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Total Knee Replacement

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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. This report on Total Knee Replacement was requested and funded by the Office of Medical Applications of Research, National Institutes of Health. 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 Outcomes and Evidence, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850.

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Structured Abstract

Context: The projected growth in the population with arthritis is likely to expand the future demand for elective arthroplasty. At present, there is no strong empirical base for the indicators in current use for what criteria should be used to identify potential candidates for Total Knee Arthroplasty (TKA)[a]; nor is there professional consensus around such indications. An NIH consensus conference has been planned to address these questions. This report summarizes the literature as part of the background for that conference.

Objectives: A systematic review of the literature was undertaken to address four questions:

1. What are the current indications for, and outcomes from, primary total knee replacement?
2. How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors, affect the short-term and long-term outcomes of primary total knee replacement?
3. Are there important perioperative interventions that influence outcomes?
4. What are the indications, approaches, and outcomes for revision total knee replacement?
5. What factors explain disparities in the utilization of total knee replacement in different populations?
6. What are the directions for future research?

Data Sources: The primary TKA literature search was performed by the National Library of Medicine, which searched PubMed from 1995 to April 2003. The access search was done using PubMed and covering the period from 1990 through April 2003. The literature search on revisions was done in two stages. A prior Medline search covering the period from 1996 through 2000 was the basis for a meta-analysis. An updated search using PubMed covered 2001 through April 2003.

Study Selection: The nature of this topic required heavy reliance on observational studies. The major criteria for identifying studies for inclusion in the indications for TKA search required that they address primary TKAs, have at least pre and post surgery data using at least one of four standard functional measures (Knee Society [KS] score, Hospital for Special Surgery [HSS] score, WOMAC, or SF-36), have a sample size of at least 100 total knee replacements, be published in English, and utilize tricompartment TKA. Sixty-two studies met the full inclusion criteria. The selection of studies on access required that they examine the relationship of at least gender or race to the performance of primary TKAs. Six articles were included. The same inclusion criteria applied to primary TKAs were applied to the update of the TKA revision study. Fourteen articles met the criteria.

[a] We use the term total knee arthroplasty instead of total knee replacement because the abbreviation is frequently confused with total knee revision.

Data Extraction: Data were abstracted by trained abstractors using a standardized abstraction tool that had been pilot tested and reviewed by the Technical Expert Panel. For the indicators search, the original abstractions were reviewed to assure reliability. All articles meeting the inclusion criteria were independently re-reviewed by each of the three principals. Information related to study and patient characteristics, baseline and followup functional status measures, perioperative complications, and revision rates were extracted using a standardized abstraction tool that had been pilot tested. The access data was abstracted by a subset of the original abstractors using another standardized tool. The TKA revision update was abstracted by an abstractor and one principal using a modification of the primary TKA tool.

Data Synthesis: Both TKA and total knee arthroplasty revision (TKAR) are associated with improved function. The strongest evidence exists over a followup period of up to two years, but the studies that extend to five and even ten years of followup show positive results as well. The average age of patients undergoing TKA in these reports was 70 years with few over aged 85. Two -thirds were female, one third were considered obese, and nearly 90% had osteoarthritis. No studies provided data on racial/ethnic status. The mean effect size (expressed as numbers of standard deviations) is considered large in magnitude and varies from 1.6 to 3.9 depending on the functional measure used and the duration of followup. There is no evidence that age, gender, or obesity are strong predictors of functional outcomes. Patients with rheumatoid arthritis show more improvement than those with osteoarthritis, but this may be related to their poorer functional scores at the time of treatment and hence the potential for more improvement. The revision rate through five or more years is 2.0% of knees and 2.1% of patients. Complications as defined by the investigator occurred in 5.4% of patients and 7.6% of knees. Patients with rheumatoid arthritis show more improvement than those with osteoarthritis. With regard to access, nonwhites receive TKAs less often than whites despite higher rates of osteoarthritis. Women receive TKAs more often than men, but the pattern is not as consistent as with race. TKA revisions are associated with consistent improvement in function on an order of magnitude similar to primary TKAs.

Conclusions: In general, the outcomes research on TKAs emphasizes before and after studies that are variations on case series of various techniques and prostheses with little attention to the role of other factors or to attrition. Although demographic and clinical factors are recorded, they are rarely used in the analysis. A consistent body of evidence suggests substantial improvement in function associated with TKA and TKAR. The follow-up periods vary but the mean is greater than five years. More informed decision making about indicators for TKAs will require stronger research designs. These need to be planned as prospective studies with multivariate analysis. Such analyses will require larger samples and more consistent and comprehensive data collection than was found in this review.

Contents

Evidence Report

Chapter 1. Introduction 1

Chapter 2. Methods and Analytic Framework 11
TKA Indicators 12
TKA Access 13
TKA Revisions 13

Chapter 3. Results 17
Baseline Characteristics of Patients 17
What is the Magnitude of Effect of Primary TKA? 18
Revisions and Complications 19
What are the Correlates of Functional Outcomes? 20
Does Access to TKA Vary with Race and Gender? 21
Total Knee Arthroplasty Revisions (TKAR) (Summary and Update of the Systematic Review by Saleh et al., 2002) 22
Does TKAR improve GKS and is this improvement related to preoperative disease severity? 23
Do patients undergoing multiple TKARs have more severe disease as judged by preoperative GKS scores compared with single TKAR cohorts? 23
Do outcomes vary between multiple and single TKAR groups as measured by KS or HSS? 24
What proportion of TKAR subjects attain excellent/good (E/G) results postoperatively as measured by GKS? Do results vary between the multiple and single knee cohorts, length of followup, or presence of infection as the proximate cause for revision? 24
What is the complication rate following TKAR? 24
Updated findings of the TKAR report 25

Chapter 4. Discussion 75
Research Recommendations 77
Lessons Learned 78
Research Agenda 80

References and Included Studies 83

Listing of Excluded Studies 89

List of Acronyms/Abbreviations 115

Appendixes

Appendix A. Measurement Scales
Hospital for Special Surgery score (HSS) 121
Knee Society (KS) score 123
Western Ontario and MacMaster University (WOMAC) Osteoarthritis Index 131
Appendix B. Technical Expert Panel Members and Reviewers 135
Appendix C. Exact Search Strings
Search Strings for Total Knee Arthroplasty (TKA) Scores 139
Search Strings for Total Knee Arthroplasty Access 141
Search Strings for Total Knee Arthroplasty Revisions 142
Appendix D. Abstracting Form 145
Appendix E. Functional Outcome Following Total Knee Arthroplasty Revision: A Meta Analysis (Saleh et al.) 163
Appendix F. Evidence Tables
Evidence Table 1. Primary TKA studies with at least a pre/post design 187
Evidence Table 2. Basic information for calculating revision rates 197
Evidence Table 3. Basic information for calculating complication rates 201

Tables

Table 1 Studies of beliefs about indications, referrals, and thresholds for total knee arthroplasty 4
Table 2 Summary of studies of clinical agreement about patient factors for either referral or surgery (set at >90% for significant agreement) 8
Table 3 Descriptive statistics on 62 studies 27
Table 4 Mean followup duration according to functional assessment scale (in months) 28
Table 5 Weighted baseline and followup scores for TKA outcomes measures 29
Table 6 Functional outcomes by measure and followup interval based on number of subjects 30
Table 7 Functional outcomes by measure and followup interval based on number of knees 37
Table 8 Meta analysis for HSS 42
Table 9 Meta analysis for KS 43
Table 10 Meta analysis for WOMAC 45
Table 11 Meta analysis for SF-36 46
Table 12 Revision rates after primary TKAs 47
Table 13 Assessmentg of TKA prostheses and surgical procedures 48
Table 14 Asessment of TKA procedures/programs 55
Table 15 Complications: Prevention of Venous Thrombosis (VT)/Pulmonary Embolism (PE) studies 57
Table 16 Complications: Prevention of infection studies 59
Table 17 Complications: Tourniquet studies 60
Table 18 Number of studies that include potential correlates of function 61

Table 19 TKA outcomes scores based on age, gender, BMI-index/obesity, and type of arthritis 62
Table 20 TKAR studies using multiple regression modeling 63
Table 21 Gender/racial disparities in total knee arthroplasty studies 65
Table 22 Summary of race and gender effects on TKA rates 67
Table 23 Updates on total knee revision studies 68
Table 24 Potential study questions 81

Figures

Figure 1 TKA article inclusion/exclusion flow chart 15
Figure 2 Mean increase in Knee Society scores (postoperative less preoperative scores) as a function of postoperative followup (months) for subjects undergoing TKA revision surgery 72
Figure 3 Mean increase in Hospital Special Surgery scores (postoperative less preoperative scores) as a function of postoperative followup (months) for subjects undergoing TKA revision surgery 72
Figure 4 Proportion of subjects undergoing TKA revision surgery in each cohort self-rated as excellent or good as a function of postoperative followup (months) 73

Appendixes and Evidence Tables are provided electronically at http://www.ahrq.gov/clinic/epcindex.htm

Agency for Healthcare Research and Quality

Evidence Report/Technology Assessment

Number 86

Total Knee Replacement

Summary

Introduction

Total knee arthroplasty is one of the most common orthopaedic procedures performed. In 2001 171,335 primary knee replacements and 16,895 revisions were performed.[1] Throughout this report we use the term total knee arthroplasty (TKA) in lieu of total knee replacement because the abbreviation for the latter may be readily confused with total knee revision. Because these procedures are elective and expensive (Medicare paid approximately $3.2 billion in 2000 for hip and knee joint replacements) and because the prevalence of arthritis is expected to grow substantially as the population ages,[2, 3] these procedures are likely to come under increasing scrutiny.

Previous reports suggest that TKAs improve functional status, relieve pain, and result in relatively low perioperative morbidity.[4] However, based on conclusions from consensus panels or surveys of health care providers, there is considerable disagreement about the indications for the procedure; that is, which patients are most likely to benefit from TKA and, conversely, in which patients is TKA contraindicated or of low value.[5-10] This evidence report, which was commissioned for an NIH Consensus Development Conference on Total Knee Replacement, was designed to systematically review, analyze, and discuss empirical data on Total Knee Replacement, to help inform the deliberations of the Consensus Panel.

In collaboration with the Office of Medical Applications of Research (OMAR), the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and the TKR Planning Committee, the Agency for Healthcare Research and Quality (AHRQ) defined the work to be performed for a comprehensive evidence report on the indications for primary TKR and revisions. The scope of the project specified that it address the following key questions regarding total knee arthroplasty:

1. What are the current indications for, and outcomes from, primary total knee replacement?
2. How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors, affect the short-term and long-term outcomes of primary total knee replacement?
3. Are there important perioperative interventions that influence outcomes?
4. What are the indications, approaches, and outcomes for revision total knee replacement?
5. What factors explain disparities in the utilization of total knee replacement in different populations?
6. What are the directions for future research?

Methods

Literature Review and Meta-Analysis

To address the first key question about the indications and outcomes of TKAs, the National Library of Medicine staff conducted a systematic literature review from 1995 to April 2003.

The titles and abstracts of the resulting 3,519 references were then screened, using our inclusion criteria (primary total knee arthroplasty studies; more than 100 knees per study; baseline data and

post-op outcomes data provided; experimental or quasi-experimental study design, English language, tricompartment).

All articles that appeared to meet the screening criteria were abstracted by trained abstractors. Of the original results, 611 references either met the inclusion criteria or needed further screening of the full article to determine if they met inclusion. Of these, 62 studies reported pre- and post-TKA functional data using at least one of the four established measures we relied on (Knee Society score, Hospital for Special Surgery score, WOMAC, or SF-36).[11-74] All but 15 studies were conducted in the United States or Canada.

One of the problems that made summarizing this area difficult was the inconsistent use of patients and knees as the unit of analysis. The reason for this practice is related to the performance of bilateral procedures, either simultaneously or sequentially, but the result is an inconsistent count. Some studies provide both units; some only one. For some types of analysis knees seem like the best measure, but for many (including function and demographics) the data apply more reasonably to patients. Wherever feasible, we present the analysis using both patients and knees.

To address key question 2 regarding prosthesis material/design or surgical factors we analyzed studies that fell within our original search parameters. We attempted to classify a study as primarily addressing either the use of a specific type of prosthesis or testing a specific surgical procedure or technique. Specific characteristics of the patient that may affect outcomes are addressed as noted in the main analyses and reported under "Outcomes of Primary TKA."

We limited our analysis of evidence to assess important perioperative interventions that influence outcomes (key question 3) to studies published since 1994. All were randomized controlled studies with the exception of one large cohort study. We categorized interventions as: prophylaxis for postoperative deep venous thrombosis/pulmonary embolism or infection. Several other procedures involved non-surgical elements of care.

We conducted a meta-analysis on the functional outcomes data. Because the data at baseline and followup was not consistent, we selected the model with random effects to simplify the interpretation. Because we did not have precise information from all studies, we treated each pre and post pair as if they were separate data sets.

In addressing key question 4, about the outcomes of TKA revisions, we relied heavily on the meta-analysis recently completed by one of the principals, which covered the period from 1966 through 2000.[75] To update this meta-analysis, a literature search was undertaken to assess the status of the literature relating to revision total knee arthroplasty after (and including) the year 2000. The literature search was done via PubMed® using a strategy based on the search described in the previously published meta-analysis; 14 new studies were uncovered.[76-89]

To answer key question 5, about the evidence for access differences (disparities in utilization) related to race and gender, we conducted a literature search via PubMed from 1995 to 2003. This search resulted in 176 references. Titles and abstracts of the references were reviewed, and 23 met preliminary inclusion criteria (primary total knee arthroplasty studies; more than 100 knees per study; gender/racial data provided; experimental or quasi-experimental design). Of these, three met inclusion criteria for analysis.[90-95] Additionally, reference lists from the above articles, and from articles recommended by colleagues, were searched. Three additional articles were found and included in the analysis.

Results

Outcomes of Primary TKAs

On average the patients were approximately 70 years of age and very few of them were over age 85; about two-thirds were female; about one-third were considered obese (using a criterion of a BMI of 30 or higher). Nearly 90 percent of patients had osteoarthritis. We did not specifically address bilateral TKAs but did separate analyses by numbers of knees and numbers of patients.

The most commonly used functional measures were the Knee Society score (KS)[96] and the Hospital for Special Surgery scale (HSS).[97, 98] The WOMAC (Western Ontario and McMaster Universities) Arthritis Scale has only been used since 1991. The physical function component of the SF-36 is a generic functional outcomes measure, not specific to knees.

The KS is associated with longer followup periods, perhaps because it was in use earlier. For example, weighting for baseline patients the mean followup for KS and HSS is 66 and 67 months, compared to 45 months for WOMAC. However, weighting for baseline knees, KS has a mean followup of 90 months and WOMAC is 68 months, but HSS is only 61 months. The longest mean followup time was 90 months (KS scores weighted for baseline knees), well less than the 10 years that has been suggested in order to evaluate long term functional results. Only ten studies had a followup time of at least 10 years.

Some information on attrition rate was reported for 49 studies. Of these the median percentage of subjects lost to followup was 2 percent, the range was 0-28 percent. If death is added to the definition, the range increases to 0-56 percent with a median of 12 percent.

Although there is no formal basis for translating the size of the scores, the generally accepted rule of thumb for the KS and HSS scales is that a score of less than 60 is considered poor; 60-69 represents a fair result; 70-84 is considered a good result; 85-100 is considered an excellent result.

The functional scores after TKA are consistently higher. The mean effect size (defined as the number of standard deviations of change from baseline scores) for the HSS studies is 3.91 for those with followup up to 2 years, 3.01 for those 2-5 years, and 2.97 for those studies with more than 5 years of followup. For the studies using KS the mean effect size is 2.35 for those 0-2 years, 2.73 for those 2-5 years, and 2.67 for those 5+ years. For WOMAC studies the mean effect size for 0-2 years of followup is 1.62. The more generic SF-36 scores had the smallest mean effect size; for the studies with 0-2 years of followup it was 1.27.

When the unit of analysis was numbers of knees operated on, the perioperative complication rate (defined as occurring within 6 months of the TKA) was 5.4 percent; when the denominator was numbers of patients, the rate was 7.6 percent. The revision rate through 5 or more years is 2.0 percent of knees and 2.1 percent of patients.

We differentiated "indications for TKA" from "correlates or factors related to outcomes." The former addresses what factors are needed to warrant a TKA (or conversely, what factors are contraindications to TKA either because the procedure is ineffective, unnecessary, or places the patient at unacceptably high perioperative risk); whereas the latter addresses whether outcomes vary according to the clinical or demographic factors. To address indicators would require a design that compared the outcomes of persons with the potential indicator with and without surgical treatment. However, it is possible to examine the potential for contraindications by examining only those who receive arthroplasties.

The number of studies that employed any analytic technique examining the functional outcome in terms of at least one independent variable of interest was limited. Only 12 of the 69 studies used any analysis that directly assessed the relationship of these patient variables to a change in functional status.[22, 23, 25, 28, 32-34, 37, 43, 64, 70] Age, obesity, or gender do not seem to be significantly correlated with TKA outcomes. Whether outcomes vary according to arthritis type is unclear. Patients with rheumatoid arthritis seem to show more improvement than those with osteoarthritis but they have lower level of function preoperatively and few studies adjust for other risk factors such as obesity.

Types of Prostheses and/or Surgical Factors

Although the sampling approach was not specifically designed to search for all outcomes associated with using different types of prostheses or different surgical approaches, we did analyze the studies that fell within the search parameters. In some cases it was difficult to classify a study as primarily addressing either the use of a specific type of prosthesis or testing a specific surgical procedure or technique. Several studies reported prostheses that were used in specific types of procedures. A number of the studies of prostheses were case series that reported generally good results. A few tested the use of a prosthesis with a specific group of patients. The studies of procedures were a mixture of case studies and comparative studies.

Perioperative Interventions

TKA studies assessing prophylaxis for postoperative deep venous thrombosis (DVT) or infection were identified by searching the 611 references meeting and not meeting inclusion criteria. The Cochrane Library was also searched back to 1994. The investigators decided a priori to include only randomized controlled trials (RCTs) with the exception of large cohort studies. Fourteen studies were identified and extracted; nine DVT, three infection, and two tourniquet studies. All included studies were randomized controlled trials with the exception of one large cohort study.[99] One trial was identified through the Cochrane Library.[100]

Several other procedures, which involved primarily non-surgical elements of care, were also described. Three of these addressed the use of continuous passive motion as a rehabilitative approach; two studies were positive. The other two studies tested different clinical pathways and showed mixed results.

The review of randomized trials addressing prevention of venous thrombosis and pulmonary embolus uncovered several studies that tested various approaches to anticoagulation and other preventive techniques. Two studies suggest that compression ultrasonography is not justified. Two find drug therapy better than mechanical approaches. Several studies compared anticoagulant drugs and drug regimens.

Three randomized trials addressed infection prevention. Each compared alternative antibiotic regimens. Two randomized trials tested the use of tourniquets in performing TKAs. One concluded tourniquets were safe and the other that they did not reduce surgical complications.

Access

Six studies addressed TKA-related access issues according to race or gender.[90-95] Several of these studies included both hip and knee replacement surgery. The conclusions with regard to the differential treatment of women are mixed, but the preponderance of evidence suggests that women are almost twice as likely to undergo a TKA as men. The evidence regarding non-white groups is quite consistent. Non-whites receive TKAs about half as often as whites. Most of these analyses report simply the rate at which the procedures were performed, with no attention to the actual size or nature of the population at risk. The argument that the higher rates of TKAs in women may be due to the higher prevalence of arthritis among women does not apply to the study by Wilson, which examined only persons with arthritis. However, it is possible that the severity or type of arthritis (OA vs. RA) varied.

Conversely, the lower rates of TKAs among blacks occurred despite a higher prevalence of osteoarthritis in this group, suggesting that the prevalence of OA was not a mitigating factor. Most of the studies that address access relied on large administrative data sets, which did not contain detailed clinical data on which to base the indications for knee surgery.

Total Knee Arthroplasty Revisions

Like all biomedical devices, total knee replacements can fail over time. The primary factors believed to cause TKA failures (and thus require consideration for TKA revision-TKAR) include trauma, chronic progressive joint disease, prosthetic loosening, and infection of the prosthetic joint. Coincident with the increased incidence of primary TKA, there has also been an increase in the number of TKAR procedures.

The primary assessment of the outcomes of TKAR for this report is derived from a systematic review of the literature published through 2000 that was done by one of the principals. It used a global knee score (GKS) measure that included the HSS and the KS, each assessed along the same range from 0-100.

There was a large improvement in GKS scores following TKAR that was both statistically and clinically significant. The preoperative combined mean KS score was 35.4 (95% CI 30.7-39.9). There was an increase of 30.8 (95% CI 26.6-35.0) points to 66.2 (95% CI 61.8-70.2) points postoperatively ($p < 0.0001$). The preoperative mean HSS score was 51.5 (95% percent CI 48.9-54.1). There was an increase of 28.3 (95% CI 25.3-31.2) points to 79.8 (95% CI 76.4-83.1) points postoperatively ($p < 0.0001$).

Although there was no difference in age or gender between the multiple and single knee reports, there was a significant difference in preoperative HSS. Patients undergoing "multiple knee TKAR" had lower preoperative scores (multiple knee HSS = 49.5, 95% CI 45.9-53.2; single knee = 54.5, 95% CI 51.4-57.5; $p < 0.1$). These results suggest that the multiple knee cohorts may have more severe disease then subjects evaluated in single knee TKAR studies. In contrast, the preoperative combined mean KS score in the multiple knees group was higher (77.0, 95% CI 64.2-89.8) than the single knee group (59.85, 95% CI 45.2,-4.5), $p > 0.1$. There was no difference in the pooled change in either the KS or HSS from pre- and postoperative scores when comparing subjects undergoing multiple vs. single TKAR.

Forty-four of 46 (95.7 percent) cohorts reported complication data on 1683 subjects who incurred 443 complications (26.3 percent). It was not possible to determine which or how many complications occurred in any given patient or patient subset. There were a total of 217 knee complications in 1,683 subjects necessitating re-revision (12.9 percent).

Discussion

The basic observations can be summarized as follows:

- Both TKA and TKAR are associated with improved function. The strongest evidence exists over a followup period of up to two years, but the studies that extend to 5 and even 10 years of followup show positive results as well.
- The average age of patients undergoing TKA in these reports was 70 years with few over age 85. Two-thirds were female, one third were considered obese, and nearly 90 percent had osteoarthritis. No studies provided data on racial/ethnic status.
- The mean effect size (expressed as numbers of standard deviations) is considered large in magnitude and varies from 1.6 to 3.9 depending on the functional measure used and the duration of followup.
- There is no evidence that age, gender, or obesity is a strong predictor of functional outcomes.
- Patients with rheumatoid arthritis show more improvement than those with osteoarthritis, but this may be related to their poorer functional scores at the time of treatment and hence the potential for more improvement.
- The revision rate through five or more years is 2.0 percent of knees and 2.1 percent of patients.
- Perioperative complications as defined by the investigator occurred in 5.4 percent of patients and 7.6 percent of knees. The vast majority were "knee related" or deep venous thrombosis. There were only 8 cardiovascular or pulmonary complications reported among nearly 6,000 patients suggesting that these adverse effects were not fully addressed in this literature.
- There is reason to suspect selection effects in both the type of patients referred for TKA and those being reported in the literature as well as the attrition on followup. Hence, these findings must be interpreted with caution as the basis for clinical practice.
- TKA revisions show a similarly positive functional effect (with the same design limitations).

These conclusions are tempered by the limitations of the designs of many studies included in the analysis. Although osteoarthritis does not seem to be a predictor of outcomes, the results seem to be somewhat better for rheumatoid arthritis, but few of these studies simultaneously controlled for other aspects of the patients.

Overall, the scientific quality of the current evidence is weak. Only a handful of studies employed any form of multivariate analysis. The outcomes of orthopaedic surgery, like most other treatments, are the results of the treatments interacting with the characteristics of the patients. Real understanding will come about only when the analytic techniques can address both sets of variables simultaneously. The analyses that come from such studies will need to employ sophisticated statistical methods,

which can examine the effects of the patient characteristics on the outcomes of interest. Orthopaedic outcomes research has made considerable strides in the last decade. Much greater attention is now paid to using established outcomes measures. The next step in this progress is to employ more sophisticated research designs that incorporate patient characteristics into the analysis.

Because orthopaedic research will likely rely heavily on observational studies instead of RCTs, it will be important to use more robust methods of study design/analysis. Particular attention must be paid to ensuring that the cohorts remain intact. Greater efforts must be made to collect outcomes information on all participants, not just those who appear for followup visits. A substantial proportion of the studies reviewed were based on retrospective reviews of clinical records. Strong levels of evidence will require prospective designs that emphasize followup.

Research Recommendations

The current state of empirical work does not provide a strong basis for making clinical recommendations regarding indications for outcomes from TKA. As pressures mount for more discrimination in identifying subjects for elective surgery, better information will be needed. The ideal study design to answer questions about indications for surgery remains a randomized trial in which persons with advanced arthritis (or other potential joint problems) are randomly assigned to medical management or joint replacement. However, given the enthusiasm for joint replacement and the generally positive effects on function, it might be difficult to recruit subjects for such RCTs, even without the prospect of sham surgery. Thus, a major component of research into the effectiveness of joint replacement and the patient characteristics associated with better outcomes will be well done observational studies.

More attention needs to be paid to the independent variables (or risk factors) associated with clinically relevant outcomes. Adequate research designs will require the use of multivariate analysis. To generate the sample size needed for multivariate analysis, these studies will likely have to be cooperative ventures. Such a plan would also broaden their representation. They will require systematic collection of data on potential indicators and risk factors and active followup to maintain the cohort, even when the patients do not return for scheduled followup clinical visits.

Although many questions remain unanswered, a few major issues need to be addressed first:

- How long will the functional benefits of TKA last and when will revision surgery likely be needed?
- How much do outcomes vary by patient characteristics and surgical factors, including volume of these procedures performed? Is the volume effect related to the surgeon or the medical center? There is strong belief that volume of surgery in a center, and perhaps experience of the surgeon, is related to better outcomes, but the strength of this relationship has not yet been well established and may be artifactual.

Many of the basic questions posed for this review remain unanswered, such as:

- What are the effects of patient characteristics on outcomes?
- What is the effect of surgical technique on outcomes?
- How does the choice of prosthesis affect outcomes?
- What is the role of rehabilitation in affecting outcomes?

Availability of the Full Report

The full evidence report from which this summary was taken was prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Minnesota Evidence-based Practice Center, Minneapolis, MN, under Contract No. 290-02-0009. It is expected to be available in December 2003. At that time, printed copies may be obtained free of charge from the AHRQ Publications Clearinghouse by calling 800-358-9295. Requesters should ask for Evidence Report/Technology Assessment No. 86, *Total Knee Replacement*. In addition, Internet users will be able to access the report and this summary online through AHRQ's Web site at www.ahrq.gov.

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Evidence Report

Chapter 1. Introduction

Throughout this report the term total knee arthroplasty will be used in lieu of total knee replacement because the abbreviation of the latter term may be confused with total knee revision.

At present, approximately 43 million individuals suffer from arthritis. Because this condition becomes increasingly prevalent with advancing age,[1, 2] given the population projections, the Centers for Disease Control estimate that by 2030 over 41 million persons aged 65 and older will have arthritis or chronic joint symptoms.[3] In particular, arthritis of the knee and accompanying joint symptoms result in considerable morbidity, loss of functional status, independence, and quality of life. The high prevalence of arthritis in the population is reflected in the high cost of treatment, which has been estimated at $95 billion per year.[4] These figures do not include the additional costs due to lost job productivity. Treatment options are primarily designed to relieve pain and improve functional status.

Standardized instruments have been developed in order to assess the severity of the symptoms and evaluate outcomes related to treatment. For example, Callahan et al., defined a generic global knee score (GKS) as "an instrument that measured patient outcomes in the domains of pain, function, and range of motion and combined these domains in a summary scale."[5] Widely used scales include the Hospital for Special Surgery score (HSS),[6] Knee Society (KS) score,[7] and Western Ontario and MacMaster University (WOMAC) Osteoarthritis Index.[8] (Copies of these scales are shown in Appendix A.) These scales typically cover aspects of pain and function (usually emphasizing walking). The HSS and KS are completed by clinicians; the WOMAC and SF-36 are designed to be completed by patients. They are intended to provide a score of 0 to 100, where a higher score implies a better outcome. For at least the HSS and KS scores, less than 60 is considered poor pain and function status; 60-69 represents fair pain and function status; 70-84 is considered good; 85-100 is considered excellent pain and function status.

Treatment options include physical therapy, analgesic and/or anti-inflammatory medications, and surgical therapy. The primary surgical treatment for patients is replacement of the native knee joint with a prosthesis (Total Knee Arthroplasty—TKA). A wide variety of prostheses and surgical techniques have been utilized but all are considered under the category of TKA. Total knee arthroplasty is one of the most common orthopaedic procedures performed. In 2001 171,335 primary knee replacements and 16,895 revisions were performed.[9] Medicare paid approximately $3.2 billion in 2000 for hip and knee joint replacements. Because these procedures are elective and expensive and because the prevalence of arthritis is expected to grow substantially as the population ages, these procedures are likely to come under increasing scrutiny. By 2030, it is estimated that there will be an 85 percent increase in TKA.[10] With this growth in mind, as well as the uncertainty related to the indications for, and outcomes associated with TKA, the Minnesota EPC was asked to conduct a systematic review of the literature to address four specific questions:

1. What are the current indications for, and outcomes from, primary total knee replacement?
2. How do specific characteristics of the patient, material and design of the prosthesis, and surgical factors, affect the short-term and long-term outcomes of primary total knee replacement?

3. Are there important perioperative interventions that influence outcomes?
4. What are the indications, approaches, and outcomes for revision total knee replacement?
5. What factors explain disparities in the utilization of total knee replacement in different populations?
6. What are the directions for future research?

The Total Knee Replacement evidence report will help inform the deliberations of the Consensus Conference Panel.

Previous reports suggest that TKA improve functional status, relieve pain, and result in relatively low perioperative morbidity. A systematic review and meta-analysis of 130 studies evaluating 154 cohorts published in 1994 by Callahan and colleagues evaluated patient outcomes following tricompartmental total knee replacement. They noted that global rating scale scores improved by 100% for the typical patient and that 89% of patients reported good or excellent outcomes after a mean followup of 4.1 years. The weighted mean complication rate was 18.1% and the mean mortality rate per year of followup was 1.5%. The overall rate of revision during 4.1 years was 3.8%.[5]

However, based on conclusions from consensus panels or surveys of health care providers, there is considerable disagreement about the indications for the procedure (Tables 1 and 2); that is, which patients are most likely to benefit from TKA and, conversely, in which patients is TKA contraindicated or of low value. For example, there is substantial variation in opinion about the indications for surgery, among orthopaedic surgeons[11-13] or between orthopaedists and rheumatologists and family physicians,[14-16] The level of agreement for primary TKA indications is significantly higher among orthopaedists than among family physicians or among rheumatologists.[14] Efforts at achieving consensus have yielded mixed results. One study found some level of agreement among a consensus panel comprised of specialty and primary care physicians, an epidemiologist, and physiotherapist around criteria such as the patient's pain at rest, severity of functional impairment, problems with caregiving, and perceived likely improvement in function.[17] Another panel composed of varied specialties found a lack of evidence on which to base decisions, especially the lack of comparison with other forms of treatment including nonsurgical intervention strategies. However, they did propose three "useful variables for surgical decision making": 1) severity of joint damage as determined by pain at night, severity of pain and function; 2) other patient-related variables (eg, patient motivation and social impact of problems); and 3) the health care system and living environment (patient's socioeconomic status, availability of surgeons).[18]

Table 1 summarizes the studies that have examined physicians' beliefs about indications and contraindications for TKAs. Based on a survey of all orthopaedic surgeons in Ontario, Canada (n=325) surgeons' enthusiasm for performing TKAs was correlated with the rate of these procedures and the dominant modifiable determinant of regional variation utilization.[15] In order to understand reasons for variation in utilization TKA, Tierney et al surveyed orthopedists in Indiana (n = 280). Analysis was limited to 188 respondents who had cared for at least one patient with osteoarthritis of the knee in the prior two weeks. Persistent weight-bearing pain was the only factor positively affecting the decision to perform knee replacement (agreed to by at least 95% respondents). Interestingly, surgeons who reported more knee replacements in the prior year had significantly higher estimates of pain relief and functional improvement following surgery, and lower estimates of prosthesis infection and failure rates. However, measured factors only

explained 24% of the variation in self-reported knee replacement performance. The authors recommended that other factors such as access to orthopaedic surgeons performing TKA, decision making of referring physicians, and patient perceptions about knee replacement should be evaluated.[11]

Table 2 summarizes studies that sought areas of consensus about the indications for knee replacement surgery. As such, it is not evidence of effectiveness. Rather, it shows the areas of agreement for either referral to an orthopaedic surgeon or proceeding with TKA (defined as 90 percent or better consensus) across such studies. Pain is the overridingly consistent element. A larger number of contraindications were noted at least twice: peripheral vascular disease, alcohol or drug abuse, mental disorders, and local skin infection. The largest group of variables, however, (the area where less than 60 percent consensus was reached) included age greater than 80 years, nursing home residents, severe hip osteoarthritis, weak quadriceps, joint instability, obesity, septic knee arthritis, patients demanding a TKA, and painful feet. The level of agreement from study to study may be influenced by the techniques used to obtain consensus.

Chapter 2. Methods and Analytic Framework

This review has three major components, which correspond to the questions posed in the charter. The major effort was directed at examining the indications for (or at least the outcomes of) primary TKA. The second component is a report of a meta-analysis of total knee revisions, which has already been published,[21] and an update of the literature since that work was completed to be sure no new developments had affected the initial conclusions. The third component was a review of the literature on access to care, especially the effects of gender and age.

The principal analytic framework for the first review (the outcomes of primary TKA) was based on the fundamental principles of outcomes research.[22] The underlying model can be briefly expressed as:

Outcomes = f(baseline status, clinical factors, demographic factors, treatment)

In general, the goal of outcomes research is to identify the effect of treatment on outcomes, adjusting for the other factors that might affect outcomes. In this case, however, we use the same model to address the predictive role of various patient characteristics on outcomes when all are treated similarly. Interpreting this relationship is somewhat more complex because factors associated with good outcomes are not necessarily indications for treatment. For example, a person with no problems may have a very good outcome, but one would not want to treat such a patient. The true test of an indication for surgery is a factor that gets worse without treatment and better with it. In effect, one would want to randomly assign patients with the specified condition to receive either TKA or medical management and then compare the clinical course with and without the treatment under study. Those factors that produced the greatest difference associated with treatment would be the strongest indicators for such treatment.

Where randomized clinical trials are available, many of the relevant confounding clinical and demographic factors can be assumed to be randomly distributed, or they may be controlled by elements of the study design that specific inclusion and exclusion criteria, and thus any differences between two groups can likely be attributed to the intervention. However, in the absence of RCTs, as is the case in most of the orthopaedic literature, strong quasi-experimental designs are needed, wherein multivariate analysis is employed to isolate the effect of treatment and address issues related to selection bias. The literature review was thus initially targeted at identifying those studies that had at least the rudiments of such a design. However, given the studies uncovered, we were forced to revise our criteria to assess a broader array of studies that provided at least some baseline and followup information.

Based on consultations with the technical expert panel (members are shown as Appendix B) and discussion with OMAR, AHRQ, and the Chair of the Consensus Panel, we determined that functional measures would be used as the primary outcome measures. We identified several demographic and clinical variables of primary interest: age, gender, baseline status (with regard to pain and function), arthritis type, and body mass index/obesity. The analysis for demographic factor effects, which correspond to the question about access, was conducted separately.

TKA Indicators

The literature search strategy for clinical predictors of TKAs was developed in consultation with the National Library of Medicine, which conducted the search. The literature search was done using a combination of MeSH headings, keywords, and publication types shown in Appendix C.

The search was limited to studies published between 1995 and April 2003. This start date was chosen because a previous review was published in 1994.[5] Animal studies were excluded, as were non-English language references and references on unicompartmental (unicondylar) knee replacement. Although unicondylar knee replacements (UKR) share many features with total knee replacement (tricompartment), these studies were excluded from our search because UKRs have 1) more specific indication ie, unicompartmental tibio-femoral arthritis with minimal involvement of the patello-femoral and 2) different patient demographics, primarily male population, low activity, minimal deformity, and good range of motion. Additionally, indications for UKRs appear to be in a transition phase. Surgeons have only recently gained experience with this reportedly less invasive procedure. Thus it was felt too early to adequately assess outcomes.

The titles and abstracts of the resulting 3,519 references were then screened, using our inclusion criteria (primary total knee arthroplasty studies; more than 100 knees per study; baseline data and post-op standardized symptom scale outcomes data provided; experimental or quasi-experimental study design).

All articles that appeared to meet the screening criteria were abstracted by trained abstractors. Extracted data included study and patient characteristics, baseline and followup symptom scale scores, revision rates, and perioperative complications as defined by the authors and occurring within six months of surgery. This workforce included medical students, two review staff, an orthopaedics fellow and several volunteer orthopaedic surgeons. A 10 percent subsample of all the abstracts was reviewed independently by a second abstractor to assure consistency. All of the studies that met the minimal criterion of having pre- and post-surgery data were re-reviewed independently by all three of the study principals.

The abstracting form (see Appendix D) included a long list of potential prognostic factors, developed with the assistance of our technical advisory committee. These included co-morbidities, x-ray evidence of joint destruction, bone loss, extensor mechanism integrity, pre-operative range of motion, alignment, tibio-femoral angle, and ligament integrity, as well as the characteristics of the operating surgeon, such as volume and experience.

Of the original results, 611 references either met the inclusion criteria or needed further screening of the full article to determine if they met inclusion. The reasons for exclusions are shown in Figure 1, which traces the flow of the articles retained. Of these, 62 studies reported pre- and post-TKA functional data using at least one of the four established measures we relied on (Knee Society score, Hospital for Special Surgery score, WOMAC, or SF-36). All but 15 studies were conducted in the US or Canada.

One of the problems that made summarizing this area difficult was the inconsistent use of patients and knees as the unit of analysis. The reason for this practice is related to the performance of bilateral procedures, either simultaneously or sequentially, but the result is an inconsistent count. Some studies provide both units; some only one. For some types of analysis knees seem like the best measure, but for many (including function and demographics) the data

apply more reasonably to patients. Wherever feasible, we present the analysis using both patients and knees.

We conducted a meta-analysis on the functional outcomes data. Meta-analysis methodology assumes that to estimate the combined effect we compute the weighted mean of the results observed in different studies. In the simplest approach weights are based on the sample size but more sophisticated methods account for the precision of the studies and thus adjust for different standard deviations. The effects in this meta-analysis were normalized by dividing to combined standard deviation of two (baseline and followup) measures. Therefore the statistical results of the meta-analysis are expressed in the units of standard deviation and reported as an "effect size." An effect size greater than 1 SD is considered to be large in magnitude. An additional benefit of this approach is that various effects obtain the same measurement scale and therefore can be compared. In modeling the effects we could use either fixed or random effect models. Because the data at baseline and followup was not consistent, we selected the model with random effects to simplify the interpretation. This model assumes that all studies come from a common population. That is, if the sample size in each study were infinite, then the effect size in all studies would be identical and the standard error of the estimate would approach zero. Because we did not have precise information from all studies, we treated each pre- and post-pair as if they were separate data sets. This is a conservative approach. An analysis using pairs would have produced even more dramatic results. All calculations were implemented using the trial version of the Comprehensive Meta Analysis™ software.[23]

TKA Access

The literature search was done via PubMed using the combination of MeSH headings and keywords shown in Appendix C.

This search resulted in 176 references. Titles and abstracts of the references were reviewed, and 153 did not meet inclusion criteria (primary total knee arthroplasty studies; more than 100 knees per study; gender/racial data provided; experimental or quasi-experimental design, English language). Articles were pulled for the remaining 23 references, and, of those, three met inclusion criteria for analysis. Additionally, reference lists from the above articles, and from articles recommended by colleagues, were searched. Three additional articles were found and included in the analysis (total of six studies).

TKA Revisions

The bulk of this analysis relied on a meta-analysis recently completed by one of the principals, which covered the period from 1966 through 2000. A literature search was undertaken to assess the status of the literature relating to revision total knee arthroplasty after (and including) the year 2000. The literature search was done via PubMed using a strategy based on the search described in the previously published meta-analysis.[21]

The search consisted of the combination of MeSH headings and keywords shown in Appendix C.

The original search for articles for the total knee revision meta-analysis resulted in 2,780 references. After titles and abstracts were reviewed, 2,551 did not meet the inclusion criteria of

revision knee arthroplasty studies, more than five patients per study, report of any post-operative outcomes, and use of a global knee rating scale. Articles were pulled for the remaining 229 references. In the end, 58 articles with a total of 1,965 patients met the initial inclusion criteria. Forty-two articles comprising 45 unique patient cohorts and a total of 1,515 patients had sufficient global knee score data for analysis and were used in the meta-analyses. (Descriptive tables for these studies are shown as part of the original paper reproduced in Appendix E)

The meta-analyses of global knee scores were undertaken using a fixed effects model with the assumption that the variances of each individual measurement were identical across studies. This assumption was necessary because data on variances were not provided in most studies. The variance of the overall estimate was derived under this model using the between-study variability, yielding a 95 percent confidence interval for each overall estimate. A weighted average of the values in each study based on sample size at followup was used.

The updated search was limited to articles published from 2001-2003. This search resulted in 229 references. Titles and abstracts of the references were reviewed, and 168 did not meet inclusion criteria (revision knee arthroplasty studies; more than five patients per study; report of any post-operative outcomes; use of a global knee rating scale). Articles were pulled for the remaining 61 references, and, of those, 14 met inclusion criteria for analysis.

Chapter 3. Results

Baseline Characteristics of Patients

The 62 studies that had pre- and post-functional data using one of the four established outcome measures (ie, the Knee Society score, the Hospital for Special Surgery score, the WOMAC, or the SF-36) are summarized in Appendix F, Evidence Table 1. All were simple pre- and post-comparisons. Although various demographic information is provided to describe the sample, that data were rarely and inconsistently used in the reported analyses.

Table 3 presents a summary of selected patient and clinical characteristics. We used the full sample from each study whenever possible. Because of the variation in reporting practices here and elsewhere, the mean rates were calculated using means weighted separately on the basis of the numbers of knees and patients in the studies. The data here used weights for numbers of patients and knees, as well as the raw averages. The weightings made little difference. Two studies did not report the numbers of patients. The discrepancy between the numbers of patients and knees reported is an artifact of which studies reported knees.

The average age of patients was approximately 75 years. Very few were over 85; about two-thirds were female; about one-third were considered obese (using a criterion of a Body Mass Index (BMI) of 30 or higher). Nearly 90 percent of patients had osteoarthritis. One-third of subjects underwent bilateral TKA. None of the studies provided information regarding racial/ethnic status. We did not separately address outcomes for patients undergoing bilateral TKAs from those undergoing unilateral procedures. However, we conducted separate analyses by numbers of knees and numbers of patients.

The most commonly used functional measures were the Knee Society score and the Hospital for Special Surgery scale. A major factor in their greater usage is likely the fact that they have existed longer. The WOMAC Arthritis Scale is considered by many in the field to be a psychometrically better measure, but it has only been used since 1991.[8] The physical function component of the SF-36 is a generic functional outcomes measure, not specific to knees.

Table 4 presents the summary data on the mean duration of study followup periods according to the type of functional outcome assessment scale used. The results are shown using various approaches to weighting the numbers of cases used. They were weighted separately by the numbers of patients and the numbers of knees. Because there is substantial sample loss, we then divided each of these categories to weight by the numbers at baseline and at followup. Several studies used more than one scale. In comparison to the demographic data cited above, there is greater variation when the different weights are applied. When weighting by numbers of patients, the generic measure (the SF-36) was used for shorter followup periods. In general, determining the sample sizes at different points in time was difficult. A substantial number of studies failed to provide adequate data to identify how many patients (or knees) were available at followup.

The longer established measure KS score is associated with longer followup periods, perhaps because it was in use earlier, allowing more time to elapse for such followup. For example, weighting for baseline patients the mean followup for KS and HSS is 66 and 67 months, compared to 45 months for WOMAC. However, weighting for baseline knees, KS has a mean followup of 90 months and WOMAC is 68 months, but HSS is only 61 months. The longest mean followup time was 90 months (KS score weighted for baseline knees), well less than the

ten years that has been suggested in order to evaluate long term functional results. Only ten studies had followup time of at least ten years.

Some information on attrition rate was reported for 49 studies. Of these the median percentage of subjects lost to followup was 2%, the range was 0-28%. In five studies more than 10% were lost to followup. If death and other exclusions are added to the definition, the range increases to 0-56% with a median of 12%. Five studies had a total loss rate of more than 40%; another five lost 30-40%; and another seven studies lost 20-30%.

The issues of outcomes addressed here looked at only the aggregate outcome in the context of having had a TKA. No special efforts were made to distinguish the relative contribution of rehabilitation or type of procedure. Although the latter was the major focus of many studies, few actually compared alternative approaches.

What is the Magnitude of Effect of Primary TKA?

Table 5 summarizes the raw data on change from pre- to post-TKA functional scores (albeit with widely varying followup periods). In each scale the range has been defined as 0-100. In general, a higher score is better, although the WOMAC was standardized such that a lower score is better. In each case there is strong evidence of improved function (and decreased pain). Of the 46 studies using KS scores only 30 provided pre- and post-intervention results according to the number of subjects enrolled (n = 12,261 subjects) (27 provided this information based on number of knees (n = 15,454 knees). There were 17 studies using HSS scores (2,546 patients) Seven studies, representing 2,925 patients reported results with the WOMAC.

Table 6 shows the mean scores at baseline and followup for each of the four major scales, organized by length of followup, analyzed in terms of patients; Table 7 shows the same data analyzed by knees. Baseline scores were highest in studies using the HSS and lowest in studies using the KS. This may reflect differences in severity of pain and function among subjects enrolled in these studies. HSS scores improved by about the same order of magnitude for each followup period; baseline scores were in the mid 50s and followup scores were in the high 80s and low 90s. The same general pattern applied to the KS scores but the results were a little less dramatic. The baseline values were in the high 30s and low 40s and the mean followup scores were high 70s and low 80s. The WOMAC scores showed more variation; the studies addressing followup at less than five years showed baseline mean values in the high 40s and followup values in the 70s, but the single study with more than five years of followup showed a mean baseline of 58.2 and a followup mean score of 98.4. The SF-36 mean functional scores increased from the mid-20s to the mid 40s, a level that still shows substantial limitations. Although there is no formal basis for translating the size of a change in the scores, the generally accepted rule of thumb for the KS and HSS scales is that a score of less than 60 is considered poor; 60-69 represents a fair results; 70-84 is considered a good results; 85-100 is considered an excellent result.

Tables 8-11 display the effect size (defined as the number of standard deviations of change) for this same data. The functional scores after TKA are consistently higher. The mean effect size for the HSS studies is 3.91 for those with followup up to two years, 3.01 for those 2-5 years, and 2.97 for those studies with more than five years of followup. For the studies using KS scores the mean effect size is 2.35 for those 0-2 years, 2.73 for those 2-5 years, and 2.67 for those 5+ years. For WOMAC studies the mean effect size for 0-2 years of followup is 1.62. The more generic

SF-36 scores had the smallest mean effect size; for the studies with 0-2 years of followup it was 1.27 (though this is still considered a "large effect size"). The effect size is considerably higher for those studies where the clinician reports the results compared to those where patient reports are used.

Revisions and Complications

Revision rates were calculated in several ways. The basic data are shown as an evidence table in Appendix F, Evidence Table 2. Table 12 summarizes the revision rates for primary TKAs. The results are organized to show the rates at different followup intervals and are grouped by both knees and patients. The revision rates are further subdivided into operations specified as revisions and all procedures performed on the knees in question. The revision rate through five or more years is 2.0 percent of knees and 2.1 percent of patients.

The data base used to calculate perioperative complication rates (defined as occurring within six months of the TKA) is shown in Appendix F, Evidence Table 3. Complications were defined by each investigator. The vast majority were "knee related" or deep venous thrombosis. When the unit of analysis was numbers of knees operated on, the complication rate was 5.4 percent; when the denominator was numbers of patients, the rate was 7.6 percent. There were essentially no cardiopulmonary complications reported. Given the number of elderly subjects undergoing a major surgical procedure this suggests that these adverse effects were not addressed in the literature.

Although the sampling approach was not specifically designed to search for all outcomes associated with using different types of prostheses or different surgical approaches, we did analyze the studies that fell within the search parameters. In some cases it was difficult to classify a study as primarily addressing either the use of a specific type of prosthesis or testing a specific surgical procedure or technique. Several studies reported prostheses that were used in specific types of procedures. Table 13 is arranged to attempt to classify the emphasis of studies by procedure or prosthesis, but some overlap is inevitable. A number of the studies of prostheses were case series that reported generally good results. A few tested the use of a prosthesis with a specific group of patients. The studies of procedures were a mixture of case studies and comparative studies.

TKA studies assessing prophylaxis for postoperative deep venous thrombosis (DVT) or infection were identified by searching the 611 references meeting and not meeting inclusion criteria. The *Cochrane Library* was also searched back to 1994. The investigators decided *a priori* to include only randomized controlled trials (RCTs) with the exception of large cohort studies. Fourteen studies were identified and extracted; nine DVT, three infection, and two tourniquet studies. All included studies were randomized controlled trials with the exception of one large cohort study.[24] One trial was identified through The *Cochrane Library*.[25]

Several other procedures, which involved primarily non-surgical elements of care, were also described. These are summarized in Table 14. Three of these addressed the use of continuous passive motion as a rehabilitative approach; two studies were positive. The other two studies tested different clinical pathways and showed mixed results.

The review of randomized trials addressing prevention of venous thrombosis and pulmonary embolus uncovered several studies that tested various approaches to anticoagulation and other

preventive techniques. These studies are summarized in Table 15. Two studies suggest that compression ultrasonography is not justified. Two find drug therapy better than mechanical approaches. Several studies compared anticoagulant drugs and drug regimens.

Table 16 summarizes three randomized trial that address infection prevention. Each compares alternative antibiotic regimens.

Table 17 shows two randomized trials that tested the use of tourniquets in performing TKAs. One concluded tourniquets were safe and the other that they did not reduce surgical complications.

What are the Correlates of Functional Outcomes?

We differentiated "indications for TKA" from "correlates or factors related to outcomes." The former addresses what factors are needed to warrant a TKA (or conversely, what factors are contraindications to TKA either because the procedure is ineffective, unnecessary, or places the patient at unacceptably high perioperative risk); whereas the latter addresses whether outcomes vary according to the clinical or demographic factors. The number of studies that employed any analytic technique examining the functional outcome in terms of at least one independent variable of interest was limited. Table 18 illustrates this point. (Indeed, the list may over-encompass in that it includes any analysis, whether or not the dependent variable came from one of the four functional measures assessed. Also, we counted instances where the analysis was alluded to, even if the results were not specifically shown.) It should be noted that the table is organized such that any study using a combination of variables will also be counted for an individual variable. Thus, a total of only 12 of the 69 studies used any analysis that directly assessed the relationship of these patient variables to a change in functional status. The descriptor most frequently used in an analysis was BMI, followed closely by age and the type of arthritis. In some instances, the report indicated an explored relationship but the specific statistical details of the analysis were not given.

Table 19 summarizes the results from the few studies that examined the relationship between patient characteristics and outcomes. Neither age nor obesity seems to be significantly correlated with TKA outcomes. In one small study, patients over age 80 (n=35) had similar improvement in pain, function, and stiffness after six month followup compared with patients less than age 80 (n=221) as evaluated by the WOMAC. Another study by Stickles (n=962) reported a trend toward greater improvement from baseline WOMAC with higher BMI (57 percent improvement from baseline for BMI >40 vs. 36 percent for BMI <25; p=0.08 for trend). In one study of 120 subjects, those with rheumatoid arthritis (n=81) had a greater percent improvement from baseline in HSS than those with osteoarthritis. However, most of these analyses examined only one independent variable at a time in simple bivariate analyses. For example, obese patients and those with rheumatoid arthritis had lower (worse) WOMAC scores compared with less obese patients or those with osteoarthritis. Therefore, improved scores at followup could be due to more severe disease preoperatively rather than the type of arthritis or presence of obesity. The few studies that did use more sophisticated statistical methods reported on followup results at one year or less but deserve further attention. Table 20 summarizes the five studies that used multiple regression analyses. All but the study by Hawker evaluated fewer than 300 subjects. The Jones study employed stepwise regression, which may eliminate variables whose contribution is accounted for by another variable.[26] They used separate models for the two

components of the WOMAC score. For pre/post change in pain the authors found no significant relationship for age, sex, and BMI at six month followup in patients with predominantly osteoarthritis. The significant patient predictor was preoperative bodily pain (from the SF-36). Other significant predictors were hospital length of stay and use of a cementless prosthesis. For change in function, the three patient factors (age, sex, BMI) were also not significant predictors. In this case, the significant predictors of function were length of hospital stay and preoperative pain, as well as preoperative joint pain and the number of comorbid conditions. That is, patients with a longer length of hospital stay, greater preoperative pain, and comorbid conditions had a larger improvement in function.

The study by Deshmukh employed hierarchical multiple regression but did not show the actual results.[27] In looking at changes in function and pain at 12 months post TKA as measured by the KS score, the authors controlled for age and sex. Their results indicated that BMI accounted for only a small amount of the explained variance.

Fortin et al. used multiple linear regression analysis to examine the effects of age and gender on WOMAC scores at six months.[28] There were no significant relationships between these characteristics for either pain or function.

A large study comprised primarily of Canadian women with osteoarthritis analyzed several sources of data in a stepwise multiple regression model with WOMAC scores as the dependent variable.[29] They found that age, gender, and BMI were not significant predictors of knee pain. However, a lower BMI did predict better physical function and greater satisfaction with the procedure.

The study by Konig used multiple linear regression analysis to assess KS scores at two years.[30] Age, gender, and BMI were not significantly related to pain or the overall KS scores. However, BMI did correlate with function.

Does Access to TKA Vary with Race and Gender?

The six studies that addressed TKA-related access issues according to race or gender are shown in Table 21. Several of these studies included both hip and knee replacement surgery. Most of the studies that address access relied on large administrative data sets, which did not contain detailed clinical data on which to base the indications for knee surgery. However, some of these studies had at least some clinical information on the underlying problems of the sample being studied. Dunlop used the AHEAD data set, which has self-reported conditions including arthritis.[31-33] Hawker identified persons with arthritis as the basis for their sample.[31] Wilson limited their study to Medicare beneficiaries with a diagnosis of osteoarthritis.[33]

The conclusions with regard to the differential treatment of women are mixed, but the preponderance of evidence suggests that women are almost twice as likely to undergo a TKA as men. The evidence regarding non-white groups is quite consistent. Non-whites receive TKAs about half as often as whites. Table 22 summarizes that evidence. With the exception of those by Hawker, Dunlop, and Wilson, studies address simply the rate at which the procedures were performed, with no attention to the actual size of the population at risk.[31-33] The results are often expressed as odds ratios, which compare the risk of one group receiving the procedure with that of another group. The argument that the higher rates of TKAs in women may be due to the higher prevalence of arthritis among women does not apply to the study by Wilson, which

examined only persons with arthritis. However, it is possible that the severity or type of arthritis (OA vs. RA) varied. Conversely, the lower rates of TKAs among blacks occurred despite a higher prevalence of osteoarthritis in this group, suggesting that the prevalence of osteoarthritis was not a mitigating factor. The study by Wilson looked at race and gender simultaneously. They report the odds ratio of race for TKA is almost the same for men (0.32) and women (0.37), and conversely the odds ratio of female gender for whites (1.26) is less than for nonwhites (2.57).

Total Knee Arthroplasty Revisions (TKAR)

(Summary and Update of the Systematic Review by Saleh et al., 2002)

Like all biomedical devices, total knee replacements can fail over time.[34] The primary factors believed to cause TKA failures (and thus require consideration for TKA revision-TKAR) include trauma, chronic progressive joint disease, prosthetic loosening, and infection of the prosthetic joint. Coincident with the increased incidence of primary TKA, there has also been an increase in the number of TKAR procedures.[35] In 2001 Medicare paid for 16,895 TKAR procedures.[9] The number of TKAR procedures is expected to continue to increase by approximately 14 percent annually as a result of complications associated with TKA, including infection, fracture, and time-dependent implant failure that necessitate re-operation.[36]

As noted earlier, information on indications differs from that for outcomes by requiring a broader set of observations with which to distinguish the clinical outcomes for those treated and untreated. Unfortunately, the data for TKAR is even more limited than for primary TKA. There are limited long-term TKAR outcome data reporting knee specific or global knee scores. Callahan et al defined a generic global knee score as "an instrument that measured patient outcomes in the domains of pain, function, and range of motion and combined these domains in a summary scale."[5] Examples of such scales include the Hospital for Special Surgery score (HSS) and Knee Society (KS) score. However, we also grouped over 30 other knee instruments that measure the same domains that under the same heading.

The primary assessment of the outcomes of TKAR for this report is derived from a systematic review of the literature published through 2000 that was done by one of the principals (shown as Appendix E). Additionally, we updated this report with articles published through June 2003. The objective of the original systematic review was to describe patient outcomes following TKAR procedures using GKS ratings. English Language articles published from 1966 through 2000, were identified through a computerized literature search and bibliography review. The specific aim was to describe patient outcomes following TKAR procedures by using GKS to address the following questions:

- Does TKAR improve function as measured by increase in GKS?
- Is there correlation between outcomes and preoperative disease severity as measured by GKS?
- What proportion of TKAR subjects attains excellent/good (E/G) postoperative results and what proportion attains satisfactory/poor (S/P) results?
- Does the proportion of subjects with E/G results, or the postoperative HSS score / KS score, vary with the length of followup, the year of study publication, or preoperative diagnosis (i.e., infection, loosening, etc.)?

- Is there a difference between the multiple and single knee revision cohorts in the percentage of subjects that attain E/G postoperatively?
- Is there a difference between the multiple and single knee revision cohorts in the preoperative HSS or KS scores or the score increases?

We report a summary of the results from the original systematic review and then describe findings from our review update of new articles published between 2000 and June 2003.

Does TKAR improve GKS and is this improvement related to preoperative disease severity?

There was a large improvement in GKS scores following TKAR that was both statistically and clinically significant. As noted earlier, the KS score can be subdivided into pain and function subscores. The preoperative *combined* mean KS score was 35.4 (95% CI 30.7-39.9). There was an increase of 30.8 (95% CI 26.6-35.0) points to 66.2 (95% CI 61.8-70.2) points postoperatively ($p < 0.0001$). The preoperative *functional* mean KS score was 30.4 (95% CI 22.8-37.9) with an increase of 27.0 (95% CI 21.8-32.2) points to 57.4 (95% CI 51.6-62.7) points postoperatively ($p < 0.0001$); the preoperative *clinical* mean KS score was 32.8 (95% CI 25.5-40.0) with a highly significant increase of 42.1 (95% CI 39.2-45.0) points to 74.9 (95% CI 68.6-80.8) points postoperatively ($p < 0.0001$). The latter two subscales were on a subset of the 15 studies on which combined results could be calculated. The preoperative *mean* HSS score was 51.5 (95% percent CI 48.9-54.1). There was an increase of 28.3 (95% CI 25.3-31.2) points to 79.8 (95% CI 76.4-83.1) points postoperatively ($p < 0.0001$). However, we found no significant correlation between the preoperative score and the amount of improvement in either the overall KS ($r = -0.09$, $p > 0.7$) or the HSS ($r = -0.263$, $p > 0.3$) studies suggesting that improvement in symptoms were not associated with preoperative knee status.

Do patients undergoing multiple TKARs have more severe disease as judged by preoperative GKS scores compared with single TKAR cohorts?

Although there was no difference in age or gender between the multiple and single knee reports, there was a significant difference in preoperative HSS. Patients undergoing "multiple knee TKAR" had lower preoperative scores (multiple knee HSS = 49.5, 95% CI 45.9-53.2; single knee = 54.5, 95% CI 51.4-57.5; $p < 0.1$). These results suggest that the multiple knee cohorts may have more severe disease then subjects evaluated in single knee TKAR studies. In contrast, the preoperative combined mean KS score in the multiple knees group was higher (77.0, 95% CI 64.2-89.8) than the single knee group (59.85, 95% CI 45.2,-4.5), $p > 0.1$. This result, however, was heavily influenced by a very low preoperative combined score of 32.8 (25.5-40.0) in one large study (n = 574 subjects or 598 knees).[37]

Do outcomes vary between multiple and single TKAR groups as measured by KS or HSS?

There was no difference in the pooled change in either the KS or HSS from pre- and postoperative scores when comparing subjects undergoing multiple vs. single TKAR ([KS multiple knee = 60.0, 95% CI 49.4-70.5; KS single knee = 64.4, 95% CI 50.3-78.5; nine studies and 953 patients/1,001 knees. [HSS multiple knee = 28.9, 95% CI 25.5-32.3; single knee HS = 27.2, 95% CI 22.5-32.0; ten studies and 1,010 patients/1,050 knees. The mean difference in both GKS increased over time up to around 60 months. Thereafter KS (Figure 2) and HSS marginally declined (Figure 3).

What proportion of TKAR subjects attains excellent/good (E/G) results postoperatively as measured by GKS? Do results vary between the multiple and single knee cohorts, length of followup, or presence of infection as the proximate cause for revision?

The percentage of subjects undergoing TKAR who attained a self-reported E/G result postoperatively was 77.7% (95% CI 75.2-80.2). In studies reporting on cohorts where some subjects had both knees revised the percentage of subjects attaining E/G was 72.7% (95% CI 69.5-76.3). In comparison, in studies where no subjects had multiple knees revised, the proportion of E/G was 82.6% (95% CI 79.1-86.3) $p < 0.05$).

Patients undergoing single TKAR had better postoperative scores than those receiving multiple TKAR. Additionally, the percentage of subjects reporting E/G results increased over followup duration until approximately 60 months (Figure 4). There was a difference in the proportion of subjects reporting an E/G outcome between articles in which a higher percentage of patients with infection as the proximate cause for revision as compared to those in which fewer patients were infected ($p < 0.05$). Series reporting outcomes from uninfected patient had a higher proportion of subjects with E/G outcomes compared to subjects from "infected series" (percent E/G uninfected = 78.5%; 95% CI 74.7%-82.3%; % E/G infected = 67.5%; 95% CI 61.5%-73.4%).

What is the complication rate following TKAR?

The results from our systematic review (as well as a previous review by Callahan and colleagues) demonstrate that the revision rate after about four years of primary TKA is approximately 3-4%. Forty-four of 46 (95.7%) cohorts reported complication data on 1,683 subjects who incurred 443 complications (26.3%). It was not possible to determine which or how many complications occurred in any given patient or patient subset. There were a total of 217 knee complications in 1,683 subjects necessitating re-revision (12.9%). Using a broad definition of complications, Callahan et al. found a 30% overall complication rate and a 7.2% revision rate in 18 bicompartmental knee arthroplasty reports with 884 enrolled patients and an 18.5% overall complication rate and a 9.2% revision rate in 46 unicompartmental knee arthroplasty (UKA) reports with 2,391 enrolled patients.[38]

Updated findings of the TKAR report

We updated the previous review by Saleh et al. to include articles published from 2000 through June 2003. An additional 27 articles were identified of which 14 (n = 638 knees) met inclusion criteria. They are summarized in Table 23. The updated findings do not alter the conclusions of the original report just described. They do add additional information related to various types of revision knee systems or surgical procedures. Descriptions of the individual reports are provided below.

Two articles assessed the effectiveness of polyethylene exchange as an isolated revision procedure. Brooks et al. assessed the effectiveness of isolated polyethylene exchange in revision TKA for tibiofemoral instability.[39] Based on 14 cases, the authors found the procedure to be an effective, low morbidity treatment to treat one type of prosthetic knee instability. Achievement of a successful result with this technique occurs with competent balanced ligaments. Patients with incompetent ligaments or with a significant flexion extension mismatch are less likely to achieve a successful result. Babis et al assessed the results of isolated tibial insert exchange during TKAR in 55 patients (n=56 TKAR).[40] The study demonstrated that isolated tibial insert exchange led to an unacceptably high early failure rate. The authors recommended that orthopedists proceed with caution in all cases in which isolated tibial insert exchange was being considered.

Miller et al. retrospectively compared UKA revision to TKA with a group of primary TKA.[41] The study revealed that UKA revisions had a higher incidence of wound infection and less improvement in Knee Society pain and function scores compared to primary TKA. In addition, the study suggested that posterior cruciate ligament (PCL) substituting designs were superior to posterior cruciate ligament sparing designs and had Knee Society pain and function scores that were comparable to the primary TKA group.

Christensen et al evaluated improvements in range of motion and Knee Society pain and function scores following revision TKA in 11 patients who presented with pain and limited range of motion.[42] The study results indicated that range of motion and Knee Society scores improved significantly following revision TKA.

Gofton et al evaluated the midterm results of revision knee procedures using a modular all-cobalt chrome stem in 97 TKARs.[43] The study compared posterior stabilized and varus/valgus constrained articular inserts. There were no differences in post-operative KS scores between the posterior stabilized and the varus/valgus constrained groups.

Nazarian et al retrospectively reviewed the results of TKAR using the Insall-Burstein constrained condylar knee implant used with and without intramedullary stems.[44] The study found no significant difference in Knee Society scores between the two above noted groups.

Three articles focused on the use of bone grafting in revision TKA. Lonner et al evaluated the short-term results of impaction cancellous allografting and molded wire mesh in the management of massive uncontained defects about the knee in revision TKA.[45] The authors found it to be an effective method of managing bone defects. Benjamin et al compared the KS scores of patients with and without morselized bone grafting used for tibial or femoral defects in patients undergoing revision TKA with one revision knee system.[46] The authors found no difference in preoperative or post operative knee scores between the two groups. They concluded that morselized bone grafting is a reasonable alternative in the reconstruction of osseous defects in patients undergoing revision TKA. Hanssen described a surgical technique for restoration of

patellar bone stock in patients with severe patellar bone loss undergoing revision TKA.[47] KS pain and function scores were improved in short to mid-term clinical results.

Two articles evaluated revision/resection of the patellar component in TKAR. Leopold et al followed 40 knees with a Miller Galante I prosthesis that underwent isolated patellar revision of TKA with or without lateral retinacular release.[48] After a mean followup of 62 months isolated patellar revision with or without lateral retinacular release was associated with an "unacceptably high rate of reoperation and a relatively low rate of success"; the gain in mean HSS score was only from 72 to 87. Parvizi et al undertook a study to evaluate the clinical and functional results of patellar component resection arthroplasty with or without revision of the tibial or femoral components for severely compromised patella for which insertion of another patellar component was not an option.[49] The study demonstrated that patients treated with isolated patellar component resection arthroplasty were more likely to require reoperation and experience persistent pain when compared with patients who had concomitant revision of the tibial and femoral components.

Werle et al. assessed the use of large (30mm) metal distal femoral augments to compensate for severe structural femoral metaphyseal bone loss in revision TKA.[50] The study found the technique to be "acceptable" as there were improvements in Hospital for Special Surgery scores, Knee Society scores and ROM upon compilation of intermediate term results (37 months).

Two articles assessed the use of a hinged prosthesis in revision TKA. Springer et al reviewed 69 knees treated with Kinematic Rotating Hinged Knee prosthesis for complex primary TKA and salvage revision TKA.[51] Based on the study results, the authors recommended that KRH arthroplasty be reserved for final salvage option of the treatment options available when performing complex primary and salvage revision knee arthroplasties. Jones et al undertook a retrospective study to delineate the success of S-ROM mobile bearing hinge total knee prosthesis for revision TKA.[26] The indication for TKA included severe instability and bone loss. The authors concluded that a satisfactory result can be achieved when using S-ROM mobile bearing hinge total knee prosthesis for the above indications.

Chapter 4. Discussion

The basic observations can be summarized as follows:

- Both TKA and TKAR are associated with improved function. The strongest evidence exists over a followup period of up to two years, but the studies that extend to five and even ten years of followup show positive results as well.
- The average age of patients undergoing TKA in these reports was 70 years with few over age 85. Two-thirds were female, one-third were considered obese, and nearly 90% had osteoarthritis. No studies provided data on racial/ethnic status.
- The mean effect size (expressed as numbers of standard deviations) is considered to be large in magnitude and varies from 1.6 to 3.9 depending on the functional measure used and the duration of followup. However, these results are based on simple pre/post designs with no blinding and large attrition rates.
- There is no evidence that age, gender, or obesity is a strong predictor of functional outcomes, but the extremes of age and obesity were not actively tested.
- Patients with rheumatoid arthritis show more improvement than those with osteoarthritis, but this may be related to their poorer functional scores (or other factors) at the time of treatment and hence the potential for more improvement.
- The revision rate through five or more years is 2.0% of knees and 2.1% of patients.
- Complications were defined by each investigator and occurred in 5.4% of patients and 7.6% of knees. The vast majority were "knee related" or deep venous thrombosis. Only eight cardiovascular or pulmonary complications were reported among nearly 6,000 patients suggesting that these adverse effects were not fully addressed in this literature.
- There is reason to suspect selection effects in the choice of patients and the attrition on followup. Hence, these findings must be interpreted with caution as the basis for clinical practice.
- TKA revisions show a similarly positive functional effect (with the same design limitations).

These conclusions are tempered by the limitations of many of the designs of the studies included in the analysis. Although osteoarthritis does not seem to be a predictor of outcomes, the results seem to be somewhat better for rheumatoid arthritis, but few of these studies simultaneously controlled for other aspects of the patients.

The original goal of this analysis was to identify indications for TKA. To do so, we would need to review studies that compared the outcomes of persons who did and did not receive the surgery. Instead the literature was limited to studies of the outcomes of the surgery performed. If well done, this database would allow conclusions only about the effect of variables on the outcomes of surgery, not on the relative benefit of the surgery for such individuals. (There would always remain the potential for "floor" and "ceiling" effects because some patients may simply be judged too sick or too well, too young or too old to be considered candidates.)

We had initially constructed a much longer list of potential factors that we had hoped would be examined in the search for prognostic features. These included co-morbidities, x-ray evidence of joint damage, bone destruction, extensor mechanism integrity, pre-operative range of motion, alignment, tibio-femoral angle, and ligament integrity. Although these were occasionally mentioned, they were not systematically reported.

The effect of hospital and orthopedic surgeon volume on complication rates and functional outcomes has been evaluated in at least two studies. Using Medicare claims data from 1985-1990 Norton and colleagues found no benefit (in terms of lower complication rates from performing more primary TKA until at least 40 operations are performed each year and there was no further benefit of performing more once 80 TKA are being performed.[128] Heck and colleagues followed an observational cohort of 291 patients with osteoarthritis undergoing TKA for at least two years and found that the maximal improvement in the physical composite score of the SF-36 was seen in patients who had their surgery performed at institutions that performed greater than 50 knee surgeries and by surgeons who performed greater than 20 TKA per year.[72] Additionally, there was a lower likelihood of complications among these higher volume institutions and surgeons.

It is possible that our results might be change if we used a different series of study inclusion filters. For example, we only included studies if they reported at least 100 knees, were written in English, and provided pre- and post-TKS functional data using at least one of the four established measurement scales. We also excluded unicompartmental procedures. We also could not assess whether our results might be affected by potentially varying patterns of referral or access of patients to orthopaedic surgeons. For example, it is likely that primary physicians may vary in their threshold (filters) for referring a given patient for TKA and/or orthopaedic surgeons have different threshold (filters) for offering TKA. Our findings are limited to the conclusions based upon published results of patients receiving TKA. Therefore, it is not possible for a particular patient or provider who is making a decision regarding TKA to directly apply these outcomes to their situations. However, compared to the findings by Callahan and colleagues reported in 1994, subjects had similarly large improvements in symptoms and function, lower rates of complications and revisions. This may reflect differences in patient populations, reporting of outcomes or improvements/refinements in the surgical procedure.

Although there is recurring evidence that total knee arthroplasties improve function and alleviate pain, much less is known about what types of patients are most likely to benefit from this surgery. As the pressure for more informed decisions grows, this type of information will be greatly needed.[128] The search for evidence about the indications for TKA was frustrating. The literature is full of articles that compare different procedures and prostheses, but relatively little attention is paid to the characteristics of the patients. (Perhaps, not coincidentally, many of these studies are supported by manufacturers.) Typically authors describe the sample under study and then ignore these characteristics in their analyses.

Overall, the scientific quality of the current evidence is weak. Only a handful of studies employed any form of multivariate analysis. The outcomes of orthopaedic surgery, like most other treatments, are the results of the treatments interacting with the characteristics of the patients. Real understanding will come about only when the analytic techniques can address both sets of variables simultaneously. The analyses that come from such studies will need to employ sophisticated statistical methods, which can examine the effects of the patient characteristics on the outcomes of interest. Orthopaedic outcomes research has made considerable strides in the last

decade. Much greater attention is now paid to using established outcomes measures. The next step in this progress is to employ more sophisticated research designs that incorporate patient characteristics into the analysis.

Because orthopaedic research will likely rely heavily on observational studies instead of RCTs, it will be important to use more robust methods of study design/analysis. Particular attention must be paid to ensuring that the cohorts remain intact. Greater efforts must be made to collect outcomes information on all participants, not just those who appear for followup visits. A substantial proportion of the studies reviewed were based on retrospective reviews of clinical records. Strong levels of evidence will require prospective designs that emphasize followup.

Research Recommendations

The current state of empirical work does not provide a strong basis for making clinical recommendations regarding indications or outcomes from TKA. As pressures mount for more discrimination in identifying subjects for elective surgery, better information will be needed. The traditional approach in orthopaedics of reporting small scale case series that examine the outcomes of a specific innovation must give way to larger, more planful studies that deliberately address the areas of interest.

The ideal study design to answer questions about indications for surgery remains a randomized trial in which persons with advanced arthritis (or other potential joint problems) are randomly assigned to medical management or joint replacement. (It would be unlikely to include some provisions for sham surgery as was done with joint arthroscopic surgery.)[129] No single study could be used to test all the variations in patient characteristics and surgical techniques. However, given the enthusiasm for joint replacement and the generally positive effects on function, it might be difficult to recruit subjects for such RCTs, even without the prospect of sham surgery. Thus, a major component of research into the effectiveness of joint replacement and the patient characteristics associated with better outcomes will be well done observational studies.

Historically much of the work in joint surgery research has gone into developing outcomes measures, but at this point, more attention needs to be paid to the independent variables than to the dependent ones. It appears that the results are robust enough to be detected by any of the major outcomes measures. The second concern is to employ designs that allow for multivariate analysis, which can assess the effects of several independent variables simultaneously. This approach was encountered only rarely in our review.

To generate the sample size needed for multivariate analysis; these studies will likely have to be cooperative ventures. Such a plan would also broaden their representation. They will require systematic collection of data on potential indicators and risk factors and active followup to maintain the cohort, even when the patients do not return for scheduled followup clinical visits.

Although many questions remain unanswered, a few major issues need to be addressed first.

- How long will the functional benefits of TKA last and when and in whom will revision surgery likely be needed? Are there patient characteristics associated with poor outcomes such that these patients should be excluded from consideration or assigned a lower priority?
- How can one trade off the benefit of surgery against the risk of needing a revision?

- How much do outcomes vary by patient characteristics and surgical factors, including type of prosthesis, volume of these procedures performed? Is the volume effect related to the surgeon or the medical center? There is strong belief that volume of surgery in a center, and perhaps experience of the surgeon, is related to better outcomes, but the strength of this relationship has not been well established and may be artifactual.

Lessons Learned

Ideally, databases can be utilized to characterize practice patterns, identify and investigate prostheses failure, establish benchmarks, develop guidelines, and quantify present and future healthcare resource utilization, but incomplete data can create serious problems The literature review performed highlights some of the pitfalls that can occur in surgeon based data collection.

Much of the data falls short of expected standards of quality and execution.[130-135] Useful studies need: 1) clear objectives and goals; 2) a valid protocol design; 3) clear inclusion and exclusion criteria; 4) a study sample that is representative of the universal population; 5) a comprehensive collection of variables necessary to answer the project objective(s); 6) mechanisms implemented to track patients and assure complete followup; 7) mechanisms implemented to ensure high data integrity; 8) blinding of data collection personnel; and 9) a method to rectify methodological problems (such as attrition bias).

At the conception of patient and surgeon based knee arthroplasty studies it is critical to define the purpose behind the data collection effort and let this guide the development process. To help in addressing these issues it is important to ask:

- *What* questions (clinical, administrative, quality outcomes) are to be answered by the study?
- *Who* will be the consumers of this data or information—patients, surgeons, or third parties? *Who* will be held responsible for ensuring the study goals are met?
- *What* protocol design would best answer the study's objectives?
- *What* are the dependent (outcome) and independent (risk factor) variables?
- *Where* should the data be collected, i.e. patients' homes, surgeons' offices, mail packages etc? Where should the data be entered and stored?
- *Who* will collect the data?
- *When* should followup data be obtained?
- *How* will the data be used to impact clinical care?
- *How* will patient confidentiality and safety be protected? Will the data be used for quality improvement, general research or physician accountability?

Many of the studies lacked critical features of a well designed time-series protocol: a) there was no clear process in place to recruit and follow patients; b) there was extensive loss on followup; c) not every study developed a detailed set of inclusion and exclusion criteria. These measures would have ensured a more homogeneous cohort that would allow better comparisons. As a consequence, the cohorts reported were probably not representative of the universal knee joint replacement population.

Pertinent independent variables need to be identified, collected, and used in the analysis. For example, no studies addressed characteristics of the surgeons performing the procedures. Deriving a conceptual model that contains the variables that must be collected to answer the

objectives and delineating the interactions between these variables not only averts important variable omissions but also helps in developing aims and forming an analytic plan.[22]

Attrition creates potential bias. The poor followup response rate resulted from insufficient monitoring and tracking. Technical solutions can be employed to achieve this goal. The field needs to define a consistent set of postoperative followup points. What is more critical, a large number of subjects did not return for followup at all rendering the analysis and interpretation of the data difficult. Followup cannot depend on patients returning for care; it must be proactive. When a subject is no longer available or able to respond, there must be mechanisms in place to approach proxy respondents identified as the person to contact on the original hospital/contact face sheet. Based on our experience, tracking some of the patients and establishing the best proxy will take some active detective work, but it can be done. No doubt permission from the appropriate legal and governmental authorities will be needed to accomplish this task. Obtaining permission in advance can overcome many of the growing number of legal obstacles (HIPAA and others) in gaining access to patients and governmental databases (Social Security, IRS, etc.) in order to complete followup information.

Followup periods of at least five to ten years are considered necessary to allow time to test the durability of prostheses. Although some loss of sample is likely in that time frame, it is important to be able to test the effect of that attrition on the findings. In these circumstances, where decline in function is expected, intention-to-treat is not the correct technique. Statistical models will need to compensate for the selective loss to followup.

Utilizing tracking techniques as outlined by Smith and Watts[136] and carrying out traces such as the Department of Motor Vehicles traces, voter registration traces, and so on, to locate orthopaedic cases is helpful but inefficient.[137] These tracking methods are not appropriate for real time studies. They are more appropriate for collecting long-term data such as ten-year followup data, but dealing with short-term data problems needs a more proactive, pre-planned strategy. Alternative potential sources for locating patients need to be built into the initial enrollment process.

As many hospitals and clinics convert to Electronic Medical Records (EMR) it is crucial that databases be able to interact with these records. Software development to establish a common standard for collecting and annotating joint replacement followup data is critical to making this data collection process efficient. Incorporation of outcomes instruments into these products would further enhance data collection efforts and the amount of useful information collected.[116] This would also assist surgeons and physicians in completing necessary forms and submitting data. This allows for immediate submission, review of information, and can minimize errors in data entry.

To be able to test the characteristics of surgeons and hospitals, the database must be set up to identify surgeons and hospitals, in order to estimate the fraction of variance explained by these characteristics. Appropriate checks must be in place to ensure participating surgeons of confidentiality and protection from any negative impact. All of these factors will serve as risk-adjustors in analyzing time trend of functional outcomes and rate of re-operation (primary outcome measure of the database).

Feedback loops need to be set up to affect not only the data collection process (as outlined above) but the consumers of this information (patient, surgeon, hospital, and third party payers). These feedback loops should improve quality of care and streamline healthcare expenditures.

There must be obvious and compelling reasons for physicians to participate. The benefits to the orthopaedic surgeon must be clear and strategies of linking participation to getting paid or becoming credentialed or recertified must be explored.

Research Agenda

A large number of questions remain to be answered. Table 24 proposes a preliminary list. These questions illustrate the range of unanswered questions. They obviously cannot all be addressed in a single study. Indeed, it will be difficult to disentangle the effects of different aspects of treatment. For example, rehabilitation can interact with surgical technique; and both can interact with patients' characteristics.

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Listing of Excluded Studies (reason for exclusion is provided in italics following each reference)

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No post-operative outcomes scores.

List of Acronyms/Abbreviations

ACL	Anterior Cruciate Ligament
AHEAD	Association of Higher Education and Disability
AHRQ	Agency For Healthcare Research And Quality
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
cf	Compared to
CI	Confidence Interval
DVT	Deep Vein Thrombosis
E/G	Excellent/Good
EMR	Electronic Medical Records
EPC	Evidence-based Practice Centers
GKS	Global Knee Score
HIPAA	Health Insurance Portability And Accountability Act
HSS	Hospital for Special Surgery
IRS	Internal Revenue Service
JA	Joint Arthroplasty
kg	Kilogram
KRH	Kinematic Rotating Hinged Knee Prosthesis
KS	Knee Society
LOS	Length of Stay
MeSH	Medical Subject Headings
NIAMD	National Institute of Arthritis and Metabolic Diseases
NIH	National Institutes of Health
OA	Osteoarthritis
OLS	Ordinary Least Square Regression
OMAR	NIH Office of Medical Applications Research
OR	Odds Ratio
p	Probability
PCL	Posterior Cruciate Ligament
POD	Post Operative Day
PVD	Peripheral Vascular Disease
r	Regression Coefficient
RA	Rheumatoid Arthritis
RCTs	Randomized Controlled Trials
ROM	Range of Motion
RR	Relative Risk
S/P	Satisfactory/Poor
S-ROM	Implant made by Depuy
THA	Total Hip Arthroplasty
THR	Total Hip Replacement
TKA	Total Knee Arthroplasty
TKAR	Total Knee Arthroplasty Revision
UKA	Unicompartmental Knee Arthroplasty
UKR	Unicondylar Knee Replacements
WOMAC	Western Ontario and Macmaster University Osteoarthritis Index

Evidence Table 1. Primary TKA studies with at least a pre/post design

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Bachmeier et al, 2001[94]	WOMAC, SF-36		108			10	72	61% Female	100% OA		Compared WOMAC and SF-36; no control variables used; WOMAC more sensitive than SF-36
Baldwin & Rubinstein, 1996[101]	HSS	300		346	301	48	67.5	58% Female			Tested only effect of bone quality
Beaupre et al., 2001[95]	WOMAC, SF-36	120	93			4.5	68.4	40% Female	91% OA		RCT to test role of exercise; no effect
Bert et al., 2000, 2001[69, 99]	KS, SF-36	279	277			12	72	70% Female		Mean=30	No effect of expected post-op activity/demand level according to pre-op activity level
Bourne et al., 1995[70]	KS	100				24	70	42 Male 83 Female	100% OA		Resurfacing patella
Brown et al., 2001[82]	KS, HSS	268	246	536		76.8	68	68% Female	89% OA 8% RA		No effect of component size asymmetry
Bullens et al., 2001[75]	KS, WOMAC	108	86	126	100	58.8	67.4		67 OA 37 RA		Done to compare KS scores and satisfaction visual anolog scale; poor correlation, No difference in RA/OA in KS scores but RA had better satisfaction
Clark et al., 2001[98]	KS, WOMAC	143	108			36	71.4		75% OA 25% RA		RCT of posterior-stabilized vs. cruciate-retaining implants; no significant difference
Cloutier et al., 2001[83]	KS	130	89	163	107	120	67	34 Male 96 Female	122 OA 41 RA		Cruciate ligament retention
Cohen et al., 1997[71]	KS	186		272		6	69.5	71 Male 115 Female	148 OA 22 RA	Mean = 177 pounds	No difference in pre- or post-op scores

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Deshmukh et al., 2002[27]	KS	180	130			12	68.8	85 Male 95 Female		31 normal, 83 over-weight 64 obese, 2 morbidly obese	Regression model included age, sex, side of arthritis, comorbidity, preop scores, and BMI R2 15.5%; age, sex, side of arthritis 3.4%; comorbidity 2.9%; baseline 9.2%; BMI accounted for almost no variance
Diduch et al., 1997[61]	HSS, KS	88	84	114	103	96	51	29 Male 55 Female	64%OA		
Duffy et al., 1998[84]	KS	104	102	120	108	120	Uncemented = 54 Cemented = 65	Cementless: 23 Male 23 Female Cemented: 23 Male 24 Female	OA: Uncemented-42 Cemented-42 RA: Uncemented-9 Cemented-6	Mean = 80.9 kg	Cemented had better survival
Elke et al., 1995[76]	KS	394		524		50.4	75.1 68.4	No difference	61 RA 415 OA		RA vs. OA no difference
Evanich et al., 1997[62]	HSS	251	169	302	212	91	66	48% Female	78% OA 17% RA		Countersunk metal-backed patellas
Ewald et al., 1999[85]	KS	412	180	539	306		63		RA 151 OA 155		Kinematic arthroplasty
Fortin et al., 1999[28]	SF-36, WOMAC	130	106			6	67	96 Male 126 Female	All had OA		In regression model, education and comorbidity did not predict outcomes for knees alone but did in pooled TKAR/THR

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Gill & Joshi, 2001[86]	KS	223	223	254	254	201.6	68	89 Male 165 Female	289 total TKAs 254 with OA, 35 with RA. ONLY studied patients with OA		Survivorship of TKAR; no further analysis. PCL retaining
Gill et al., 1999[108]	KS	139	63	159	72	206.4	61	21 Male 42 Female	68 OA 3 RA		Total condylar TKA; survival analysis
Gioe & Bowman, 2000[103]	KS, SF-36	296	195	324	213	49	69±6	285 Male 11 Female	272 OA		RCT of tibial components; no multivariate analysis
Griffin et al., 1998[110]	KS, HSS	120	56	165	73	127.2	67.8	15 Male 41 Female	51 OA	20 obese 30 nonobese	Obese showed more improvement
Harwin, 1998[102]	KS, HSS	336	326	366	356	61.2	65.1	138 Male 188 Female	241 OA 109 RA		Symmetrical TKA; pre/post only. Results reported separately by OA and RA
Hawker et al., 1998[29]	WOMAC, KS	1496	1193			24-84	72.6	70% Female	87% OA 6% RA	Mean BMI=28	Primary & revision: education, race, income, living environment. Correlates of pain at followup: pre-op pain, osteotomy before replacement, low SF-36 social function & emotional role function, high SF-36 pain, less satisfaction; none significant in multivariate. Age, BMI not related to outcomes

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Hasegawa et al., 2002[54]	HSS	140		221		12-60	68	16 Male 124 Female	129 OA 92 RA	Mean = 53 kg	Risk factors for heterotopic ossification: knee flexion, effusion (bivariate only);age, gender, arthritis, BMI not significant
Healy et al. 2002[63]	KS, HSS	159	142	159	142	96 (no CP) 60 (CP)	69.9		100% OA	Mean = 84.5 kg	Clinical pathway vs. no clinical pathway. Clinical pathways reduced hospital cost for TKA without affecting short-term patient outcome.
Heck et al. 1998[72]	KS, WOMAC, SF-36	291	268	330		24	70.2	109 Male 182 Female	100%OA	Mean Body Mass Index = 30.2	Logistic regression found maximal improvement in SF-36 physical component score in subjects who had surgery at institutions performing ≥50 TKA/year, had a better mental health status at baseline, and were treated with physical composite sparing device.
Hsu et al., 1998[55]	HSS	113	113	140	140	57.6	62.6	73% Female	135 OA 5 RA		Test hybrid: uncemented femur/cemented tibia, decreased pain, increased muscle strength
Hube et al., 2002[104]	KS	221		297	276	36.2	66.3 (33-81)	123 Male 153 Female	261 OA 33 RA 3 infection		Midvastus approach; pre/post only
Ilkejiani et al., 2000[64]	HSS	185	185	185	185	78	67	79 Male 121 Female	OA	Weight recorded	Patellar resurfacing; pre/post
Indelli et al., 2002[87]	KS	91	85	100	92	90	69 (57-85)	13 Male 72 Female	All with OA		Prosthesis; pre/post

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Jenny & Jenny, 1998[77]	KS	125	125	125	125	30	69	39 Male 86 Female			Anterior cruciate ligament-retaining vs. replacing prostheses; pre/post
Jones et al., 2001[96]	WOMAC, SF-36	257	257	257	257	6	70.7	63% Female	93% OA	Mean Body Mass Index 31.4	Education, age, gender, BMI, prior joint surgery, living arrangement, comorbidity included in regression model. Age not associated with improvement in WOMAC. Gains in WOMAC & SF-36 but not significant OLS: pain (WOMAC): LOS -, preop pain (SF36 +, cementless -; function (WOMAC): LOS-, preop joint pain (WOMAC)-, # comorb-, preop bodily pain (SF36)
Jordan et al., 1997[105]	KS	375		473	410	56.4	68	113 Male 261 Female	427 OA 45 RA	Weight recorded	Cementless miniscal bearing TKAs; pre/post
Kiebzak et al., 2002[100]	SF-36	415				24		234 Female			American Society of Anesthesiologists (ASA), number of cormorb, differences greater for men (except role emotional). Only 54 used in analysis
Konig et al., 1997, 1998, 2000[30, 106,111]	KS	357	294	399	329	56.4	69.4	56 Male 238 Female	278 OA 34 RA 16 other		Preop walking distance related to pain on followup; none predicted KS score; KS function score predicted by: preop walk distance, age, BMI, preop patient category

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Larson et al., 2001[56]	HSS	94	82	127	118	48	67 (41-81)	20 Male 62 Female	87 OA 30 RA	Mean 28 (17-44) 26 obese 1 morbidly obese	Mean BMI same with and without patellar complications 50% of patellar fracture or anterior knee pain obese cf 32% without; not significant. No significant difference in age, gender, preop diagnosis, knee score, followup time; range of motion; lateral release; knee manipulation; type of prosthesis
Lin et al., 2002[73]	KS	122	78			24	67.7-70		100% OA		Impact of clinical pathway; affected utilization but not outcomes
Liu & Chen, 1998[57]	HSS	88		176		31	67.4	97.5% Female	82 OA 6 RA		No sign diff
Lombardi Jr et al., 2001[112]	HSS, KS	240	240	351	351	77	65.5	Reported	223 OA 23 RA	Reported	No difference in followup KS, significant difference in pain improvement & outcome improvement stabilized > retain
Malkani et al., 1995[65]	HSS, KS,	118	84	168	119	120	64			Height and weight reported	Improvement
Martin et al., 1997[88]	KS	290	231	378	306	78	67	60 Male 171 Female	202 OA 91 RA		Followup knee and function scores significant by Charnley scores. Function pre/post difference significant by Charnley score. No difference by surfaced patellas. Cemented femur had better function score

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Matsueda & Gustilo, 2000[74]	KS	365	291	425	336	6	68.4	90 Male 211 Female	253 OA 27 RA other 11		Compared subvastus and medial parapatellar approaches; no functional difference
Meding et al., 2001[78]	KS	1888	1888	2759	2759	30	70.6	60% Female		Recorded	Preop KS and KS functional score related to radiographic changes but not pain score
Miyasaka et al., 1997[89]	KS	83	46	108	60	169	61	22 Male 39 Female	RA: 38 OA: 21	Weight recorded	Pre/post valgus deformity
Mokris, et al., 1997[90]	KS	90	90	105	105	51	68.7	34 Male 56 Female	97 OA 6 RA		Pre/post
Mont et al., 1999[91]	KS	104	101	121	118	65	70	38 Male 63 Female (62% Female)	97 OA 2 RA		Pre/post
Moskal & Diduch, 1998[58]	HSS	514	488	646	617	51.6	64	69.6% Female		Mean height & weight	Test role of post op x-rays; pre/post
O'Rourke et al., 2002[66]	KS, HSS	134	114	176	153	76.8	72.4	59.4% Female		Mean BMI 30.9	Improved osteolysis correl with KS. Trend towards anterior knee pain with higher BMI
Pereira et al., 1998[59]	HSS		107	163		36	69	40 Male 103 Female	130 OA 8 RA		PCL sparing vs. sacrificing associated with greater improvement
Ranawat et al., 1997[79]	KS	118	96	150	125	58.7	70		OA vs. RA		Functional status for OA significance better than for RA Knee score for OA better than for RA
Rand & Gustilo, 1996[60]	KS	202	182	277	251	27.6	69	69 Male 113 Female	156 OA 19 RA		Inset vs. resurfacing patellar prostheses; resurfacing had better function; pain score higher

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Regner et al., 1997[67]	HSS	120	88	144		81.6	61	22 Male 98 Female			Pre- and post-op reported by OA/RA. Revision rate not affected by age, sex, arthritis, alignment or prosthesis
Rinta-Kiikka et al., 1996[92]	KS	97	89	102	94	64	67	77% Female	74 OA 16 RA	Reported	Correlates of survival: age; extension deficit, knee score, function score, pain score at last review. BMI not associated
Ritter et al., 1995[109]	KS	3054		4583		180	70.4	60 Female	87% OA		
Rodriguez et al., 1996[80]	HSS KS	99	67	145	104	52	12.7 (5-18)	91Male 13 Female	All with RA		RA patients stage II/IV
Schroder et al., 2001[68]	HSS	102	52	114	58	120	78		48 OA 10 RA		Pre/post OA/RA no difference
Sextro et al., 2001[93]	KS	118	50	168	66	188.4	65.1	72 Female	109 OA knees 52 RA knees		
Stickles et al., 2001[97]	WOMAC, SF-36	4161	1011			12	69.9	637 Female	100% OA	Mean 31.2	No difference in WOMAC, SF physical component score, mental component score by BMIcategories in multiple regression model
Title et al., 2001[107]	KS	128	128	148	148	51	63	53 Female	122 OA knees 24 RA knees		Total condylar prosthesis vs. press fit condylar – 2 cohorts matched for age, diagnosis, gender, and body weight
Ververeli et al., 1995[52]	HSS	103	103			24	69.5	73 Female	100% OA		Continuous passive motion better than physical therapy alone

Evidence Table 1. Primary TKA studies with at least a pre/post design (continued)

Reference	Measure	N Patients Baseline	N Patients Followup	Knees Baseline	Knees Followup	Followup (months)	Age	Gender	Arthritis	BMI	Notes
Worland et al., 1998[53]	HSS	91	80	114	103	6	70.2	53 Female 27 Male	100% OA		RCT, Continuous passive machine vs. professional physical therapy. Continuous passive motion adequate rehabilitation alternative with lower costs and no differences in results vs. physical therapy
Yang et al., 2001[81]	KS	90	86	113	109	36	69	13 Male 73 Female	82 OA 4 RA		

Evidence Table 2. Basic information for calculating revision rates

Study	Patients	Knees	Followup - Years	Revisions Related to Knee Prosthesis	Unit of Reporting	Total Reoperations (Revisions + Other)	Notes
Bachmeier et al., 2001[94]	108	NR	0.5	0	subjects	0	
Baldwin & Rubinstein, 1996[101]	300	346	4	9	knees	17	17 reoperations total (revisions + infections)
Beaupre et al., 2001[95]	120	NR	0.5	0	subjects	0	
Bert et al., 2001[69]	279	NR	1	1	both	1	From Bert et al., 2000
Bourne et al., 1995[70]	100	NR	2	2	subjects	2	Not due to infection, pat-femoral joints resurfaced due to pain
Brown et al., 2001[82]	268	536	6.4	0	both	0	
Bullens et al., 2001[75]	108	126	4.9	1	knees	5	Survival rates, no numbers; 5 reoperations total
Clark et al., 2001[98]	143	NR	3	NR		NR	
Cloutier et al., 2001[83]	130	163	10	3	knees	7	3 due to infection
Cohen et al., 1997[71]	186	272	0.5	0	both	0	6 month followup
Deshmukh et al., 2002[27]	180	NR	1	NR		NR	12 month followup
Diduch, et al., 1997[61]	88	114	18	4	subjects	6	3 subjects had a revision of patellar component only; 2 revised because of infection
Duffy, et al., 1998[84]	104	120	10	37	knees	38	25 patellar revisions plus 10 cementless and 2 cemented, femoral or tibial aseptic loosening only, 1 infection
Elke et al., 1995[76]	394	524	4.2	28	knees	38	All problems, including infections (6), others (4)
Evanich et al., 1997[62]	251	302	7.6	11	subjects	12	One deep wound infection requiring removal of knee
Ewald et al., 1999[85]	412	539	=10	15	knees	20	10 patellar loosening, 3 extensive polyethylene wear, 2 for other loosenings
Fortin et al., 1999[28]	130	NR	0.5	0	both	1	1 severe infection requiring removal of knee; 6 month followup
Gill et al., 2001[86]	223	254	16.8	9	knees	10	1 knee revised for infection
Gill et al., 1999[108]	139	159	17.2	1	knees	1	3 failures, only 1 revised
Gioe & Bowman, 2000[103]	296	324	4.1	5	knees	13	8 for infection
Griffin et al., 1998[110]	120	165	10.6	3	knees	3	

Evidence Table 2. Basic information for calculating revision rates (continued)

Study	Patients	Knees	Followup - Years	Revisions Related to Knee Prosthesis	Unit of Reporting	Total Reoperations (Revisions + Other)	Notes
Harwin et al., 1998[102]	336	366	5.1	0	knees	10	8 for infection
Hasegawa et al., 2002[54]	140	221	12-60	NR			
Hawker et al., 1998[29]	1496	NR	24-84	NR			
Healy et al., 2002[63]	159	159	5,8	2	both	8	6 for manipulation
Heck et al., 1998[72]	291	330	2	0	both	0	
Hsu et al., 1998[55]	113	140	4.8	20	knees	23	3 infections. Knee-related includes 4 Insall operations
Hube et al., 2002[104]	221	276	3	0			1 arthroscopic resection to correct patella clunk syndrome
Ikejiani et al., 2000[64]	145	185	6.5	1	subjects	1	
Indelli et al., 2002[87]	91	100	7.5	0	both	0	1 revision recommended
Jenny & Jenny 1998[77]	125	125	2.5	8	subjects	8	
Jones et al., 2001[96]	257	257	0.5	0	subjects		6 month followup
Jordan et al., 1997[105]	375	473	4.7	19	both	24	5 infections
Kiebzak et al., 2002[100]	415	NR	2	NR			Focuses on use of SF-36
Konig et al., 1998[30]	357	399	4.7	1	knees	2	Exchange operations from Konig et al., 2000
Larson et al., 1999[138]	94	127	4	0	both	0	
Lin et al., 2002[73]	122	NR	2	0			
Liu & Chen, 1998[57]	88	176	2.6	NR			
Lombardi et al., 2001[112]	240	351	4.4	0	knees	17	No revisions due to aseptic loosening
Malkani et al., 1995[65]	118	168	10	6	knees	21	13 for manipulation, 1 infection, 1 fracture
Martin et al., 1997[88]	290	378	6.5	12	both	17	2 due to infection, 2 hemarthroses, 1 crepitus
Matsueda & Gustilo, 2000[74]	365	425	.5	0		0	Retrospective - No revisions
Meding et al., 2001[78]	1888	2759	2.5	NR			
Miyasaka et al., 1997[89]	83	108	14.1	3	knees	6	2 for infection, 1 for trauma
Mokris et al., 1997[90]	90	105	4.25	0		0	
Mont et al., 1999[91]	104	121	5.4	0	knees	5	4 subjects
Moskal & Diduch, 1998[58]	514	646	4.3	0	both	6	Retrospective, included 57 revision subjects
O'Rourke et al., 2002[66]	134	176	6.4	3	knees	5	2 subjects

Evidence Table 2. Basic information for calculating revision rates (continued)

Study	Patients	Knees	Followup - Years	Revisions Related to Knee Prosthesis	Unit of Reporting	Total Reoperations (Revisions + Other)	Notes
Pereira et al., 1998[59]	107	163	3	NR			
Ranawat et al., 1997[79]	118	150	4.9	1	knees	3	2 for infection
Rand & Gustilo, 1996[60]	202	277	2.3	0	knees	4	2 manipulation, 1 deep infection, 1 fracture
Regner et al., 1997[67]	120	144	6.8	17	knees	17	
Rinta-Kiikka et al., 1996[92]	97	102	5.3	4	knees	5	1 for trauma
Ritter et al., 2001[139]	3054	4583	15	68	knees	68	6 femoral, 19 tibial, 15 all polyethylene, 28 metal-back patellar components
Rodriguez et al., 1996[80]	99	145	4.3	2	knees	7	revision = 2 subjects
Schroder et al., 2001[68]	102	114	10	2	both	4	1 infection, 1 fracture
Sextro et al., 2001[93]	118	168	15.7	12	knees	13	1 trauma fracture
Stickles et al., 2001[97]	4161	NR	1	Noted but not reported			
Title et al., 2001[107]	128	148	4.3	0			
Ververeli et al., 1995[52]	103	NR	2	0	both	1	1 infection
Worland et al., 1998[53]	91	114	5	NR			
Yang et al., 2001[81]	90	113	3	0	both	8	6 for infection, 1 for pain, 1 for fracture

Evidence Table 3. Basic information for calculating complication rates

Study	Patients	Knees	Complications	Number of Knees	Number of Subjects	Notes: Complications
Bachmeier, et al., 2001[94]	108	NR	14	14	14	Adverse events requiring hospitalization, 10 maniupulations, 3 infections, 1 DVT
Baldwin & Rubinstein, 1996[140]	300	346	41	39	NR	4 DVT, 7 pulmonary embolisms, 3 deep infections, 3 manipulations, 6 subluxations. Revisions included.
Beaupre et al., 2001[95]	120	NR	20	20	20	Adverse events requiring hospitalization. 14 knee-related, 4 DVT, 2 increased hemovac drainage, 4 cardiovascular, 1 pulmonary embolism
Bert et al., 2001[69]	279	NR	27	22	22	All complications, non-device (21) and device (6).
Bourne et al., 1995[70]	100	NR	2	2	2	"Reoperations" for disabling pain
Brown et al., 2001[82]	268	536	15	NR	NR	2 DVT, 3 late infections, 1 arthrofibrosis (requiring manipulation), 1 hemarthrosis (requiring evacuation).
Bullens et al., 2001[75]	108	126	12	12	NR	Knee-related including 7 maniupulations, 1 tibial fissure, 1 femur shaft perforation. 5 reoperations (3 infections, 1 fracture, 1 looseneing)
Clark et al., 2001[98]	143	NR	NR			
Cloutier et al., 2001[83]	130	163	12	12	NR	Knee-related only, 1 operative drainage
Cohen et al., 1997[71]	186	272	40	NR	NR	26 local (16 infections , 3 manipulations), 14 systemic (2 pulmonary embolisms, 1 DVT
Deshmukh et al., 2002[27]	180	NR	NR			
Diduch et al., 1997[61]	88	114	3	3	3	Dislocations only
Duffy et al., 1998[84]	104	120	8	8	NR	8 complications minus revisions including 3 DVT, 3 deep, 1 fibrous ankylosis infections,
Elke et al., 1995[76]	394	524	NR	NR	NR	Revisions only
Evanich et al., 1997[62]	251	302	20	20	20	4 perioperative, skin slough, superficial wound infection, transient peroneal nerve palsy, deep wound infection. 16 postop knee manipulations 4-8 weeks from procedure.
Ewald et al., 1999[85]	412	539	NR			Revisions only
Fortin et al., 1999[28]	130	NR	3	3	3	Requiring hospitalization (1 angina, 1 infected knee, 1 manipulation)
Gill et al., 2001[86]	223	254	13	13	NR	Knee related, 3 infections, 10 fractures

Evidence Table 3. Basic information for calculating complication rates (continued)

Study	Patients	Knees	Complications	Number of Knees	Number of Subjects	Notes: Complications
Gill et al., 1999[108]	139	159	5	5	NR	Knee related - 4 fractures, 1 tendon rupture
Gioe & Bowman, 2000[103]	296	324	NR			Requiring revision only
Griffin et al., 1998[110]	120	165	11	11	NR	"Symptoms of the patellofemoral joint," including patellar clunk and fractures
Harwin, 1998[102]	336	366	15	NR	NR	5 patellofemoral complications plus 10 reoperations (infection, fracture, sublaxation)
Hasegawa et al., 2002[54]	140	221	10	10	NR	Heterotopic ossification, study focus
Hawker et al., 1998[29]	1496	NR	NR			
Healy et al., 2002[63]	159	159	7	7	7	7 readmissions to hospital, 6 manipulations under anesthesia
Heck et al., 1998[72]	291	330	94	NR	NR	In hospital complications, including 5 DVT
Hsu et al., 1998[55]	113	140	23	23	NR	Knee-related only, including revisions
Hube et al., 2002[104]	221	276	2	2	2	Knee-related only, 2 patellar clunk syndrome.
Ikejani et al., 2000[64]	145	185	10	10	10	7 falls, 1 DVT, 1 phlebitis, 1 revision
Indelli et al., 2002[87]	91	100	10	10	10	Postoperative (6 DVT, 2 urinary tract infections, 1 hematoma, 1 mobilization).
Jenny & Jenny, 1998[77]	125	125	8	NR	NR	Knee-related only (3 deep infections, 2 fractures, 2 loosenings, 1 ligamnet instability).
Jones et al., 2001[96]	257	257	29	29	29	In-hospital (9 DVT, 12 urinary tract infections, 4 infection)
Jordan et al., 1997[105]	375	473	24	NR	NR	12 polyethylene fractures, 5 tibial subluxations, 2 loosenings, 5 infections.
Kiebzak et al., 2002[100]	415	NR	NR			
Konig et al., 1998[30]	357	399	20	NR	NR	(From Konig et al., 2000) 10 DVT (2 pulmonary emobolisms), 1 peroneal palsy, 1 ruptured tendon, 2 mobilizations, 4 deep infections, 1 exchange of femoral component
Larson et al., 1999[138]	94	127	3	3	NR	3 patellar fractures
Lin et al., 2002[73]	122	NR	NR			No readmissions within 30 days
Liu & Chen, 1998[57]	88	176	22	NR	NR	Postoperative (including 1 DVT, 6 subluxations, 3 infections)

Evidence Table 3. Basic information for calculating complication rates (continued)

Study	Patients	Knees	Complications	Number of Knees	Number of Subjects	Notes: Complications
Lombardi et al., 2001[112]	240	351	17	17	NR	"Subsequent surgeries only"
Malkani et al., 1995[65]	118	168	26	26	23	5 hematomas postop, 5 infections, loosenings and fractures, 2 thrombophlebitis, 2 gastro intestinal hemorrhages, 1 peptic ulcer, 1 peptic ileus. Includes revisions
Martin et al., 1997[88]	290	378	17	17	17	Requiring reoperations including wear of previously used metal-backed patellas, loosenings and infections, 1 knee crepitus, 2 hem arthroses
Matsueda & Gustilo, 2000[74]	365	425	6	6	NR	Sublaxations only
Meding et al., 2001[78]	1888	2759	NR			
Miyasaka et al., 1997[89]	83	108	3	3	3	Knee-related only, 3 fractures
Mokris et al., 1997[90]	90	105	14	14	11	3 DVT, 3 subluxations, 2 infections, 2 fractures, 2 hematomas, 1 cerebro vascular accident, 1 wound slough.
Mont et al., 1999[91]	104	121	5	5	4	Reoperations only (2 infection, 1 fracture, 1 tendon rupture, 1 due to instability)
Moskal & Diduch, 1998[58]	514	646	10	10	10	3 late fractures, 7 soft tissue complications
O'Rourke et al., 2002[66]	134	176	11	11	10	3 manipulations, 4 fractures, 1 avulsion of the medial collateral ligament, 1 wound necrosis, 1 hematoma, 1 DVT. Revisions excluded
Pereira et al., 1998[59]	107	163	NR			
Ranawat et al., 1997[79]	118	150	10	10	NR	Complications of the patellofemoral joint
Rand & Gustilo, 1996[60]	202	277	18	18	17	Includes infections, fractures, pulmonary emboli (4), myocardial infarction, manipulations (2).
Regner et al., 1997[67]	120	144	NR			Revisions only
Rinta-Kiikka et al., 1996[92]	97	102	6	6	NR	Superficial infections
Ritter et al., 2001[139]	3054	4583	NR			Revisions only
Rodriguez et al., 1996[80]	99	145	8	8	7	Knee failures only, 6 due to sepsis
Schroder et al., 2001[68]	102	114	6	6	6	Knee failures only, 3 due to fractures

Evidence Table 3. Basic information for calculating complication rates (continued)

Study	Patients	Knees	Complications	Number of Knees	Number of Subjects	Notes: Complications
Sextro et al., 2001[93]	118	168	35	NR	NR	Includes 7 hematomas, 5 superficial wound infections, 2 pulmonary embolisms, 1 amputation/fracture, 2 femoral and 4 patella fractures, 16 subjects requiring manipulation
Stickles et al., 2001[97]	1011	NR	90	NR	90	Based on total complication rates. Complications included medical (DVT) and orthopaedic (hematoma, fracture, infection, loosening, failure).
Title et al., 2001[107]	128	148	NR			
Ververeli et al., 1995[52]	103	NR	9	9	9	Perioperative: 3 pulmonary embolisms; 5 persistent serious drainage. Late: 1 infected knee
Worland et al., 1998[53]	91	114	NR			
Yang et al., 2001[81]	90	113	45	NR	NR	Perioperative: 8 calf swellings (1 DVT), 17 UTI, 8 superficial infections, 3 deep infections, 1 myocardial infarction, 1 cerebro vascular accident. Late: 3 deep infections, 1 manipulation, 1 fracture, 2 loosenings

Appendix A
Measurement Scales

The Hospital for Special Surgery (HSS)
Knee Society Score
Western Ontario and MacMaster University (WOMAC) Osteoarthritis Index

The Hospital for Special Surgery (HSS)

KNEE SERVICE

Knee Rating Sheet

Name_____ HSS#_____ Preoperative date_____

		LEFT						RIGHT					
	Score	pre	6 mo	1 yr	2 yr	3 yr	4 yr	pre	6 mo	1 yr	2 yr	3 yr	4 yr
PAIN (30 points)													
Walking: None	15												
Mild	10												
Moderate	5												
Severe	0												
At rest: None	15												
Mild	10												
Moderate	5												
Severe	0												
FUNCTION (22 points)													
Walk: Walking & standing unlimited	12												
5-10 blocks, standing > 30 min	10												
1-5 blocks, standing 15-30 min	8												
Walk <1 block	4												
Cannot walk	0												
Stairs: Normal	5												
With support	2												
Transfer: Normal	5												
With support	2												
ROM (18 points)													
Each 8° = 1 point													
MUSCLE STRENGTH (10 points)													
Cannot break quadriceps	10												
Can break quadriceps	8												
Can move through arc of motion	4												
Cannot move through arc of motion	0												
FLEXION DEFORMITY (10 points)													
None	10												
5-10°	8												
10-20°	5												
>20°	0												
INSTABILITY (10 points)													
None	10												
0-5°	8												
6-15°	5												
>15°	0												
TOTAL													
SUBSTRACTIONS:													
One cane	1												
One crutch	2												
Two crutches	3												
Extension of lag of 5°	2												
10°	3												
15°	5												
Deformity (5° = 1 point)													
Varus													
Valgus													
TOTAL SUBTRACTIONS													
KNEE SCORE													

Knee Society Score (KS)

Example Questionnaire

(Your Clinic Information Here)

Patient Name_____
Date of Birth_____ Date of Surgery_____

Patient Reporting

Thank you for taking the time to help us better understand how your knee problem affects your daily life.

Please circle the answer that best describes your knee:

1. How much pain do you have when you are walking?

- None
- Mild or Occasional
- Moderate
- Severe

2. How much pain does your knee cause when going up and down stairs?

- None
- Mild or Occasional
- Moderate
- Severe

3. How much pain does your knee cause when you are at rest?

- None
- Mild
- Moderate
- Severe

4. How does your knee affect your walking ability?

- I can walk unlimited distances.
- I can walk 10-20 blocks.
- I can walk 5-10 blocks.
- I can walk 1-5 blocks.
- I can walk less than one block.
- I cannot walk at all.

5. How do you go up stairs?

- I go up stairs normally one foot in front of the other.
- I use the hand rail for balance.
- I use the hand rail to pull myself up.
- I cannot climb stairs.

6. How do you go down stairs?

- I go down stairs normally one foot in front of the other.
- I use the hand rail for balance.
- I use the hand rail to support myself.
- I cannot come down stairs.

7. How do you get out of a chair?

- I get out of a chair normally without support.
- I use the arm rests for balance.
- I use the arm rests to push myself.
- I cannot get out of a chair.

8. What type of support do you use when walking?

- None
- Cane
- 2 Canes
- Crutches
- Walker

Clinical Assessment

9. Range of Motion

- _____ Degrees

10. Extension Lag

- _____ Degrees

11. Flexion Contracture

- _____ Degrees

12. Medial/Lateral Stability

- 0-5 mm
- 5-10 mm
- >10 mm

13. Anterior/Posterior Stability

- 0-5 mm
- 5-10 mm
- >10 mm

14. Alignment

- _____ Degrees

Calculating the Knee Score and the Functional Score

This scoring system is the version of the knee score as modified by Dr. John Insall in 1993. The scoring system combines a relatively objective Knee Score that is based on the clinical parameters and a Functional Score based on how the patient perceives that the knee functions with specific activities.

The maximum Knee Score is 100 points and the maximum Functional Score is 100 points.

To calculate the two scores the answers to the questions and the findings on the examination are given a value based on the results. To obtain the Knee Score and the Functional Score the result of each question is totaled. Notice that some results are negative to denote that they are deductions to the score.

Knee Findings

Pain	50 (Maximum)

Walking ☐

(Insert the value associated with the results of question 1)

None	35
Mild or occasional	30
Moderate	15
Severe	0

Stairs ☐
(Result of question 2)

None	15
Mild or occasional	10
Moderate	5
Severe	0

R.O.M. 25 (Maximum)
(Result of question 9)

8º= 1 point

Stability 25 (Maximum)

Medial/Lateral
(Result of question 12)

0-5 mm	15
5-10 mm	10
> 10 mm	5

Anterior/Posterior
(Result of question 13)

0-5 mm	10
5-10 mm	8
> 10 mm	5

Deductions

Extension lag
(Result of question 10)

None	0
<4 degrees	-2
5-10 degrees	-5
>11 degrees	-10

Flexion Contracture
(Result of question 11)

< 5 degrees	0
6-10 degrees	-3
11-20 degrees	-5
> 20 degrees	-10

Malalignment
(Result of question 14)

5-10 degrees (5º = -2 points)	0

Pain at rest
(Result of question 3)

Mild	-5
Moderate	-10
Severe	-15
Symptomatic plus objective	0

(Now, simply total the scores of each of these questions to obtain the total Knee Score for the patient.)

Knee Score 100 (Maximum) =

Functional Findings

Walking (Result of question 4)		
Unlimited	55	
10-20 blocks	50	
5-10 blocks	35	
1-5 blocks	25	
< block	15	
Cannot	0	
Stairs Up (Result of question 5)		
Normal	15	
Hands balance	12	
Hands pull	5	
Cannot or bizarre	0	
Stairs Down (Result of question 6)		
Normal	15	
Hands balance	12	
Hands hold	5	
Cannot or bizarre	0	
Chair (Result of question 7)		
Normal	15	
Hands balance	12	
Hands pull	5	
Cannot	0	

Functional Deductions
(Result of question 8)

Cane	-2
Crutches	-10
Walker	-10

Functional Score 100 (Maximum) = ☐

Western Ontario and MacMaster University (WOMAC) Osteoarthritis Index

1. The following questions concern the amount of pain you are currently experiencing in your knee. For each situation, please enter the amount of pain you have experienced in the past 48 hours.

	None	Mild	Moderate	Severe	Extreme
a. Walking on a flat surface					
b. Going up or down stairs					
c. At night while in bed					
d. Sitting or lying					
e. Standing upright					

The following questions concern the amount of joint stiffness (not pain) you have experienced in the last 48 hours in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

	None	Mild	Moderate	Severe	Extreme
2 How severe is your stiffness after first waking in the morning?					

	None	Mild	Moderate	Severe	Extreme
3. How severe is your stiffness after sitting, lying, or resting later in the day?					

4. The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours in your knee.

What degree of difficulty do you have with:	None	Mild	Moderate	Severe	Extreme
a. Descending (going down) stairs					
b. Ascending (going up) stairs					
c. Rising from sitting					
d. Standing					
e. Bending to the floor					
f. Walking on a flat surface					
g. Getting in and out of a car					
h. Going shopping					
i. Putting on socks/stockings					
j. Rising from bed					
k. Taking off socks/stockings					
l. Lying in bed					
m. Getting in/out of bath					
n. Sitting					
o. Getting on/off toilet					
p. Heavy domestic duties (such as mowing the lawn, lifting heavy grocery bags, vacuuming)					
q. Light domestic duties (such as tidying a room, dusting, cooking)					

Appendix B
Technical Expert Panel Members and Reviewers

Evidence Based Practice Center (EPC) – Total Knee Arthroplasty
Technical Expert Panel Members

We are indebted to the Technical Expert Panel Members for providing both consultation during the development of this project and feedback on the initial draft.

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Appendix C
Exact Search Strings

Search Strings for Total Knee Arthroplasty (TKA) Outcomes

The literature search was done using the following combination of MeSH headings, keywords, and publication types:

(arthroplasty, replacement, knee [mh] OR
knee prosthesis [mh] OR
"knee replacement" OR
"knee implant" OR
((TKAR OR prosthesis design [mh]) AND
(knee [mh] OR knee injuries [mh] OR knee joint [mh])))

AND

(meta-analysis [pt] OR
clinical trial [pt] OR
controlled clinical trial [pt] OR
randomized controlled trial [pt] OR
review [pt] OR
review literature [pt] OR
review, multicase [pt] OR
multicenter study [pt] OR
guideline [pt] OR
practice guideline [pt] OR
consensus development conference [pt] OR
evaluation studies [pt] OR
validation studies [pt] OR
clinical trials [mh] OR
controlled clinical trials [mh] OR
cohort studies [mh] OR
retrospective studies [mh] OR
prospective studies [mh] OR
followup studies [mh] OR
cross-sectional studies [mh] OR
double-blind method [mh] OR
comparative stud y[mh] OR
questionnaires [mh] OR
outcome assessment (health care) [mh] OR
treatment outcome [mh] OR
statistics [mh] OR
small-area analysis [mh] OR
cross-cultural comparison [mh] OR
cross-over studies [mh] OR
epidemiologic studies [mh] OR
longitudinal studies [mh] OR
multicenter studies [mh] OR
nursing evaluation research [mh] OR

multivariate analysis [mh] OR
psychometrics [mh] OR
evaluation studies [mh] OR
empirical research [mh] OR
data collection [mh] OR
"systematic revie w*" OR
"systematic literature review*" OR
meta-analysis OR
meta-analysis OR
meta-analyses OR
evidence-based OR
"case series")

Search Strings for Total Knee Arthroplasty Access

The literature search was done via PubMed using the following combination of MeSH headings and keywords:

knee prosthesis/ut

OR

((arthroplasty, replacement, knee [mh] OR
knee prosthesis [mh])

AND

(gender OR
race OR
bias OR
prejudice OR
disparity OR
physician's practice pattern [mh]))

Search Strings for Total Knee Arthroplasty Revisions

The search consisted of the following combination of MeSH headings and keywords:

((arthroplasty, replacement, knee[mh] OR
knee prosthesis[mh])

AND
(reoperation [mh] OR
revision, joint [mh])).

Appendix D
Abstracting Form

Total Knee Replacement Article Abstraction Form
(Data search from 1995 through 2002)

Author: _____ Study Unique Identifier:_____

Journal: _____

Year Publication: _____

Country: _____
(where study performed)

Reviewer: _____

Funding Source: Government Pharmaceutical Private
Non-funded Unknown

VERIFICATION/SELECTION OF STUDY ELIGIBILITY

Reported on primary total knee arthroplasty	Yes	No	Unclear
Reported any postoperative outcomes	Yes	No	Unclear
Experimental or Quasi-experimental	Yes	No	Unclear
Study sample 100 or > knees	Yes	No	Unclear
Baseline data provided	Yes	No	Unclear

Stop if any of the above is "NO"

Reported on revision knee procedures only *Yes* *No* *Unclear*

Stop if "Yes"

TYPE OF STUDY *(circle one)*

SPECIAL POPULATION (write in):_____
(*examples age (<50 or >80), trauma, hemophiliacs, patients with CHD*)

1. Quasi-experimental cohort: (investigator studies the effect of intentionally altering 1 or more factors under controlled conditions) Retrospective vs. Prospective
2. Case Control
3. Randomized controlled trial
4. Other _____

ASSESSMENT OF STUDY QUALITY *(based on "Systems to Rate the Strength of Scientific Evidence, AHRQ Publication No. 02-E016, April 2002*)

Score each domain on a scale of 0 (poor, not defined) to 5 (excellent, clearly defined)

Observational Studies Quality Domains/Elements	Score
Study question clearly focused and appropriate *Notes:*	
Description of Study Population *Notes:*	
Clear definition of intervention *Notes:*	
Primary/secondary outcomes defined *Notes:*	
Statistical Analysis: Assessment of confounding attempted Did the analysis adjust for or examine the effects of various factors (i.e., population baseline characteristics, characteristics of surgeons, training, surgical procedures, types of prostheses mentioned/ incorporated into the analyses) *Notes:*	
Statistical methods used to take into account the effect of more than one variable on the outcome such as multiple regression, multivariate analysis, regression modeling -*see methods in paper* *Notes:*	
Measure of effect for outcomes and appropriate measure of precision *Notes:*	
Conclusions supported by results with possible bias and limitations taken into consideration *Notes:*	
Single versus Multi-site study (*note one of the other*) *Notes:*	
Patients evaluated with radiographs for outcomes *Notes:*	
Comorbidities mentioned *Notes:*	
Comorbidities incorporated in the analyses *Notes:*	
Attrition accounted for *Notes:*	
Death rates recorded *Notes:*	

Patient characteristics

	Group Values	***Noted but no values provided***	***Not Indicated***	***Variable used in the analysis (yes/no)***
Total Number of Subjects				
Number of subjects lost to attrition				
Number of subjects that died				
Subjects examined in the clinic				
Subjects evaluated with questionnaire and readiographs and not in the clinic				
Total # Knees				
Patients with bilateral knee surgeries				
Age, average and range % by age group <55 55-64 65-74 75-85 85				
Women, # and %				
Men, # and %				
Race/ethnicity: White # and %				
Race/ethnicity: Black # and %				
Race/ethnicity: Asian # and %				
Race/ethnicity: Hispanic # and %				
Height				
Weight				
Body Mass Index (BMI)				
# of Obese subjects				
Prior history, # and % With previous knee surgery				
Prior history, # and % With previous joint surgery				
Rheumatoid arthritis, # and %				

	Group Values	*Noted but no values provided*	*Not Indicated*	*Variable used in the analysis (yes/no)*
Osteoarthritis, # and %				
Severity/ e xtent of OA in other joints - degree of involvement in	other knee: hips : spine: other:			
Comorbidities, diabetes				
Comorbidities, stroke				
Comorbidities, neuro-muscular disease				
Comorbidities, CHD				
Comorbidities, CHF				
Comorbidities, HTN				
Comorbidities, COPD				
Comorbidities, other				

Patient characteristics: Knee factors

	Group Values	*Noted but no values provided*	*Not Indicated/ Reported*	*Variable used in the analysis (yes/no)*
Preoperative range of motion				
Tibio-femoral angle, in degrees)				
Extensor mechanism integrity *quadriceps tear, patellar fracture or, tendon rupture*				
Ligament integrity Medial Lateral	intact stretched not intact			

Prosthesis Characteristics

	Group Values	***Noted but no values provided)***	***Not Indicated/ Reported***	***Variable used in the analysis (yes/no)***
Material Cobalt/chromium Titanium Polyethelene				
Fixation tibia uncemented cemented stem femur uncemented cemented stem				
Augmentation • Augments on femur posterior anterior • Augments on tibia medial lateral • allograft morsellized structural				
Type of knee prosthesis • posterior cruciate (PS) ligament substitution • posterior cruciate retaining (CR) • semi constrained • constrained /rotating hinge • unicondylar				

Surgical Factors

	Group Values	***Noted but no values provided***	***Not Indicated/ Reported***	***Variable used in the analysis (yes/no)***
Experience (years of practice)				
Volume				
Hospital volume				
Hospital training program				
Surgical approach • extensile • rectus snip • v-y turndown • tibial tubercle turndown • paprapatellar • tourniquet use				
Type of anesthetic • regional • general				

Postoperative Conditions/Complications

	Group Values	***Noted but no values provided***	***Not Indicated/ Reported***	***Variable used in the analysis (yes/no)***
Total # of complications				
Pulmonary embolus				
DVTs				
Pneumonia				
Cardiac infarct				
Stroke				
Other				
Other				
Other				
Other				

Knee-Related Postoperative Conditions/Complications

	Group Values	***Noted but no values provided***	***Not Indicated/ Reported***	***Variable used in the analysis (yes/no)***
Total # of complications				
Death, related to the procedure				
Percent required revision/failed				
Wound infection Superficial Deep Early, ≤3 months Late, >3 months				
Bleeding				
Delayed wound healing				
Wound drainage				
Hematoma				
Knee effusions				
Aspetic loosening				
Other				
Other				

Postoperative Interventions

	Group Values	***Noted but no values provided***	***Not Indicated/ Reported***	***Variable used in the analysis (yes/no)***
Anticoagulation • when				
Prophylactic antibiotics				
Vena caval filters				
TEDS				
Physical Therapy • when (pod)*				
Occupational Therapy • when (pod)				

	Group Values	*Noted but no values provided*	*Not Indicated/ Reported*	*Variable used in the analysis (yes/no)*
CPM (Continuous flexion machine)				
Anti-inflammatory				
Preop medical optimization (i.e., cardiac, pulmonary, glucose control) ♦ when				
Postoperative medical management	Routine: Consult:			
Weight loss ♦ when				
Blood loss				
Erythropoietin				
Preop patient education				
Other				
Other				

Pod = post operative day

Radiographic Findings

	Variable recorded (yes/no)	*Variable used in the analysis (yes/no)*
Extremity alignment, mechanical axis		
Component – Tibia alignment		
Component – Femur alignment		
Tibiofemoral angle		

Outcome Scores: If more than one followup is reported, record and note each time interval.
Postop (Postoperative) Followup: please indicate years, or months

Outcome Scores

	Group Values (record standard deviations or errors, range and p-values if provided)	***Number of Subjects analyzed if provided***	***Noted but no values provided***
Global Knee Scale (GKS) (*write in %s for each* Poor: xx% Fair/Satisfactory: xx% Good: xx% Excellent: xx%	**Baseline** Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____ ***Postop Followup (write in):*** _____ Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____		
Knee Society (KS) (*measures pain and function-walking and stair climbing)* (*write in %s for each* Poor: xx% Fair/Satisfactory: xx% Good: xx% Excellent: xx%	Clinical/Pain (indicate whether just pain was recorded): Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____ Functional: Baseline score:_____ ***Postop Followup (write in):*** _____(yrs, mos.) Score:_____ Total Score: Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____ Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____		

	Group Values (record standard deviations or errors, range and p-values if provided)	*Number of Subjects analyzed if provided*	*Noted but no values provided*
Hospital for Special Surgery (HSS): 0-100 points *write in %s for each* Poor: xx% Fair/Satisfactory: xx% Good: xx% Excellent: xx%	Baseline: Score:_____ ***Postop Followup (write in):*** **_____** Score:_____ Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____		
Western Ontario McMaster Osteoarthritis Index (WOMAC)	**<u>Function</u>:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **<u>Stiffness</u>:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **<u>Pain</u>:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Total Score:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		

	Group Values (record standard deviations or errors, range and p-values if provided)	*Number of Subjects analyzed if provided*	*Noted but no values provided*
Short Form Health Survey (SF-36)	**General health:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Body pain**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Role emotional**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Mental health**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Physical function**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Role physical**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Social function**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Vitality**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		

	Group Values (record standard deviations or errors, range and p-values if provided)	***Number of Subjects analyzed if provided***	***Noted but no values provided***
	<u>Combined physical</u>: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **<u>Combined mental</u>**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		
Other, write in name of scale_____ Measures:_____ *(function, pain, walking, etc.)*	Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		
Other, write in name of scale__ _____ Measures:_____ *(function, pain, walking etc.)*	Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		

Subgroup Outcome Scores (attach additional sheets if necessary)

***Subgroup (write in)*:**_____

	Group Values (record standard deviations or errors, range and p-values if provided)	***Number of Subjects analyzed if provided***	***Noted but no values provided***
Global Knee Scale (GKS) (*write in %s for each* Poor: xx% Fair/Satisfactory: xx% Good: xx% Excellent: xx%	**Baseline** Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____ ***Postop Followup (write in):*** _____ Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____		
Knee Society (KS) **(*measures pain and function-walking and stair climbing)*** (*write in %s for each* Poor: xx% Fair/Satisfactory: xx% Good: xx% Excellent: xx%	<u>Clinical/Pain (indicate whether just pain was recorded)</u>: Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____ <u>Functional</u>: Baseline score:_____ ***Postop Followup (write in):*** _____(yrs, mos.) Score:_____ <u>Total Score</u>: Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____ Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____		

	Group Values (record standard deviations or errors, range and p-values if provided)	*Number of Subjects analyzed if provided*	*Noted but no values provided*
Hospital for Special Surgery (HSS): 0-100 points *write in %s for each* Poor: xx% Fair/Satisfactory: xx% Good: xx% Excellent: xx%	Baseline: Score:_____ ***Postop Followup (write in):*** **_____** Score:_____ Poor: # and %:_____ Fair/Satisfactory: # and %:_____ Good: # and %:_____ Excellent: # and %:_____		
Western Ontario McMaster Osteoarthritis Index (WOMAC)	**<u>Function</u>:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **<u>Stiffness</u>:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **<u>Pain</u>:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Total Score:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		

	Group Values (record standard deviations or errors, range and p-values if provided)	*Number of Subjects analyzed if provided*	*Noted but no values provided*
Short Form Health Survey (SF-36)	**General health:** Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Body pain**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Role emotional**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Mental health**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Physical function**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Role physical**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Social function**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____ **Vitality**: Baseline score:_____ ***Postop Followup (write in):*** **_____** Score:_____		

	Group Values (record standard deviations or errors, range and p-values if provided)	***Number of Subjects analyzed if provided***	***Noted but no values provided***
	<u>Combined physical</u>: Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____ **<u>Combined mental</u>**: Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____		
Other, write in name of scale_____ Measures:_____ *(function, pain, walking, etc.)*	Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____		
Other, write in name of scale_____ Measures:_____ *(function, pain, walking etc.)*	Baseline score:_____ ***Postop Followup (write in):*** _____ Score:_____		

Appendix E

Functional Outcome Following Total Knee Arthroplasty Revision: A Meta-analysis

Functional Outcome Following Total Knee Arthroplasty Revision: A Meta-analysis

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Functional Outcome Following Total Knee Arthroplasty Revision: A Meta-analysis

ABSTRACT

Objective- The objective of this study was to perform a systematic literature review to describe patient outcomes following Total Knee Arthroplasty Revision (TKAR) procedures using various Global Knee Score (GKS) ratings. **Data Sources**-English Language articles published from 1966 through 2000, were identified through a computerized literature search and bibliography review. **Study selection**-A multistage assessment was used to determine those articles containing data that could meet our objective. **Analysis**- Meta-analyses of Global Knee Scores were undertaken using a fixed effects model with the assumption that the variances of each individual measurement were identical across studies. **Results**- 58 articles with a total of 1965 patients met the initial inclusion criteria. Forty-two articles comprising 45 unique patient cohorts and a total of 1515 patients had sufficient GKS data for analysis and were used in the meta-analyses. **Conclusions**- Revision total knee arthroplasty is an effective procedure for failed knee replacements based on global knee rating scales.

INTRODUCTION

Arthritis is generally a slowly progressive disease that afflicts more than two-thirds (68%) of Americans older than 55 years of age.[1] It becomes increasingly prevalent with advancing age.[2,3]. At present, 43 million individuals have arthritis. By the year 2020, it is estimated that 59.4 million persons will be affected by this disease.[1] The high prevalence of arthritis in the population is reflected in the high cost of treatment and has been estimated to cost 95 billion dollars (US) per year.[1]In 1996 over 607,000 hip and knee replacements were performed in the U.S.[6] By the year 2030, it is estimated that there will be an 85 % increase in knee replacements and an 80% increase in hip replacements[7]

Like all biomedical devices, total knee replacements can fail over time.[16] Coincident with the increased incidence of primary TKA, there has also been an increase in the number of total knee arthroplasty revision (TKAR) procedures.[17] In 1995, 19,138 TKAR procedures were performed in the U.S.[18] Using Ontario 1989-94 discharge data, Coyte[18] derived an annual growth rate of 14.1% for TKAR procedures. The number of TKAR procedures is expected to continue to grow as a result of complications associated with TKA, including infection, fracture and time-dependent implant failure that necessitate re-operation.[21].

Unfortunately, long-term TKAR outcome data reporting knee specific or Global Knee Scores (GKS) in the arthroplasty literature is deficient. Callahan et al[24] defined a Global Knee Score as "an instrument that measured patient outcomes in the domains of pain, function, and range of motion and combined these domains in a summary scale." Examples of such scales include the Hospital for Special Surgery score (HSS) and Knee Society (KS) score. The specific aim of this study was to perform a systematic literature review to describe patient outcomes following TKAR procedures by using GKS to examine the following questions:

- Is there a significant increase from the preoperative GKS to the postoperative GKS?
- Is there correlation between preoperative GKS and the increase in the postoperative scores?
- What proportion of TKAR subjects attains excellent/good (E/G) results postoperatively, and what proportion attains satisfactory/poor (S/P) results?
- Does the proportion of E/G, or the postoperative values of HSS and KS scores, vary with the length of followup, the year of study publication, or preoperative diagnosis (i.e., infection, loosening, etc.)?

Arthritis tends to involve multiple joints, and as a result we wanted to examine the outcome of cohorts with subjects that had multiple knees revised versus cohorts that were comprised of subjects who only had a single knee revised:

- Is there a difference between the multiple and single knee cohorts in the percentage of subjects that attain E/G postoperatively?
- Is there a difference between the multiple and single knee cohorts in the preoperative HSS or KS scores or the score increases?

Finally we considered the entire data set of studies in order to assess the rates of complication following TKAR.

METHODS

Literature Search

We performed a computerized literature search using Medline to identify all citations concerning prosthetic knee procedures published from 1966 through 2000 using the MeSH terms "knee", "prosthesis" and "replacement". We obtained a copy of the abstracts for each identified English-language citation. We then used a multistage assessment similar to Callahan et al.[24] to identify articles relevant to our questions. At the first stage, two study investigators (KS and TG) each reviewed the abstracts to determine which articles 1) reported any postoperative outcomes 2) reported on revision knee procedures and 3) had a study sample greater than five subjects. At the second stage, these articles were then extracted and reviewed. The bibliography sections in all review articles were examined and missed citations were retrieved. At the third stage of assessment the same investigator excluded any study articles that did not report results using a global knee rating scale.

Data Abstraction

Data entry was carried out by two trained data abstractors (AR and RS). We analyzed variables that were reported across the majority of studies. Difficulties in abstracting data came from non-reported information or data that were reported on only a subset of the studies. Variables that were not consistently reported included: race, weight, medical comorbidities, previous numbers of surgeries on the index knee, time elapsed since the previous knee replacement, method of anesthesia, operative techniques (such as exposure, component removal, cement use, type of prosthesis, treatment of cruciate ligaments and allograft or metal augmentation), perioperative antibiotics, thrombosis prophylaxis, and postoperative rehabilitation course. Studies also showed variability in reporting complication rates; hence local complications including delayed wound healing, wound drainage, hematoma, knee effusions, and pressure sores could not be evaluated. Systemic complications including cardiac, gastrointestinal, neurologic, urologic, also could not be analyzed. Variables such as prosthetic design and source of research funding also were not consistently reported. Finally, the specifics of score administration methodology were not consistently reported.

Data Analysis

For both KS (functional, clinical and averaged) and HSS scales, the preoperative and postoperative scores and the mean differences between preoperative and postoperative scores, were meta-analyzed to provide overall estimates for these values. Similar meta-analyses were carried out on the number of years of followup, age of patients, and other variables.

These meta-analyses were all "fixed effects"[25] carried out under the assumption that the variances of each individual measurement are identical across studies. This assumption, also made by Callahan et al.[24] is needed since information on variances is usually not given in these studies. Improving on the methodology of Callahan et al.,[24] the variance of the overall estimate

was derived under this model using the between-study variability, leading to a 95% confidence interval (CI) on each overall estimate.

This analysis calculates a weighted average of the values in each study, where the weights are the study sizes, as in Callahan et al.[24] Study size was taken to be the reported number of subjects in each study minus the number reported as lost to followup. In some studies it was not clear if the size of study used in calculating the mean was the original number enrolled or the number minus those lost to followup. Therefore we also carried out the majority of the analyses using the total enrolled to see if this affected the overall answers. No changes of any importance occurred as a result.

Many studies also contained a classification into excellent/good (E/G) results versus satisfactory/poor (S/P) results, and a fixed effects meta-analysis of these E/G proportions (corrected for zero counts) was also carried out. The variances in this context were estimated using binomial methods, again allowing estimation of a 95% CI.

For further analysis the studies were divided into two groups: those with the "number of knees" reported as greater than the number of subjects, and those with the same number of subjects and knees reported. These groups were analyzed separately for each of the variables above. The hypothesis that the groups were different was tested, using single sample t-tests on the meta-analyzed values.

The dependence of the results on the number of years of followup was investigated. After consideration of the data, separate regressions were fitted to the studies that carried out followup for less than 60 months versus those that had longer followup periods. These results are exploratory, since this cut-off was subjective and accordingly we could not formally test the hypothesis that the periods were different.

Temporal trends in the data were analyzed against the mid-year of the stated study period to assess changes in results as newer methods were introduced. There were limited data to carry out this investigation, but there was no evidence of any secular trend in any of the measured scores. Studies also were grouped into those where all patients were treated because of infection and compared to those where < 10% were treated because of infection, and the proportions scoring E/G were compared. There were too few articles to allow a meaningful comparison for the KSS and HS scores. Finally, complications were tabulated and categorized into systemic and mechanical failure requiring re-revision.

RESULTS

Literature Description

A total of 2780 abstracts were identified in the literature using the above MeSH terms. Two hundred eighty-seven proceeded to the second stage after the abstracts were retrieved and examined. We then obtained a copy of the 287 articles and the bibliographies were reviewed for additional citations. The bibliographic review resulted in the addition of two studies to the candidate pool of articles. Fifty-eight of the 289 articles passed through the final filter and became the final data set.

These 58 articles from thirty-one different academic institutions were published from 1973 through 1994 (Appendix E-1). Pre- and postoperative KS scores were reported in fifteen studies (Table E-1), and HSS scores in seventeen (Table E-2). Two of these studies reported both KS and HSS data. Thirty-five studies reported a pre- and postoperative categorical outcome data that were stratified into four groups as: excellent, good, satisfactory, and poor (Table E-3). Overall, 46 unique patient cohorts from 42 articles had sufficient data to enable analysis of KS scores, HSS scores, or categorical E/G outcome data. The remainder had a variety of other global scores, with not enough of any one to support systematic analysis.

Patient Characteristics

For the 58 studies extracted there were a total of 1965 patients. A subgroup of 42 papers with 1,515 patients was used in the main analyses (Appendix E-1). The mean patient age across these 42 papers was 66.6 years. Approximately 61% of the enrolled subjects were women (based on thirty-seven studies who reported the gender data). This ranged from a minimum of 28% to a maximum of 82%. Osteoarthritis was the primary reason for the index knee replacement. The average number of months of followup for the studies reporting KS was 53.1 (95% CI 44.5-61.7) and for HSS was 55.2 (95% CI 47.4-63.0); this difference was not statistically significant ($p>0.1$). The patients' race and socio-economic status were not systematically reported.

Summary of Findings

Is there a significant increase from the preoperative GKS to the postoperative GKS?

The preoperative combined mean KS score was 35.4 (95% CI 30.7-39.9) and there was a highly significant increase of 30.8 (95% CI 26.6-35.0) points to 66.2 (95% CI 61.8-70.2) points postoperatively ($p<0.0001$). The preoperative functional mean KS score was 30.4 (95% CI 22.8-37.9) with a highly significant increase of 27.0 (95% CI 21.8-32.2) points to 57.4 (95% CI 51.6-62.7) points postoperatively ($p<0.0001$); the preoperative clinical mean KS score was 32.8 (95% CI 25.5-40.0) with a highly significant increase of 42.1 (95% CI 39.2-45.0) points to 74.9 (95% CI 68.6-80.8) points postoperatively ($p<0.0001$). Note that the latter two subscales were on a subset of the 15 studies on which combined results could be calculated. The preoperative mean HSS score was 51.5 (95% CI 48.9-54.1) and there was a highly significant increase of 28.3 (95% CI 25.3-31.2) points to 79.8 (95% CI 76.4-83.1) points postoperatively ($p < 0.0001$).

Is there correlation between preoperative GKS and the increase in the postoperative scores?

There is no significant correlation between the preoperative score and the amount of improvement in either the overall KS ($r = -0.09$, $p > 0.7$) or the HSS ($r = -0.263$, $p > 0.3$) studies.

Is there a difference in the preoperative scores between the multiple and single knee cohorts?

Although there was no difference in age or gender between the multiple and single knee reports, there was a significant difference in preoperative HSS scores, multiple knee (49.5, 95% CI 45.9-53.2) and the single knee (54.5, 95% CI 51.4-57.5) studies ($p<0.1$). The preoperative combined mean KS score in the multiple knees group was, in contrast, higher (77.0, 95% CI 64.2-89.8) than the single knee group (59.85, 95% CI 45.2-74.5), which is just significant ($p>0.1$) in the other direction. This result is, however, heavily influenced by a preoperative combined score of only 4.2 in one fairly large study. These results indicate that the multiple knee cohorts may be more severe preoperatively then their counterparts, although this is not conclusive.

Is there a difference in the increase in KS or HSS scores between the multiple and single knee groups?

The meta-analyzed averaged KS mean difference between pre- and postoperative scores was statistically not significant between the multiple knee (60.0, 95% CI 49.4-70.5) and single knee (64.4, 95% CI 50.3-78.5) studies. The meta-analyzed HSS mean difference between pre- and postoperative scores was statistically not significant between the multiple knee (28.9, 95% CI 25.5-32.3) and single knee (27.2, 95% CI 22.5-32.0) studies.

Does the increase in HSS or KS scores vary with the length of followup?

On an exploratory basis, the mean difference increases on both GKS scores up to around 60 months, thereafter KS (Figure E-1) and the HSS score marginally declines (Figure E-2).

What proportion of TKAR subjects attains excellent/good (E/G) results on the GKS postoperatively, and what proportion attains satisfactory/poor results?

The percentage of subjects attaining an excellent/good postoperatively was 77.7% (95% CI 75.2-80.2).

Is there a difference in the percentage of subjects that attain E/G ratings postoperatively on the GKS between the multiple and single knee cohorts?

The percentage of subjects attaining E/G was 72.7% (95% CI 69.5-76.3) in studies reporting on cohorts where some subjects had both knees revised, compared to 82.6% (95% CI 79.1-86.3) in studies reporting on cohorts where no subjects were reported to have had multiple knees revised. This difference is significant ($p < 0.05$). Those patients in whom single revision knee replacements were performed had better postoperative scores.

Does the proportion of E/G vary with the length of followup?

On an exploratory basis, the percentage of E/G subjects increase up to around 60 months (Figure E-3).

Does the proportion of E/G vary with the presence of infection as a proximate cause for revision?

There was a significant difference in the proportion of E/G outcomes between those articles in which a higher percentage of patients with infection as the proximate cause for revision as compared to those in which fewer patients were infected. ($p < 0.05$) Uninfected patient series do better with the proportion of E/G outcomes equal to 78.5% (95% CI 74.7%-82.3%). The greater proportion of infected patient series have worse outcomes with the proportion E/G equal to 67.5% (95% CI 61.5%-73.4%).

What is the complication rate following TKAR?

Forty-four of 46 (95.7%) cohorts reported complication data on 1,683 subjects who incurred 443 complications (26.3%). It was not possible to determine which or how many complications occurred in any given patient or patient subset (Table E-4). There were a total of 217 knee complications in 1,683 subjects necessitating re-revision (12.9%). Callahan et al. found a 30% overall complication rate and a 7.2% revision rate in 18 bicompartmental knee arthroplasty reports which 884 enrolled patients and an 18.5 overall complication rate and a 9.2% revision rate in 46 unicompartmental knee arthroplasty reports which 2,391enrolled patients.[27]

DISCUSSION

Ideally, clinical information is gathered through large, carefully controlled and randomized prospective studies. However, such studies are technically and logistically complex, expensive, and often impractical or impossible. Meta-analysis, which is less complex, specifically increased the statistical power of our study and reduced the chance of type II statistical errors.[24] In this situation, the results produced meaningful information that was not apparent on the basis of the smaller studies alone. It is not always the case that there is perfect concordance between the results of meta-analyses and subsequent randomized controlled trials.[26] However, this technique is helpful in allowing an investigator to better design and appropriately power subsequent clinical trials.

In the case of TKAR, epidemiological studies have clearly demonstrated a rapidly growing demand for this surgery.[7] However, knowledge regarding its outcomes has been lacking. In this communication, we report the results of a systematic review of the literature concerning patient outcomes following TKAR. Although TKAR is among the most technically challenging orthopaedic procedures, it is clear from these results that patients attain favorable outcomes following this procedure.

The majority of patients reported significant improvement in GKS following TKA. Patients reported mean postoperative KS and HSS scores which were 87.3% and 49.2% greater than their respective preoperative values, with slightly greater than three-quarters (77.7%) of patients reporting "excellent" or "good" outcomes. While this study supports the common belief that

revision arthroplasty surgery is generally less successful than primary procedures, these data compare favorably with those reported in meta-analyses of primary knee replacement outcomes. Using literature synthesis data, Callahan et al. reported mean improvements in global rating scale scores of 63%, 93%, and 100%, and good or excellent outcomes in 80%, 73%, and 90% of patients following primary unicompartmental,[27] bicompartmental,[2], and tricompartmental knee arthroplasty,[24] respectively. Cohorts consisting exclusively of single-knee TKAR subjects had significantly higher proportions of subjects reporting E/G outcomes than those that included subjects with bilateral TKAR. However, although patients in the bilateral knee cohorts had slightly lower mean preoperative HSS scores and slightly higher mean preoperative KS scores, we found no significant difference in the degree to which patients improved following single-knee TKAR or revision surgery of both knees. This finding, which has not been previously observed, is consistent with our general finding that preoperative GKS does not appear to affect the magnitude of the reported success of the procedures. A thorough assessment of any clinical procedure must weigh the benefits of the procedure against its complications.

There was insufficient data reported to analyze the rates of preoperative or postoperative mortality. However, the majority (95.7%) of studies included in this analysis reported at least some complication data, with an overall complication rate of 26.3%. While the rates of most TKAR complications were consistent with those reported for primary TKA, an unusually high incidence of patellar component failure (11.1%), arterial injuries (10.3%), fracture of the proximal tibia (7.1%), and deep wound infection (6.7%) was identified in this study. This effect may have been falsely inflated secondary to our study-rule that assumes all complications were not screened for and only reported when they arose, artificially deflating the denominator and increasing the rate. The subgroup of patients with infection as a proximate cause for revision appears particularly challenging as their likelihood of achieving excellent or good outcomes is reduced.

Certain limitations are inherent to meta-analysis methodology. The results of data synthesis from multiple publications is limited by the quality and quantity of data reported in the included studies. In this analysis, we discovered considerable variation in the existing TKAR literature with respect to study size and design, followup period, and the authors' style of reporting many salient variables. As in previous meta-analyses, insufficient data were present to assess the impact of patient demographic characteristics, socio-economic status, implant characteristics, details of the surgical procedures, or postoperative care regimens on the outcome of TKAR. Accordingly, although we demonstrate significant overall favorable outcomes following TKAR surgery, we are unable to identify those particular factors that lead to improvement in postoperative

Scores. Similarly, complication data were only variably reported and particular complications were seldom attributable to particular patients.

CONCLUSION

TKAR appears to be an effective treatment for most patients facing the painful, disabling and clinically challenging effects of failed knee arthroplasty. Clearly, the existing literature regarding outcome of TKAR is deficient, in experimental methodology and longer-term results. Future studies investigating the results of TKAR should utilize better experimental design, including validated assessment tools, independent assessment of outcomes, larger patient samples, and

longer followup. Additionally, future reports must adhere to improved reporting standards, including better reporting of loss to followup information, surgical and implant details, outcome measures, complications and patient characteristics including socioeconomic status, comorbidity, proximate cause for revision, and extent of local disease at the time of revision.

Appendix E-1

58 Articles identified in the literature search which were included in the final Meta-analytic data set

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Table E-1. Fifteen studies reporting Knee Society (KS) scores

Paper	Number of Subjects	Number of Knees	Mean Age, years (range)	Average Followup (months)	Preoperative Clinical (or combined◆) KS Score	Postoperative Clinical (or combined◆) KS Score	Preoperative Functional KS Score	Postoperative Functional KS Score
Barrack et al., 1998	15	15	69.6 (NR)	NR	◆ 79	◆ 125	NR	NR
Barrack et al., 1998	51	51	71.3 (NR)	NR	◆ 97	◆ 138	NR	NR
Bradley, 2000	21	19	69 (43-89)	33	◆ 60	◆ 147	NR	NR
Elia et al., 1991	38	40	64.5 (22-91)	41	41	77.6	43	56
Hanssen et al., 1994	86	89	68 (28-85)	52	32.3	77	27.6	56
Hartford et al., 1998	16	16	NR	60	38	85	24	58
Kraay et al., 1992	7	7	74 (NR)	44	◆ 71	◆ 83	NR	NR
Lai et al., 1993	45	48	64 (45-84)	65	41	80	47	74
Murray et al., 1994	35	40	67.2 (47-92)	58.2	38	83.7	46.6	64.8
Pagnano et al., 1998	25	25	65 (NR)	37.2	45	90	42	75
Partington et al., 1999	99	107	68 (52-80)	44.4	◆ 86	◆ 131	NR	NR
Rand 1991	19	21	65 (56-71)	48	21	71	11	56
Takahashi et al., 1994	36	39	70.8 (56-91)	24	50.5	82.7	35.9	56.1
Van Loon et al., 1999	18	18	61 (38-79)	34.1	44.8	80.9	28.8	44.7
Whiteside et al., 1998	63	63	71 (57-91)	108	3.3	48.2	5	41.1
	574	598	67.7 (22-92)	53.1 (44.5-61.7)*	32.8 (25.5-40.0)*	74.9 (68.6-80.8)*	30.4 (22.8-37.9)*	57.4 (51.6-62.7)*

* weighted values (95% CI)
NR = not reported in article

Table E-2. Seventeen studies reporting Hospital for Special Surgery (HSS) scores

Paper	Number of Subjects	Number of Knees	Mean Age (range)	Average Followup (months)	Preoperative HSS	Post-operative HSS
Donaldson et al., 1988	14	14	68 (56-82)	NR	44.8	51.2
Engh et al., 1997	26	26	68.8 (31-87)	NR	54	86
Fehring et al., 1998	36	36	64 (45-84)	56	59	82
Fehring et al., 1998	27	27	62 (38-79)	44	62	88
Gustilo et al., 1996	51	56	68 (50-84)	99.6	54.7	79.3
Haas et al., 1995	76	78	54 (28-73)	42	49	76
Hanssen et al., 1988	53	53	NR	37	58	82
Insall et al., 1982	72	72	62 (22-88)	NR	49	83
Jackson et al., 1994	23	24	74 (38-90)	46	52	70
Kim, 1987	14	14	NR	50.4	58	81
Knight et al., 1997	12	12	65 (26-85)	27	56	86
Lai et al., 1993	45	48	NR	64.8	57	82
Mow et al., 1994	16	17	65 (56-71)	72	52	87
Peters et al., 1997	55	57	69	62	47	82
Rand, 1991	19	21	NR	48	41	73
Rand et al., 1998	51	54	62.3 (36-74)	57.6	52	81
Rosenberg et al., 1991	42	43	65	NR	36	74
	632	652	65.2 (22-90)	55.2 (47.4-63.0)*	51.5 (48.9-54.1)*	79.8 (76.4-83.1)*

* weighted values (95% CI)
NR = not reported in article

Table E-3. Studies reporting pre- and postoperative GKS and stratifying subjects categorically as excellent / good / satisfactory / poor

Paper	Adjusted Numberof subjects	Adjusted Number of Knees	Postoperative Number Excellent/Good	Postoperative Number Satisfactory/Poor	Postoperative Excellent/Good Proportion
Cameron et al., 1981	62	62	22	38	0.367
Chotivichit et al., 1991	18	18	14	4	0.778
Donaldson et al., 1988	14	14	7	2	0.778
Dorr et al., 1986	14	14	7	0	1
Elia et al., 1991	38	40	30	10	0.75
Engh et al., 1997	26	26	22	4	0.846
Fehring et al., 1998	20	20	14	6	0.7
Fehring et al., 1998	27	27	18	3	0.857
Goldman et al., 1996	60	64	46	18	0.719
Gustilo et al., 1996	51	56	50	6	0.893
Hartford et al., 1998	16	16	13	1	0.929
Hirakawa et al., 1998	54	55	31	10	0.756
Insall et al., 1982	72	72	64	8	0.889
Jacobs et al., 1989	9	9	5	4	0.556
Karpinski et al., 1987	51	52	12	40	0.231
Knight et al, 1997	10	10	9	1	0.9
Lachiewicz et al., 1996	21	21	20	1	0.952
Lai et al., 1993	45	48	39	9	0.813
Nicholls et al., 1990	12	13	5	8	0.385
Otte et al., 1997	28	29	20	9	0.69
Padgett et al., 1991	17	19	16	3	0.842
Pagnano et al., 1998	25	25	0	2	0
Pagnano et al., 1995	32	32	16	1	0.941
Peters et al., 1997	55	57	45	12	0.789
Rand et al., 1987	20	20	16	5	0.762
Rooser et al., 1987	55	69	29	11	0.725
Rosenberg et al., 1991	35	36	25	10	0.714
Wilde et al., 1988	13	13	7	4	0.636
Wilde et al., 1990	10	12	9	3	0.75
	910	949	611	233	77.7 (75.2-80.2)*

* weighted value (95% CI)

Table E-4. Complications

Description of Complication	Number of Studies Reporting Complication	Number of Knees in Reporting Studies	Number of Complications (%)
Prosthesis fracture, tibial	1	23	5 (21.7)
Failed patellar component	5	171	19 (11.1)
Deep vein thrombosis	5	154	16 (10.4)
Arterial injury	3	39	4 (10.3)
Wound, retained foreign body	7	321	30 (9.3)
Other complications	34	1182	97 (8.2)
Bone graft, nonunion	2	26	2 (7.7)
Unstable total knee	7	254	19 (7.5)
Unexplained pain	7	271	20 (7.4)
Fracture proximal tibia	1	14	1 (7.1)
Wound infection, deep	25	1258	84 (6.7)
Wound infection, superficial	12	504	24 (4.8)
Urinary tract infection	7	286	13 (4.5)
Wound hematoma	8	324	14 (4.3)
Gastrointestinal bleed	2	79	3 (3.8)
Cardiac arrhythmia	1	28	1 (3.6)
Implant loosening, F+T	3	140	5 (3.6)
Dislocation, patella	2	142	5 (3.5)
Septicemia	3	118	4 (3.4)
Wound dehiscence	3	145	5 (3.4)
Dislocation	5	213	7 (3.3)
Fracture, femur, undisplaced	5	192	6 (3.1)
Pulmonary embolus	4	161	5 (3.1)
Implant loosening, tibia	8	338	10 (3.0)
Patellar tendon rupture	10	400	12 (3.0)
Fracture, femur, displaced	4	210	6 (2.9)
Bone graft, resorption	1	40	1 (2.5)
Fracture, patella	7	417	10 (2.4)
Stroke	1	43	1 (2.3)
Implant loosening, femur	5	225	5 (2.2)
Pneumonia	2	92	2 (2.2)
Implant loosening, patella	1	48	1 (2.1)
Peroneal nerve injury	3	140	3 (2.1)
Ligament rupture	2	117	2 (1.7)
Modular component dissociation	1	78	1 (1.3)
			443 (26.3)

F = Femoral component
T = Tibial component

Figure E-1. Mean increase In Knee Society scores (postoperative less preopertive Scores) as a function of postoperative followup (months)

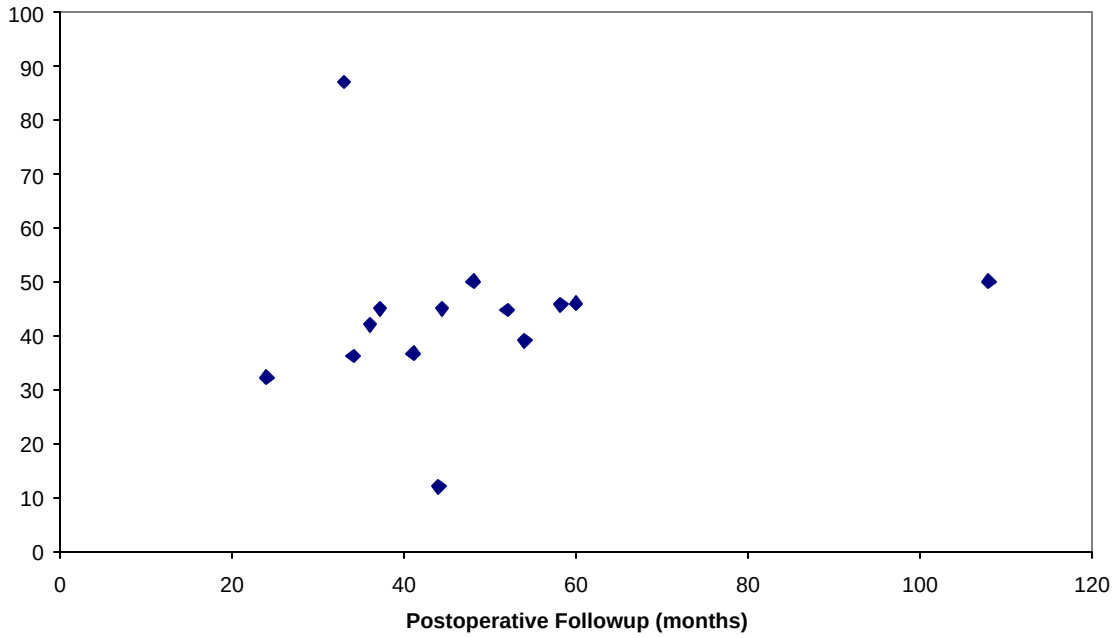

Figure E-2. Mean increase In Hospital Special Surgery scores (postoperative less preopertive scores) as a function of postoperative followup (months)

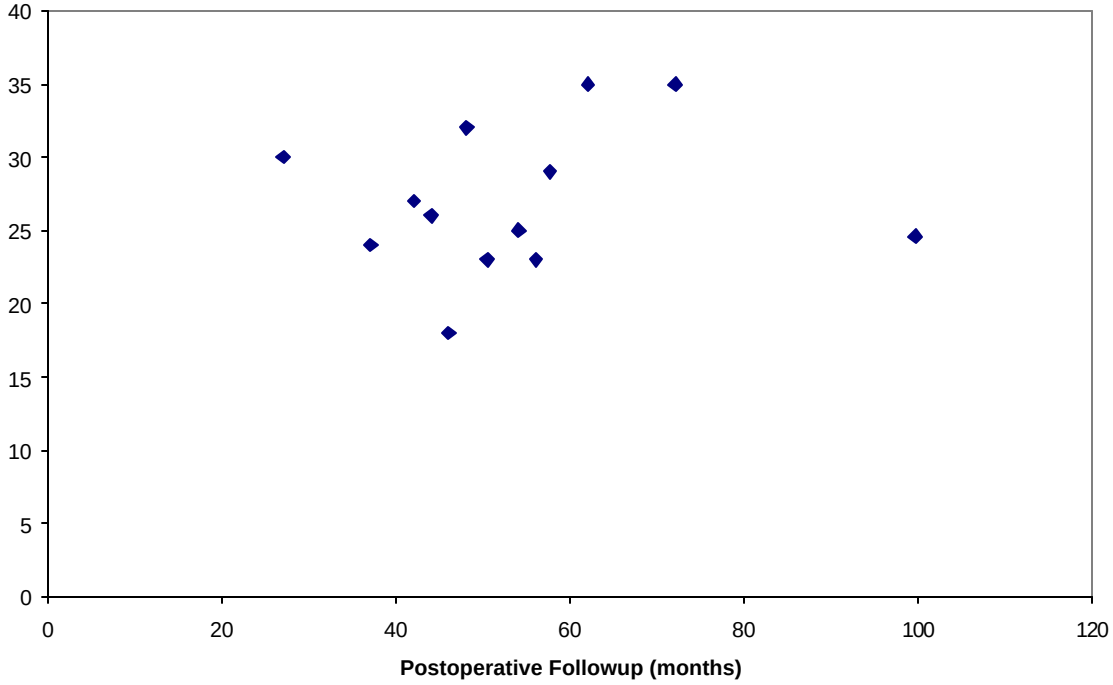

Figure E-3. Proportion of subjects rated as excellent or good as a function of postoperative followup (months)