes; No*
Reported duration of condition before trial	Check box: *Yes; No*
Are prior treatments reported?	Check box: *Yes; No*
Reported ethnic origin of patients	Check box: *Yes; No*
Reported number of patients employed at start of trial	Check box: *Yes; No*

Are charges or cost of treatment or diagnosis reported?	Check box: *Yes or No*
Are patient income or economic data reported?	Check box: *Yes or No*
Are the number of patients who smoked reported?	Check box: *Yes or No*
Are patient comorbidity reported? Quality Assessment Question	Check box: *Yes or No*
Are the number of patients who consumed alcohol reported?	Check box: *Yes or No*
Describe how alcohol consumption was defined	*Enter a description of how alcohol consumption was defined*
Are complications and adverse effects of treatment reported? Quality Assessment Question	Check box: *Yes or No. Check this box whenever any kind of information on complications or adverse effects are presented even if they are sketchy. The Complication and Adverse Effects Form will be used to enter specific information.*
Was a power analysis performed before the start of the trial? Quality Assessment Question	Check box: *Yes or No*
Were statistical methods and p-values adequately described and appropriate? Quality Assessment Question	Check box: *Yes or No. Define adequate*
Reported Extent of Disease	Check box: *Yes or No*
How many categories are reported for extent of disease?	*Enter number*
Description of how extent of disease was determined	*In this box describe how the publication defines the extent of disease for each category.*

The Patient Groups – Treatment and Characteristics input form has entries for the number of patients in each severity category and provides for up to 5 categories listed A to E. Additional entries for more categories can be inserted in this form if needed. Category A will be used for the healthiest patients and Category E for the least healthy patients. As a guide when publications use undefined phrases such as Mild, Moderate, or Severe, the following definitions can be used for each category, A: Mild, B: Mild to Moderate, C: Moderate, D: Moderate to Severe, E: Severe. The extent of disease may be based on the signs and symptoms or some other measure of disease severity (example: degree of stenosis of the lumbar spinal column).

Diagnostic Clinical Trial Information Form

Standard Input Form for Diagnostic Clinical Trial Information Table

A separate record is entered for each diagnostic test (excluding the reference or gold standard) used in a trial. Trial and Patient information (including patient selection and patient characteristics) are entered in the Trial Information Table, the Patient Treatment and Characteristics Table, and the Patient Signs and Symptoms Table. If a diagnostic test is considered outdated, do not enter it in the database.

First column: What appears in the form	**Second column: What should be entered in the database**

Trial Identification Number

Unique ID Number for Trial Publication:	*Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*

Diagnostic Test and Study Design

Were the diagnostic tests used for screening, diagnosis, or relative risk assessment?	Drop-down box: *Screening; Diagnosis; Relative risk*
Name of the diagnostic test	*Enter the name of the diagnostic test. See the attached list of names of diagnostic tests.*
Is this test being compared to the accepted reference standard for this disorder?	Check box: *Yes; No*
Was clinical followup or established test used as a "gold" or reference standard?	Drop-down box: *Clinical followup; Established test*
Name the "gold" standard or reference test	*Enter the name of the "gold" standard or reference*
Enter the specific name and manufacturer of any device used in the diagnosis	*Enter the name of the device and its manufacturer*

Were all patients given the diagnostic test and reference test?	Check box: *Yes; No*
Was a historical or concurrent control group without disease used?	Drop-down box: *Historical; Concurrent; No control group*
Was a retrospective chart review used?	Check box: *Yes; No*
Is blinding of readers applicable to this diagnostic test?	Check box: *Yes; No*
If yes, was blinding reported?	Check box: *Yes; No*
Were the diagnosticians blinded to patient condition/history?	Drop-down box: *Yes; No; Not applicable; Not reported*
Were the diagnosticians blinded to patient identity?	Drop-down box: *Yes; No; Not applicable; Not reported*
Were the diagnosticians blinded to diagnostic modality?	Drop-down box: *Yes; No; Not applicable; Not reported*
Were the diagnosticians blinded to results of other tests?	Drop-down box: *Yes; No; Not applicable; Not reported*
Were the diagnosticians blinded to readings by other diagnosticians?	Drop-down box: *Yes; No; Not applicable; Not reported*

Sensitivity, Specificity, Positive, and Negative Predictive Value Reporting

Were sensitivity and specificity reported?	Check box: *Yes; No*
What was the sensitivity?	*Enter number*
What was the specificity?	*Enter number*

Were the number of positive and negative test results reported?	Check box: *Yes; No*
Number of patients with positive test results	*Enter number*
Number of patients with negative test results	*Enter number*
Was a 2 by 2 table reported?	Check box: *Yes; No*
Number of patients with true positive test results	*Enter number*
Number of patients with false positive test results	*Enter number*
Number of patients with true negative test results	*Enter number*
Number of patients with false negative test results	*Enter number*
Can a 2 by 2 table be derived from data in the publication?	Check box: *Yes; No*
The analyst was able to recalculate the data in the 2 by 2 table and independently verify sensitivity, specificity, positive predictive value, and negative predictive value as reported	Check box: *Yes; No*

Testing Information Reporting

Was individual patient data reported?	Check box: *Yes; No*
Were the characteristics of patients with positive or negative test results reported?	Check box: *Yes; No*
Were correlations between two diagnostics reported (no test characteristics presented)?	Check box: *Yes; No*

What was the longest allowed interval between multiple tests (days)?	*Enter number*
Were test characteristics reported?	Check box: *Yes; No*
Describe the test characteristics	*Enter a description of the test characteristics*
Was treatment given only to patients with positive test?	Check box: *Yes; No*
How many diagnostic thresholds were tested?	*Enter number*
How many diagnosticians were used?	*Enter number*
Was consensus among diagnosticians required for diagnosis?	Check box: *Yes; No*
Were the results of diagnosticians tabulated separately?	Check box: *Yes; No*
Was spectrum bias present?	Check box: *Yes; No*
Select the reason for spectrum bias	Drop-down box: Referral bias; Test-referral bias; Referral bias and test-referral bias
Comments about the quality and design of the trial	*Enter comments on the quality and usefulness of this trial*

Treatments and Characteristics of Patient Groups within Clinical Trials Form

Standard Input Form for Patient Group – Treatment and Characteristics Table

A separate record (line in the table) is entered for each patient group within a trial, this includes control groups, treatment groups, and stratified groups. Patient groups are treatment arms and stratified patient groups for which data on treatment and characteristics are reported. Each Patient Group is distinguished by its Unique Trial ID number (linked to Trial publication) and Unique Patient Group ID Number.

First column: What appears in the form	**Second column: What should be entered in the database**

Patient Group Identification

Unique Trial ID Number	*Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*
Unique Patient Group ID Number	*This number is a combination of the Alex number followed by a dash and the patient group number (01, 02, 03, etc.) assigned by the analyst. This number links all of the patient group information entered in other data tables. The number 00 is reserved for recording patient information when reported only for all patients in the study.*
Patient Group Number	*Enter the patient group number (01, 02, 03, etc.)*

Unique patient group characteristic used to define this group or stratify data reporting	*This entry is used to describe subgroups within particular disorders. For example, all patients in a trial may have carpal tunnel syndrome but one patient group may also have diabetes while the another patient group is composed of non-diabetics, or data are reported separately for all male and all female patients. Enter a one, two, or three-word description that best describes the patient group. A drop-down box can be constructed if general terms and conditions are known.*
Description of unique patient group characteristic or stratification for data reporting	*Enter a detailed description of patient characteristic used to define a patient group or stratification as presented in the trial. Use this box if the simple description in the previous box is not adequate to describe the patient group.*
Specific type of disorder or subclassification of the disorder	Drop-down box: *See attached list of specific disorder names. An entry is made only when a specific subclass of the disorder is being examined. For example, the general disorder may be central lumbar stenosis, but all of the patients in this group had stenosis at L5 or they all had multiple stenosis.*
Detailed description of disorder	*Enter a detailed description of the disorder as presented in the trial. Use this box if the short description in the previous box is not adequate to describe the specific disorder in this patient group, otherwise leave blank.*

Description of Treatment Received by Patient Group

Type of Treatment	Drop-down box: *See the attached list of treatments. Use the name of the drug category, surgical procedure, device category, other procedures used in treatment, or the type of control treatment received. Specific names are entered in the next box.*
Detailed Description of Treatment	*Enter a detailed description of the treatment received by this group of patients. Length of treatment and dosing should be described. Provide run-in times and washout times for drug trials if reported.*
For drugs trials, was there a run-in period?	Drop-down box: *Yes; No; Not applicable; Not reported*

Specific drug or device name and manufacturer	*Enter the specific drug or device name and the name of the manufacturer if used in this trial to treat this patient group.*
For drugs trials, was there a washout period?	Drop-down box: *Yes; No; Not applicable; Not reported*

"Not applicable" refers to trials not investigating drug treatment or where the trial explains that no run-in or washout period was not needed.

Was patient compliance reported?	Drop-down box: *Yes; No; Not applicable; Not reported*
Described how patient compliance was monitored?	*Enter a description of how patience compliance was monitored?*
Number of compliant patients in this patient group	*Enter the number if reported*
Measure of patient compliance	*Enter the value (number) for the measure of patient compliance. This is a measure such as percent of pills consumed, etc.*
Were any concurrent treatments or therapies reported?	Check box: *Yes; No*
Description of any concurrent treatment or therapy	*Enter a detailed description of any concurrent therapy received by this patient group.*
Description of any prior treatments	*Enter a detailed description of any prior treatment or therapy received by this patient group.*

When entering patient information a 0 signifies that no patients had that characteristic. Leave an entry blank if the publication does not report data on a characteristic.

Attrition in Patient Group

Number of patients originally allocated to this patient group	*Enter number of patients*
Total Attrition in this patient group	*Enter number of patients to drop out at some time during the study. If data on attrition is only available for the study as a whole, then information on patient attrition is entered in the Trial Information Form only.*
Attrition due to death in this patient group	*Enter number of patients who died at some time during the study*
Attrition due to concurrent unrelated illnesses in this patient group	*Enter number of patients who withdrew from the study due to concurrent unrelated illnesses*
Attrition due to unwanted treatment effects in this patient group	*Enter number of patients who withdrew from the study due to unwanted treatment effects (dissatisfaction with treatment, adverse side effects)*
Attrition due to changed treatment in this patient group	*Enter number of patients who withdrew from the patient group due to receiving another treatment (moved to another treatment group). This does not include patients that changed treatment as part of a planned crossover design.*
Attrition recorded as lost to followup in this patient group	*Enter number of patients to drop out at some time during the study and were considered lost to followup*

Patient Group Characteristics at Start of Trial

Patient characteristics reported for the study as a whole (no individual patient group data reported)	Check box: *Yes; No. If Yes, then record the patient data in a form with the Patient Group Number 00 and leave the other information blank.*

Are characteristics reported for patients who started, completed, or both started and completed trial?	Drop-down box: *Started trial; Completed trial; Both started and completed trial*

When characteristics are reported for both started and completed patient groups, this information is extracted for both groups. In the Unique Patient Group ID Number *and* Patient Group Number *listed above, use an* S *after the group number to designate patients who started the trial and a* C *to designate patients who completed the trial. For example,* 1S *and* 1C.

Individual patient data reported	Check box: *Yes; No*
Is age reported as Mean or Median?	Drop-down box: *Mean; Median; Not reported*
Age of patient group	*Enter mean or median age if reported*
Standard deviation of patient group age	*Enter if reported or can be calculated using the data reported in the trial*
Lower 95% confidence limit of patient group age	*Enter if reported or can be calculated using the data reported in the trial*
Upper 95% confidence limit of patient group age	*Enter if reported or can be calculated using the data reported in the trial*
Age of youngest patient in patient group	*Enter if reported*
Age of oldest patient in patient group	*Enter if reported*
Number of patients under the age of 18 years	*Enter if reported*
Number of patients over the age of 65 years	*Enter if reported*
Number of Males in patient group	*Enter if reported*
Number of Females in patient group	*Enter if reported*
Number of pregnant patients	*Enter if reported*

Number of patients in menopause	*Enter if reported*
Number of patients using oral contraceptives	*Enter if reported*
Is duration of condition reported as Mean or Median?	Drop-down box: *Mean; Median; Not reported*
Standard deviation of duration	*Enter if reported*
Lower 95% confidence limit of duration	*Enter if reported*
Upper 95% confidence limit of duration	*Enter if reported*
Shortest period of duration before treatment (months)	*Enter if reported*
Longest period of duration before treatment (months)	*Enter if reported*
Number of patients of African origin	*Enter if reported*
Number of patients of Asian origin	*Enter if reported*
Number of patients of Hispanic origin	*Enter if reported*
Number of patients of Caucasian origin	*Enter if reported*
Number of patients of Other origin	*Enter if reported*
Number of patients with above normal alcohol use	*Enter if reported; the definition of above normal alcohol use and alcohol consumption are entered in the Trial Information Form*

What is the average alcohol consumption in this patient group (drinks per day)?	*Enter if reported*
Number of patients who smoke	*Enter if reported*
Number of overweight patients	*Enter if reported; an actual definition of overweight will need to be determined and placed in the label*

Extent of Disease

Five categories for extent of disease have been provided in this portion of the database. The definition for each category is entered in the Trial Information Form. Category A contains the healthiest patients and Category E contains the least healthy patients.

Number of patients in extent of disease category A	*Enter if reported – Mild*
Number of patients in extent of disease category B	*Enter if reported – Mild to Moderate*
Number of patients in extent of disease category C	*Enter if reported – Moderate*
Number of patients in extent of disease category D	*Enter if reported – Moderate to Severe*
Number of patients in extent of disease category E	*Enter if reported – Severe*

Education, Income, and Employment Information

Select the educational category that best describes this patient group:	Drop-down box: *Less than 9th grade; 9th to 12th grade, no diploma; High School graduation; Some college (no degree); Associate degree; Bachelor's degree; Master's degree; Doctorate degree; Professional degree. These are the education levels used by the U.S. Bureau of Labor Statistics and the Bureau of the Census in their Annual Demographic Survey.*[661]
Select the occupational category that best describes this patient group:	Drop-down box: *See the attached table of occupational categories from the Bureau of Labor Statistics.*[662]
Number of patients	Enter if reported

employed at start of trial	
Number of patients not able to work at start of trial	*Enter if reported*
Is income level reported as Mean or Median?	Drop-down box: *Mean; Median; Not reported*
Select the income level that best describes this patient group:	Drop-down box: *At or below poverty level; Between poverty level and mean or median income level; At or above mean or median income level to $99,999; $100,000 and above*

The U.S. Census Bureau has historical tables for both the poverty threshold from years 1959 to 1999 [663] *and for mean and median income from years 1980 to 1999* [664]*. Use the poverty threshold listings for a household with four people and the mean or median income level for all households.*

Number of patients receiving workers' compensation at start of trial	*Enter if reported*
Number of patients filing a workers' compensation claim at start of trial	*Enter if reported*
Number of patients retaining a lawyer at start of trial	*Enter if reported*

Signs and Symptoms of Patient Groups within Clinical Trials

Standard Input Form for Information on Patient Signs and Symptoms in Clinical Trials Table

A separate record (form) is entered for each sign or symptom in a patient group within a trial. Patient groups are treatment arms and stratified patient groups for which data on patient signs and symptoms are reported. Each Patient Group is distinguished by its Unique Trial ID number (linked to Trial publication) and each Patient Group's Unique Group ID Number. Signs and symptoms are considered to be part of a patient's history and physical before treatment has begun.

First column: What appears in the form	**Second column: What should be entered in the database**

Patient Group Identification

Unique Trial ID Number	*Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*
Unique Patient Group ID Number	*This number is a combination of the Alex number followed by a dash and the patient group number (01, 02, 03, etc.) assigned by the analyst. This number links all of the patient group information entered in other data tables. The number 00 is reserved for recording patient information when reported only for all patients in the study.*

Patient Signs and Symptoms Before Treatment

Is the sign or symptom reported for the study as a whole (no individual patient group data reported)?	Check box: *Yes; No. If Yes, then record the patient sign and symptoms in a form with the Patient Group Number 00 and leave the other information blank.*
Is the sign or symptom reported for patients who started trial, completed trial, or both started and completed trial?	Drop-down box: *Started trial; Completed trial; Both started and completed trial*
Is the sign or symptom data reported for individual patients?	Check box: *Yes; No*

Reported sign or symptom	Drop-down box: *Select the reported sign or symptoms to be entered in the database. See attached sub-table for a list.*
Number of patients in patient group with sign or symptom	*Enter the number of patients with the selected sign or symptom.*

This form may appear in one of two designs. The first design contains only one box per form for selected the sign or symptom and the number of patients being entered in the database for a single patient group. For each new sign or symptoms in a patient group a new form must be completed. This design works well when only a few signs or symptoms are reported per patient group. The second design has multiple entry boxes for signs and symptoms and the number of patients. The selection boxes are still linked to the single drop-down list of signs and symptoms, but now all of the signs and symptoms can be entered in one form per patient group. This design works well when numerous signs and symptoms are reported and avoids repeated reentry of trial and patient group ID numbers. The first design has advantages in sorting and reporting signs and symptoms and the second design has advantages in reducing the time needed for data entry.

Comorbidities Among Patient Groups within Clinical Trials

Standard Input Form for Information on Patient Comorbidities in Clinical Trials Table

A separate record (form) is entered for each comorbidity in a patient group within a trial. Patient groups are treatment arms and stratified patient groups for which data on patient comorbidity are reported. Each Patient Group is distinguished by its Unique Trial ID number (linked to Trial publication) and each Patient Group's Unique Group ID Number.

First column: What appears in the form	**Second column: What should be entered in the database**

Patient Group Identification

Unique Trial ID Number	*Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*
Unique Patient Group ID Number	*This number is a combination of the Alex number followed by a dash and the patient group number (01, 02, 03, etc.) assigned by the analyst. This number links all of the patient group information entered in other data tables. The number 00 is reserved for recording patient information when reported only for all patients in the study.*

Patient Comorbidity

Type of comorbidity	Drop-down box: *See attached sub-table for examples.*
Number of patients in patient group with comorbidity	*Enter number of patients*
If necessary, provide the specific name of the comorbidity	*Enter specific name or short description of comorbidity. If "Other" was selected in the prior box, a name or description must appear in this box.*
Is the comorbidity reported for the study as a whole (no individual patient group data reported)?	Check box: *Yes; No. If Yes, then record the Patient Group Number as 00 and be sure that a 00 patient group is entered for this trial in the Patient Treatments and Characteristics Form.*

Is the comorbidity reported for patients who started trial, completed trial, or both started and completed trial?	Drop-down box: *Started trial; Completed trial; Both started and completed trial*
Is the comorbidity data reported for individual patients?	Check box: *Yes; No*

Treatment Complications and Adverse Effects of Patient Groups within Clinical Trials

Standard Input Form for Information on Treatment Complications and Adverse Effects in Clinical Trials Table

A separate record (form) is entered for each complication or adverse effect in a patient group within a trial. Patient groups are treatment arms and stratified patient groups for which data on complications and adverse effects are reported. Each Patient Group is distinguished by its Unique Trial ID number (linked to Trial publication) and each Patient Group's Unique Group ID Number.

First column: What appears in the form	**Second column: What should be entered in the database**

Patient Group Identification

Unique Trial ID Number	*Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*
Unique Patient Group ID Number	*This number is a combination of the Alex number followed by a dash and the patient group number (01, 02, 03, etc.) assigned by the analyst. This number links all of the patient group information entered in other data tables. The number 00 is reserved for recording patient information when reported only for all patients in the study.*

Patient Signs and Symptoms Before Treatment

Type of complication	Drop-down box: *See attached sub-table.*
Number of patients in patient group with this complication	*Enter if reported*
Mean or Median time of complication	Drop-down box: *Mean; Median.*
Time in months post treatment when complication was recorded	*Enter number*
Standard deviation of time of complication	*Enter number*
Lower limit of 95% confidence interval of time for complication	*Enter number*
Upper limit of 95% confidence interval of time for complication	*Enter number*
Minimum time in months post treatment when complication was recorded	*Enter number*
Maximum time in months post treatment when complication was recorded	*Enter number*

Name and Description of Treatment Outcome Measurements within Clinical Trials

Standard Input Form for Name and Description of Treatment Outcome Measurements Table

A single table and form is used to enter all definitions of outcome measurements used to evaluate treatments for the disorder of interest. Each Outcome Measure is pre-assigned a unique ID number in a sub-table in the database. This requires that the most important and appropriate outcome measurements be decided upon before extracting information for the database. By limiting the number of outcome measures that will be assessed, the time spent abstracting data will be greatly reduced. Multiple entries per trial for the same outcome measurement may be necessary if more than one means of measuring the same outcome is used. As an example, Pain is an outcome measurement that can be evaluated using a visual analog scale (reported as mean and standard deviation) and by asking patients if their pain has improved, stayed the same, or become worse (categorical scale). In the predetermined outcome list both Pain – visual analog scale and Pain – patient rated categorical scale will appear. Each means of evaluating Pain as an outcome would be entered on a separate form along with its predetermined Unique ID Number for Outcome Measure. If both a patient-rated and physician-rated evaluation is used for the same outcome measurement then each gets entered in a separate form and with a separate Unique ID Number for Outcome Measure.

First column: What appears in the form	**Second column: What should be entered in the database**

Trial and Outcome Measurement Identification Number

Unique ID Number for Trial Publication:	*000000: Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*
Name of outcome measurement (An outcome ID number will appear but not be entered in the database)	Drop-down box: *See the attached list of Outcome Measurement Names and their ID numbers*

Trial and Outcome Measurement Number	*000000-00. This is a two part number. The first part is the Trial ID number. The second part is the Outcome Measure ID number which appears in the drop-down box in the previous field. This two-part number will be used again in the Outcome Measurement Table and Form to link the outcome measurement definition for a particular trial to the actual outcome measurement from that trial.*

Outcome Measurement Definition

Definition and Description of Outcome:	*Describe how the publication defined the outcome measurement.*

Was a continuous scale involved from which a group mean was obtained or were patients put into categories of recovery after treatment. Give the range of the scale. Define the categories and designate them A, B, C, D, E, or F with A being the best outcome and F being the worst outcome. For example, A: Excellent, B: Good, C: Fair, D: Poor, E: Very Poor, F: not used. If dichotomous data are reported provide a definition of success and failure. Every publication using the same outcome measurement does not define it or use it in the same way.

What type of outcome measurement was used?	Drop-down box: *Continuous; Dichotomous; Non-dichotomous categorical*

A continuous variable is a number that can have an infinite number of decimal points, and be negative or positive. A dichotomous variable can only have two events or categories such as Success or Failure. A non-dichotomous categorical value is used when more than two categories are used in an outcome measurement; the value is usually a discrete variable such as integer variable or count of the number of patients in a particular category.

Were both pre-treatment and post-treatment data reported or was only post-treatment data reported for this outcome measurement?	Drop-down box: *Pre- and post-treatment data reported; Post data only reported. This questions applies to single arm trials and parallel group trials as well.*
Were individual patient outcome data reported?	Check box: *Yes or No*
How were the followup outcome data obtained?	Drop down box: *Phone interview; Mailed questionnaire; Phone followup of mailed questionnaire; Office visit and questionnaire; Office visit and physical exam; Office visit and phys. or bioch. measure; Office visit and performance test; Hospital records; Other; Not reported*
What method of blinding was used for this outcome measure?	Drop-down box: *No Blinding; Rater/Physician Blinding Only; Patient Only; Double Blinding; Not reported*
Was a multivariate test used to analyze this outcome measure?	Check box: *Yes or No, was this type of analysis calculated and reported*

Describe the multivariate analysis	*Describe the multivariate analysis and what variables were compared.*

Multiple Measurements After Treatment

Were multiple measurements post-treatment reported?	Check box: *Yes or No*
Was the timing of multiple measurements after treatment fixed or not-fixed?	Drop-down box: *Fixed or Not-fixed*
Describe the timing of multiple measurements after treatment	*How long and how often were the outcomes measured after treatment began*

Reported Statistics for Outcome Measurements within Clinical Trials

Standard Input Form for Reported Statistics and Calculated Effect Sizes for Outcome Measurement Table

This form is used to record the reported statistics for outcome measurements. Each outcome measurement will entered in the same table and form in the database. Entries (rows) are made for each patient group comparison for each outcome reported in the publication at each time point a comparisons was made.

First column: What appears in the form **Second column: What should be entered in the database**

Trial and Outcome Identification Numbers

Unique ID Number for Trial Publication:	*Enter the Alex (Procite) number given to the publication, this number links all of the information from this trial entered in other data tables*
Trial and Outcome Measurement Number	*000000-00. This is a two part number. The first part is the Trial ID number. The second part is the Outcome Measure ID number. This number will be used again in the Outcome Measurement Table and Form to link the outcome measurement definition for a particular trial to the actual outcome measurement from that trial.*

Patient Groups Being Compared

Comparison within one Patient Group	Check box: *Yes; No. If this is a comparison of pre-treatment data to post-treatment data within a single patient group check Yes.*
Patient Group number for one group comparison	*Enter two part group number (trial number plus patient group number)*
Comparison between two patient groups	Check box: *Yes; No. If this is a comparison of data between two patient groups check Yes.*

First Patient Group in two group comparison	*Enter two part group number (trial number plus patient group number)*
Second Patient Group in two group comparison	*Enter two part group number (trial number plus patient group number)*
Time in months after treatment when comparison was made	*Enter time in months after treatment when outcome measurement was made for the groups being compared*
Type of statistical comparison being made	Drop-down box: *See attached list*
Type of statistical test used to evaluate the comparison	Drop-down box: *See attached list*
If statistical test is "Other" please give name	*Enter name of statistical test*
Description of comparison	*Describe as briefly as possible which patient groups are being compared and how.*

Reported Value of Comparison and Test Statistic

Enter only values that are reported in the publication. Do not calculate any new values.

Value of Comparison	*Enter the value of the statistical comparison given above*
Standard deviation of comparison	*Enter if reported or can be calculated*
Standard error of comparison	*Enter if reported or can be calculated*
Lower limit of 95% Confidence Interval	*Enter number*
Upper limit of 95% Confidence Interval	*Enter number*
Value of test statistic	*Enter number*

Is the exact or relative p value for the test statistic reported?	Drop-down box: *Exact; Relative*
P-value of test statistic	*Enter the exact value if reported. If the p-value is relative, enter one decimal place less than what is reported. For example, if the p-value is less than 0.05 enter 0.049; if the p-value is less than 0.01, then enter 0.009*
Power to detect a 25% difference	*Enter the analyst calculated power of the study to detect a 25% difference*
Power to detect a 50% difference	*Enter the analyst calculated power of the study to detect a 50% difference*
Comment on the statistical analysis used to evaluate this outcome measurement	*Direct comments at the appropriateness of the statistics and test used.*

Reported Results of Outcome Measurements within Clinical Trials

Standard Input Forms for Reported Results of Outcome Measurements Table

Three forms are available for entering data on treatment outcomes. A separate table and form is used for Continuous Outcome Measurements, for Non-dichotomous Scale Outcome Measurements, and for Dichotomous Outcome Measurements. Because the forms have similar information, they are all described in this section. A separate entry (row in the table) is made for each patient group within a trial and for each time period for which data on a specific outcome measurement are reported for a patient group. Entries indicated by # are specific for certain conditions and may not appear in all databases.

First column: What appears in the form	**Second column: What should be entered in the database**

Trial, Outcome Measurement, and Patient Group Identification

Unique Trial ID Number:	*000000. Enter the Alex number given to the publication, this number links all of the information from this trial entered in other data tables*
Unique Patient Group ID Number	*000000-00. This number is a combination of the Alex number followed by a dash and the patient group number (01, 02, 03, etc.) assigned by the analyst. This number links all of the patient group information entered in other data tables.*
Trial and Outcome Measurement Number	*000000-00. This is a two part number. The first part is the Trial ID number. The second number is the Outcome Measure ID number. This number was entered in the Outcome Measurement Table and Form to link the actual outcome measurement to the outcome measurement definition for a particular trial.*

General Information about Outcome Measurements:

This section is common to all three forms for recording treatment outcomes.

Number of patients evaluated	*Enter number of patients for which data on this outcome is reported for this time period*

Number of arms evaluated	*Enter number of arms, limbs, or other units for which data on this outcome is reported for this time period. The inclusion of this entry will depend on the condition or disorder being assessed.*
Was the outcome measurement reported for intent-to-treat or completed protocol patients (available for analysis)?	Drop down box: *Intent-to-treat; Completed protocol*
Is this pretreatment baseline data for this patient group?	Check box: *Yes or No*
Is this longest followup data for this patient group?	Check box: *Yes or No*
Time in months when outcome was measured	*Enter the time in months after treatment started when the outcome was measured. If these are pretreatment/baseline data, enter 0 in this box. Use 30.5 days per month for conversion of days to months.*
Standard deviation of outcome measurement time	*Enter number if reported or can be calculated using the data reported in the trial*
Standard error of outcome measurement time	*Enter number if reported or can be calculated using the data reported in the trial*
Lower limit of 95% confidence interval for time of measurement	*Enter if reported or can be calculated using the data reported in the trial*
Upper limit of 95% confidence interval for time of measurement	*Enter if reported or can be calculated using the data reported in the trial*
Minimum measurement time	*Enter if reported*
Maximum measurement time	*Enter if reported*

Continuous Outcome Measurements:

Only enter what is reported in the publication. Do not enter any calculations made by the analyst

Was the outcome measurement reported as Mean or Median?	Drop-down box: *Mean; Median*
Reported outcome measurement	*Enter mean or median outcome measurement if reported*
Standard deviation of outcome measurement	*Enter if reported or can be calculated using the data reported in the trial*
Standard error of outcome measurement	*Enter if reported or can be calculated using the data reported in the trial*
Lower 95% confidence limit of outcome measurement	*Enter if reported or can be calculated using the data reported in the trial*
Upper 95% confidence limit of outcome measurement	*Enter if reported or can be calculated using the data reported in the trial*
Minimum outcome measurement	*Enter if reported*
Maximum outcome measurement	*Enter if reported*

Non-dichotomous Scale Outcome Measurements:

The description of how patients were rated A, B, C, D, E, or F is entered in the Outcome Definition Table and Form. The 'A' category is used for the best outcome and 'F' for the worst outcome. See the Outcome Definition Table and Form for examples of how these scales can be recorded in the database.

Number of Patients rated A	*Enter if reported*
Number of Patients rated B	*Enter if reported*
Number of Patients rated C	*Enter if reported*
Number of Patients rated D	*Enter if reported*
Number of Patients rated E	*Enter if reported*
Number of Patients rated F	*Enter if reported*

Dichotomous Outcome Measurements:

The definition of how patients were considered successful is entered in the Outcome Definition Table and Form

Number of patients considered to have a successful treatment outcome	*Enter if reported*