

## Complete Summary

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### **GUIDELINE TITLE**

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 12: pedicle screw fixation as an adjunct to posterolateral fusion for low-back pain.

### **BIBLIOGRAPHIC SOURCE(S)**

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 12: pedicle screw fixation as an adjunct to posterolateral fusion for low-back pain. J Neurosurg Spine 2005 Jun;2(6):700-6. [18 references] [PubMed](#)

### **GUIDELINE STATUS**

This is the current release of the guideline.

## **COMPLETE SUMMARY CONTENT**

SCOPE  
METHODOLOGY - including Rating Scheme and Cost Analysis  
RECOMMENDATIONS  
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CATEGORIES  
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## **SCOPE**

### **DISEASE/CONDITION(S)**

Low-back pain due to degenerative lumbar disc disease or low-grade degenerative spondylolisthesis

### **GUIDELINE CATEGORY**

Assessment of Therapeutic Effectiveness  
Management  
Technology Assessment

## **CLINICAL SPECIALTY**

Internal Medicine  
Neurological Surgery  
Neurology  
Orthopedic Surgery  
Physical Medicine and Rehabilitation

## **INTENDED USERS**

Health Plans  
Managed Care Organizations  
Physicians

## **GUIDELINE OBJECTIVE(S)**

To establish whether the medical evidence in the scientific literature demonstrates a clinical benefit of internal pedicle screw fixation as an adjunct to posterolateral fusion (PLF) in the treatment of patients with low-back pain due to degenerative lumbar disc disease or low-grade degenerative spondylolisthesis

## **TARGET POPULATION**

Patients with low-back pain due to degenerative lumbar disc disease or low-grade degenerative spondylolisthesis

## **INTERVENTIONS AND PRACTICES CONSIDERED**

Pedicle screw fixation

**Note:** See "Major Recommendations" for specific indications.

## **MAJOR OUTCOMES CONSIDERED**

Effectiveness and safety of pedicle screw fixation as an adjunct to posterolateral fusion (PLF) in terms of pain relief, fusion success rates, daily activities, return-to-work rates, and complication rates

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

A computerized search of the National Library of Medicine database of the literature published from 1966 to June 2003 was performed. A search using the

subject heading "spinal fusion, lumbar, treatment outcome, low-back pain" yielded 1030 citations. Clinical series reported in English-language journals dealing with adult patients who had fusion with instrumentation for degenerative lumbar disease were selected (333 references). Among the articles reviewed, references were included that dealt with the comparison of fusion techniques with or without instrumentation. These references are summarized in Table 1 in the original guideline document. All of these articles reported at least 1 year of clinical and radiographic follow up.

## **NUMBER OF SOURCE DOCUMENTS**

14 articles

## **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

## **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

### **Classes of Evidence**

**Class I** Evidence from one or more well-designed, randomized controlled clinical trials, including overviews of such trials

**Class II** Evidence from one or more well-designed comparative clinical studies, such as nonrandomized cohort studies, case-control studies, and other comparable studies, including less well-designed randomized controlled trials

**Class III** Evidence from case series, comparative studies with historical controls, case reports, and expert opinion as well as significantly flawed randomized controlled trials

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

The group culled through literally thousands of references to identify the most scientifically robust citations available concerning each individual topic. Not every reference identified is cited. In general, if high-quality (Class I or II) medical evidence was available on a particular topic, poorer-quality evidence was only briefly summarized and rarely included in the evidentiary tables. If no high-quality evidence existed, or if there was significant disagreement between similarly classified evidence sources, then the Class III and supporting medical evidence were discussed in greater detail. If multiple reports were available that provided similar information, a few were chosen as illustrative examples.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

In January 2003, a group was formed at the request of the leadership of the Congress of Neurological Surgeons (CNS) by the executive committee of the American Association of Neurological Surgeons/CNS Joint Section on Disorders of the Spine and Peripheral Nerves to perform an evidence-based review of the literature on lumbar fusion procedures for degenerative disease of the lumbar spine and to formulate treatment recommendations based on this review. In March 2003, this group was convened. Invitations were extended to approximately 12 orthopedic and neurosurgical spine surgeons active in the Joint Section or in the North American Spine Society to ensure participation of nonneurosurgical spine surgeons. The recommendations that were developed represent the product of the work of the group, with input from the Guidelines Committee of the American Association of Neurological Surgeons/CNS and the Clinical Guidelines Committee of North American Spine Society.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

### **Grades of Recommendation**

**Standards** Recommendations of the strongest type, based on Class I evidence reflecting a high degree of clinical certainty

**Guidelines** Recommendations based on Class II evidence reflecting a moderate degree of clinical certainty

**Options** Recommendations based on Class III evidence reflecting unclear clinical certainty

## **COST ANALYSIS**

Lumbar fusion may be associated with a high short-term cost, especially if instrumentation is placed; however, there appear to be long-term economic benefits associated with lumbar fusion including resumption of employment. To describe the economic impact of lumbar fusion for degenerative disease adequately, it is important to define the patient population treated with fusion and to compare efficacy as well as the costs of other treatment alternatives. Any such analysis should include both short- and long-term costs and benefits.

See "Part 3: assessment of economic outcome" in the "Availability of Companions Documents" field for the complete analysis.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The committee presents data that have been reviewed by the major organizations representing neurological surgery and orthopedic surgery. The Board of Directors of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) Executive Committee have reviewed these Lumbar Fusion Guidelines and formally voted their approval. In addition, input and approval was received and greatly appreciated from the AANS/CNS Guidelines committee.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

The grades of recommendations (standards, guidelines, and options) and classes of evidence (I–III) are defined at the end of the "Major Recommendations" field.

**Standard.** There is insufficient evidence to recommend a treatment standard.

**Guidelines.** There is insufficient evidence to recommend a treatment guideline.

**Options.** 1) Pedicle screw fixation is recommended as a treatment option for patients with low-back pain treated with posterolateral fusion (PLF) who are at high risk for fusion failure because the use of pedicle screw fixation improves fusion success rates. 2) Pedicle screw fixation as a routine adjunct to PLF in the treatment of patients with chronic low-back pain due to degenerative disc disease (DDD) is not recommended because there is conflicting evidence regarding a beneficial effect of pedicle screw fixation on functional outcome, and there is consistent evidence that the use of pedicle screw fixation is associated with higher costs and complications.

### Summary

This review focused on an examination of the literature on the surgical treatment of low-back pain in patients with degenerative disc disease or low-grade degenerative spondylolisthesis treated with PLF, with or without the use of pedicle screw fixation. All Class I and the majority of Class II and Class III medical evidence on this topic indicates that the addition of pedicle screw fixation to PLF increases fusion success rates when assessed based on plain x-ray films with dynamic imaging. Although there does appear to be a positive relationship between radiographic fusion and clinical outcome, no convincing correlation has been demonstrated. Although several reports suggest that clinical outcomes are improved with the addition of pedicle screw fixation, there are conflicting findings from similarly classified evidence sources (primarily Class II and III). Furthermore, the largest contemporary randomized controlled study on this topic failed to demonstrate a significant beneficial effect for the use of pedicle screw fixation in patients treated with PLF for chronic low-back pain.

This absence of proof should not, however, be interpreted as a proof of absence. For example, in this same study, patient satisfaction scores improved from approximately 60% to approximately 70% with the addition of pedicle screw fixation. This difference in outcome may be clinically relevant. Similarly, the improvement in Oswestry Disability Index (ODI) scores was 40% greater in the

group of patients treated with pedicle screw fixation compared with those treated with PLF alone. If an analysis to determine the sample size necessary to ensure a power of 0.8 (or an 80% chance of detecting a significant effect) in a study in which the good outcome rate is 60% in the control group and 70% in the treatment group is performed, approximately 355 patients would be needed in each treatment group (<http://department.obg.cuhk.edu.hk>). Alternatively, if a similar analysis is performed using the differential scores obtained in the Oswestry Disability Index measurements reported in a paper by Fritzell, et al.\*, approximately 225 patients would be needed per treatment group. Although Fritzell, et al., did not detect a significant benefit associated with the use of pedicle screw fixation as an adjunct to PLF, their sample size severely limited the power of their study to detect such a benefit. All studies reviewed suffer from similar lack of power. Therefore, no definitive statement regarding the efficacy of pedicle screw fixation as a means to improve functional outcomes in patients undergoing PLF for chronic low-back pain can be made. There appears to be consistent evidence suggesting that pedicle screw fixation increases the costs and complication rate of PLF. It is recommended, therefore, that the use of pedicle screw fixation as a supplement to PLF be reserved for those patients in whom there is an increased risk of nonunion when treated with PLF. High-risk patients include, but are not limited to patients who smoke, who are undergoing revision surgery, or who suffer systemic diseases known to be associated with poor bone healing.

\* Fritzell P, Hagg O, Wessberg P, et al.: Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish Lumbar Spine Study Group. Spine 27:1131-1141, 2002.

### **Definitions:**

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#### **Classes of Evidence**

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## CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate use of pedicle screw fixation as an adjunct to posterolateral fusion for low-back pain

### POTENTIAL HARMS

There is consistent evidence that the use of pedicle screw fixation is associated with higher costs and complications (malpositioned screws, increased blood loss and reoperation rate, new radiculopathy, leg dysesthesias).

## QUALIFYING STATEMENTS

### QUALIFYING STATEMENTS

The strength of an evidence-based document is only as strong as the foundation on which it is built. This comprehensive document chronicles the state of scientific information in 2005. Many of the published reviews presented flawed results due to poorly defined outcome measures, inadequate numbers of patients, and comparison of dissimilar treatment groups. These studies of "apples and oranges" gleaned little scientific information; therefore, for the purpose of this review, the authors have discarded Class III studies whenever stronger scientific evidence was available. The result is that most of the published studies on lumbar fusion were not included on this document. When Class I or II scientific evidence was available, standards and guidelines were formulated; however, in most cases, the scientific data were only adequate to support recommendations for treatment options. The aforementioned results do not detract from the importance of this document; rather, the need for the neurosurgical community to design and complete prospective randomized controlled studies to answer the many lingering clinical questions with rigorous scientific power can clearly be seen. As more data continue to be accumulated, revisions of this document will be needed.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## **INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES**

### **IOM CARE NEED**

Getting Better  
Living with Illness

### **IOM DOMAIN**

Effectiveness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

### **BIBLIOGRAPHIC SOURCE(S)**

Resnick DK, Choudhri TF, Dailey AT, Groff MW, Khoo L, Matz PG, Mummaneni P, Watters WC 3rd, Wang J, Walters BC, Hadley MN, American Association of Neurological Surgeons/Congress of Neurological Surgeons. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 12: pedicle screw fixation as an adjunct to posterolateral fusion for low-back pain. J Neurosurg Spine 2005 Jun;2(6):700-6. [18 references] [PubMed](#)

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

### **DATE RELEASED**

2005 Jun

### **GUIDELINE DEVELOPER(S)**

American Association of Neurological Surgeons - Medical Specialty Society  
Congress of Neurological Surgeons - Professional Association

### **SOURCE(S) OF FUNDING**

This project was funded entirely by a grant from AANS/CNS Section on Disorders of the Spine. No funding was received from any commercial entity to support the production or publication of these guidelines.

### **GUIDELINE COMMITTEE**

Guidelines Committee of the American Association of Neurological Surgeons/Congress of Neurological Surgeons (CNS)



## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

## **ENDORSER(S)**

North American Spine Society - Medical Specialty Society

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site](#).

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: [Resnick@neurosurg.wisc.edu](mailto:Resnick@neurosurg.wisc.edu).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Introduction to the guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. 2005 Jun. 1 p. Available in Portable Document Format (PDF) from the [AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site](#).
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 1: introduction and methodology. 2005 Jun. 2 p. Available in Portable Document Format (PDF) from the [AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site](#).
- Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 3: assessment of economic outcome. 2005 Jun. 6 p. Available in Portable Document Format (PDF) from the [AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves Web site](#).

Print copies: Available from Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792; Email: [Resnick@neurosurg.wisc.edu](mailto:Resnick@neurosurg.wisc.edu).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on January 8, 2007. The information was verified by the guideline developer on January 29, 2007.

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