Lumbar Fusion (Re-Review)

Draft Evidence Report: Comment & Response

October 16, 2015

Draft Report
Public Comments and Response

Lumbar Fusion

October 16, 2015

Response to Public Comments

The Institute for Clinical and Economic Review (ICER) is an independent vendor contracted to produce evidence assessment reports for the Washington HTA program. For transparency, all comments received during the public comment period are included in this response document. Comments related to program decisions, process, or other matters not pertaining specifically to the draft key questions, project scope, or evidence assessment are acknowledged through inclusion only.

This document responds to comments from the following parties:

Draft Report

- Gracie Farias, Senior Manager Reimbursement, Medtronic

- Gary Franklin, MD, MPH, Chief Medical Officer, WA Department Labor and Industries

- H. Hunt Batjer, MD, President, American Association of Neurological Surgeons; Nathan R. Sheldon, MD, PhD, President, Congress of Neurological Surgeons; Praveen Mummaneni, Chairman, AANS/CNS Joint Section on Disorders of the of Spine and Peripheral Nerves; Farrokh Farrokhi, MD, President, Washington State Association of Neurological Surgeons

Comment	Response
Gracie Farias, Senior Manager Reimbursement, Medtronic	
1 While the report title implies that its topic relates to lumbar fusion, the report's purpose is rather to assess the clinical evidence associated with treatment options for individuals afflicted with low back pain and degenerative disc disease who have no radicular pain, no spondylolisthesis greater than Grade 1, no spinal stenosis, and who have not experienced acute trauma or have systemic disease.	*Thank you for your comments and references. We have changed the title of the report to more accurately reflect the specific patient population of interest to this review.*
2 This patient population, individuals with back pain but without radicular pain due to nerve root irritation, has been described in the Journal of the American Medical Association (JAMA) to be associated with abnormal psychological profiles, multiple chronic pain processes, and compensation issues. Further, JAMA notes that longitudinal studies have found that that the severity of chronic pain illness in this group is more highly correlated with comorbid psychosocial or generalized neurophysiological conditions than with degenerative findings.	*No changes made. We acknowledged that the presence of DDD alone correlates poorly with the presence and severity of low back pain, making it difficult to attribute symptoms specifically to disc degeneration, and have described the literature evaluating comorbid conditions as potentially influencing outcomes in Key Question 4.*
3 In view of the nature of this patient population as described above, it is not surprising that this HTA was unable to find compelling clinical evidence of the benefits of lumbar fusion when used as a component of their treatment. It is important that the readers of this HTA be cautioned against applying its findings to patients excluded from this analysis, namely those with radicular pain, spinal instability, and/or spinal stenosis. Lumbar fusion is a very successful treatment for patients meeting medical necessity, as described in the Premera BC Medical Policy; and deserve to have access, despite the lack of studies due to abnormal psychological profiles.	*As previously mentioned, we have changed the title of the report to more accurately reflect the patient population represented in the report. We have also added clarifying language that we are focusing on patients with uncomplicated DDD throughout the report, where appropriate.*

Comment	Response
Gary Franklin, MD, MPH, Chief Medical Officer, WA Department Labor and Industries	
1	Page ES-4. It may be important to point out the average duration of the intensive multidisciplinary programs is 3-4 weeks. The 15 weeks is an outlier and perhaps older information.	*Thank you for your comments and references. We have modified the report based on the suggested revision.*
2	Page ES-9. General treatment success and specific a priori definition of %improvement in specific measures of pain and function are very different ways of measuring outcomes. The more general impression of success is nothing like the degree of improvement on a validated instrument... Similarly, on Page-31, the "better vs much better" and "excellent vs good" outcome measures are not the same as pre-specified proportions of improvement on validated instruments. Can you treat these two types of improvement differentially in the report?	*We clarified that most of the studies we identified did not use validated instruments to define treatment success, and have clearly separated those studies using validated approaches from those using general patient- or clinician-reported measures.*
3	Page ES-19 and Page-33. Regarding surgical complications or adverse events, there is a study published recently on complications following lumbar fusion for low back pain and/or radiculopathy (Verla et al 2015. J Clinical Neuroscience. 22:342), which is not included in the evidence report. This is a rather large study (n=1498) using a multi-institutional, prospective spine outcomes registry. Complications occurred in 7.68% of the patients included in the study. The most common complications were cerebrospinal fluid leak (49.18%), bleeding requiring transfusion (13.11%), nerve root injury (9.83%) and surgical site infections (9.28%).	*We have added this study to the section of the report describing large database studies that did not meet our inclusion. We also emphasized that these studies do not represent the population of interest to this review, but may provide additional context on complications associated with lumbar fusion across indications.*
4	Page ES-32 and Page-47. "...ranged from $27,480 for decompression alone to $67,773 to complex fusion to $92,766 for complex fusion". The sentence is difficult to understand, and a typo is suspected. A suggested revision would be: "...ranged from $27,480 for decompression alone to $67,773 for simple fusion to $92,766 for complex fusion".	*We have modified the report based on the suggested revision language.*
5	Page ES-32 and Page-48. "The difference in	*We agree that this statement could potentially*

Comment	Response
quality-adjusted survival between groups was 0.068 in favor of surgery". This statement is rather confusing here, especially to readers who are not very familiar with the concepts of "utility" and "quality-adjusted survival". It could be incorrectly interpreted as "fusion is superior to rehabilitation" in this context. In addition to the fact that the difference was not statistically significant (CI: -0.02 to 0.156, P=0.13), it reflects a difference in utility (quality of life of the two groups) existed at baseline prior to the interventions. Removal of the statement is recommended to avoid any confusion.	*be confusing and have clarified this language in the report.*
6	Page-13. Blue Cross Blue Shield of North Carolina was the first to do a more restrictive fusion policy. In addition, the WA Dept of Labor and Industries has long had a guideline on lumbar fusion, which was updated following the 2007 HTA decision.	*Blue Cross Blue Shield of North Carolina is not a regional payer relevant to the state of Washington. However, we have added guidelines from the WA State Department of Labor and Industries to the Clinical Guidelines section of the report.*
7	Regarding reoperation rates, the two large population-based retrospective cohort studies done in WA state were consistent even though the two cohorts were separated by 8 years-both showed 22-23% reoperation within 2 years of fusion-this data should be added to the adverse event section (Franklin GM, et al. Spine 1994: 17: 1897-1904; Juratli et al, Spine 2006:31: 2715-23).	*No changes made. The first study (Franklin, 1994) is outside the timeframe of our literature search. The second study (Juratli, 2006) is also outside the scope (i.e., not in an uncomplicated DDD population) but is discussed in Key Question 4 as it provides additional context for differential effectiveness according to age. We have already included a 2009 study by the same primary author which evaluates complication and mortality rates in the same population described in the 2006 publication.*
8	One adverse outcome the evidence report mentioned only briefly in the introduction section is the so called Failed Back Surgery Syndrome. This is persistent pain after spine surgery that can be worse than the pain that led to the surgery. Some publications have found a high prevalence of epidural fibrosis among patients following spine surgery. (see eg, Bosscher HA, Heavner JE. Incidence and severity of epidural fibrosis after back surgery: an endoscopic study. Pain Pract 2010: 10: 18-24.)	*Unfortunately none of the studies we identified for this review quantified failed back surgery syndrome as an outcome. Rather, we focused on whether patients experienced sustained improvement based on data in the available long-term studies, as well as on the incidence of subsequent treatment and/or reoperation. We have removed mention of "failed back surgery syndrome" in the Background section of the report to prevent any confusion that this was an outcome we were able to evaluate.*

Comment	Response
H. Hunt Batjer, MD, President, American Association of Neurological Surgeons; Nathan R. Sheldon, MD, PhD, President, Congress of Neurological Surgeons; Praveen Mummaneni, Chairman, AANS/CNS Joint Section on Disorders of the of Spine and Peripheral Nerves; Farrokh Farrokhi, MD, President, Washington State Association of Neurological Surgeons	
1	The document prepared by the Institute for Clinical and Economic Review (ICER) is a thorough review of the literature. However, as we stated when the HTA program first suggested that the 2008 HTA Lumbar Fusion for DDD coverage policy be revisited, we do not believe that there is a substantial change in evidence for this procedure and we do not support a change to the current policy, which was based on significant stakeholder input and a robust review by the HTCC.	*Thank you for your comments and references. No changes made.*
2	The key questions for the report are specific to the treatment of chronic low back pain and uncomplicated DDD. As such, the title of the draft report is slightly misleading as it gives the impression that it pertains to all lumbar fusions, and not the specific disease entity of chronic low back pain and uncomplicated DDD. ICER should clarify this in the title of the final report. The focus of the HTCC meeting discussion should be limited to the specific topic of chronic low back pain and uncomplicated DDD.	*As mentioned in prior responses, we have changed the title of the report as well as added clarifying language that we are focusing on patients with uncomplicated DDD.*
3	As is the case with any review of the literature, it is very difficult to find studies that precisely provide information on the desired subject matter, as the diagnosis of chronic low back pain and uncomplicated DDD might not apply to the subjects enrolled in the clinical trials for Key Question #1. Brox et al, Fritzell et al, and Fairbanks et al. all included patients with previous surgeries. The duration of symptoms in all of these studies was 8 years. Some of these patients with prior surgery who did not improve may have entered the trial with a diagnosis of failed back syndrome, and possible neuropathic symptoms. Average symptoms were present for 8 years.	*We have mentioned several times throughout the report that the patient populations being studied in the available literature are diverse. However, we have emphasized this heterogeneity by providing additional details on study inclusion criteria. It should also be noted that we did not exclude studies based on symptom duration.*
4	In the sport trial data, surgery was associated	*No changes made. The SPORT trial evaluated a*

	Comment	Response
	with significantly better outcomes when symptom duration was less than 12 months. (Radclif et al 2011, Spine (Phila Pa 1976). 2011 Dec 1; 36(25): 2197–2210. PMCID: PMC3236684). In this sense, the studies used to answer Key Question # 1 might not completely reflect what the HTA program is attempting to study. It is possible that patients in these reported clinical trials may have benefitted to a greater extent from surgery if they were referred to spine surgeons at an earlier date.	*patient population that was not relevant to this review (i.e., lumbar fusion for degenerative spondylolisthesis).*
5	Furthermore, the core studies used in the review have many well-known limitations as they are from outside the United States (US)—from the United Kingdom, Norway, and Sweden specifically. This introduces a serious population selection bias compared to our US and Washington state populations. Because these groups differ substantially to the US population, we do not feel that we can draw valid conclusions on how to manage our patients from this data. This issue was raised at the November 2007 HTCC meeting and it was clear that significant differences in culture and alternative treatments exist between the United States and Europe.	*We have emphasized this point in the section on overall study quality.*
6	Regarding the section on complications from spine surgery, it is important to note mention of Goz et al's study using the NIS data to evaluate three different primary interbody fusion cohorts (923,038 fusions) over nine years. In this study, patients with uncomplicated DDD represented a majority of patients for each fusion group. A recent article by Gologorski et al (J Neurosurg Spine. 2014 Dec;21(6):984-93. doi: 10.3171/2014.8.SPINE131113) demonstrates that primary ICD-9-CM codes extracted from large administrative databases (NIS in particular) do not accurately reflect the surgeon's indication. As such, we cannot extrapolate on complication rates of lumbar fusion using datasets that might not even correctly portray the patients with diagnosis of interest.	*Concerning our inclusion of large database studies generally, we have added language to highlight the fact that these studies may not accurately represent safety outcomes for uncomplicated DDD patients given the mixed populations and procedure-specific outcomes being evaluated. We have also added the suggested citation as an additional caveat for readers to consider when reviewing studies that evaluate large administrative databases. Nevertheless, we feel that these studies provide additional context for potential harms associated with lumbar fusion, given the difficulty in extrapolating these data from shorter-term RCTs and comparative cohort studies.*

Comment	Response
7	We feel that it would be important to include results from Level 1 data on the purest of LBP populations-–artificial disk replacement versus fusion. Data from the fusion arm is not represented adequately in the ICER report. Including this data would provide valuable high quality context for important quality of life and function as well as safety data. In addition, this data frequently comes from the US. We suggest the use of the Washington state Surgical Care Outcomes Assessment Programs (SCOAP) data base as a realistic patient safety assessment as it contains helpful real time data on complications. Furthermore it may be helpful to examine other high quality data registries such as the AANS/CNS National Neurosurgery Quality and Outcomes Database (N2QOD).	*No changes made. As mentioned in the Methods section of our report, studies comparing lumbar fusion to artificial disc replacement were excluded, as artificial discs represent a separate review topic for the HCA.*
8	Incremental cost effectiveness of lumbar fusion when compared to non-operative treatments needs to be assessed on a long term basis. Numerous studies will demonstrate costly treatments in the fusion group. However, the true cost effectiveness of surgery is not realized until several years after fusion surgery. Further long term data will need to be collected to demonstrate long term cost effectiveness and long lasting effect of spine fusion despite the known risks of spine surgery. Andersen et al recently report that spinal fusion surgery in older patients does not generate excess hospital-based health care use in the longer term as compared with the background population. (Eur Spine J. 2013 May;22(5):977-84. doi: 10.1007/s00586-012-2479-5. Epub 2012 Aug 21. PMID: 22907726).	*No changes made. We agree that additional long-term data need to be collected to assess the long-term cost-effectiveness associated with surgery. However, the currently available long-term clinical effectiveness studies, which are described in detail in Key Question 1, do not demonstrate a sustained improvement over conservative treatment. The suggested reference (Anderson, 2013) did not meet our inclusion criteria because <75% of patients had uncomplicated DDD.*
9	We also feel that cognitive based therapy (CBT) is not a standard treatment alternative to fusion surgery. First of all, there is no clear definition to CBT. In addition, extreme selection bias exists with regard to which CBT therapy would apply to which patients. The Cochrane review concluded that CBT was useful for treatment of chronic pain , but different types of studies and analyses are needed to identify which components of CBT	*No changes made. We have not suggested that CBT represents a standard alternative to surgery. Rather, CBT is described as one component of a structured, multidisciplinary program that may represent a benefit over unstructured or non-intensive physical therapy and exercise programs as described in the available literature.*

Comment	Response
work for which type of patient on which outcomes and why (Williams, Cochrane 2012). Rather than asking if CBT or fusion is the better treatment modality, we really need to ask who needs either or both treatments and whether access to this kind of treatment specifically for uncomplicated DDD exists in the state of Washington or anywhere else in the US.	

Medtronic

Comments

Washington State Health Care Authority's Technology Assessment Draft Report entitled "Lumbar Fusion (Re-Review)," dated August 15, 2015.

While the report title implies that its topic relates to lumbar fusion, the report's purpose is rather to assess the clinical evidence associated with treatment options for individuals afflicted with low back pain and degenerative disc disease who have <u>no radicular pain</u>, <u>no spondylolisthesis greater than Grade 1</u>, <u>no spinal stenosis</u>, and who have not experienced acute trauma or have systemic disease.

This patient population, individuals with back pain but without radicular pain due to nerve root irritation, has been described in the Journal of the American Medical Association (JAMA)[1] to be associated with abnormal psychological profiles, multiple chronic pain processes, and compensation issues.[2,3] Further, JAMA notes that longitudinal studies have found that that the severity of chronic pain illness in this group is more highly correlated with comorbid psychosocial or generalized neurophysiological conditions than with degenerative findings.[4,5]

In view of the nature of this patient population as described above, it is not surprising that this HTA was unable to find compelling clinical evidence of the benefits of lumbar fusion when used as a component of their treatment. It is important that the readers of this HTA be cautioned against applying its findings to patients excluded from this analysis, namely those with radicular pain, spinal instability, and/or spinal stenosis.

Lumbar fusion is a very successful treatment for patients meeting medical necessity, as described in the Premera BC Medical Policy[6]; and deserve to have access, despite the lack of studies due to abnormal psychological profiles.

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Surgery for Degenerative Lumbar Spondylosis: Updated Cochrane Review

J.N. Alastair Gibson, MD, FRCS, and Gordon Waddell, DSc, MD, FRCS

Study Design. An updated Cochrane review.

Objective. To review current scientific evidence on the effectiveness of surgical interventions for degenerative lumbar spondylosis.

Summary of Background Data. There is still limited scientific evidence on spinal surgery.

Methods. Use of standard Cochrane review methods to analyze all randomized controlled trials published to March 31, 2005.

Results. A total of 31 randomized controlled trials were identified. Most of the earlier trials reported mainly surgical outcomes; more of the recent trials also reported patient-centered outcomes of pain or disability. There is still very little information on occupational outcomes or long-term outcomes beyond 2–3 years. Seven heterogeneous trials on spondylolisthesis, spinal stenosis, and nerve compression permitted limited conclusions. There were two new trials on fusion that showed conflicting results. One trial showed that fusion gave better clinical outcomes than conventional physiotherapy, and the other showed that fusion was no better than a modern exercise and rehabilitation program. There were 8 trials that showed that instrumented fusion produces a higher fusion rate, but any improvement in clinical outcomes is probably marginal.

Conclusions. No conclusions are possible about the relative effectiveness of anterior, posterior, or circumferential fusion. The preliminary results of three small trials of intradiscal electrotherapy suggest it is ineffective, except possibly in highly selected patients. Preliminary data from three trials of disc arthroplasty do not permit firm conclusions.

Key words: Cochrane Review, decompression, degenerative disc disease, disc arthroplasty, fusion, instrumented fusion, lumbar spondylosis, meta-analysis, outcomes, randomized controlled trials, spinal stenosis, surgery, systematic review. **Spine 2005;30:2312–2320**

This review includes all forms of surgical treatment of degenerative conditions affecting the lumbar spine. The latter are variously described as lumbar spondylosis or degenerative disc disease, which we regard as one entity; whether or not they are regarded as the effects of aging, secondary to trauma or "wear and tear," or degenerative disease, and whether they involve the intervertebral discs, vertebrae, and/or associated joints. Included are the associated pathologies or clinical syndromes of instability, spinal stenosis, and/or degenerative spondylolisthesis. We have termed the collective conditions "degenerative lumbar spondylosis."

Spinal stenosis is probably now the most common and fastest growing reason for spinal surgery in adults older than 65 years.[1] There are two meta-analyses based either entirely[2] or mainly[3] on largely retrospective case series. One suggests that, on average, 64% of patients will obtain a satisfactory outcome from surgery.[2] The other suggests that decompression without a fusion will give a 69% satisfactory outcome, whereas with fusion (solid in 86%), this figure would increase to 90%.[3] However, there is a lack of data on the diagnostic criteria and natural history of the condition, indications for surgery and choice of surgical procedures, and clinical or patient characteristics associated with a favorable outcome.

After more than 90 years, there is continued dispute as to whether lumbar fusion is an appropriate and effective method of treating back pain in patients with degenerative lumbar spondylosis. There is heated debate and a lack of clear evidence on the nature and role of "instability," and the clinical indications for surgery are not well defined.[4] There is also wide variation in the surgical techniques used, technical success, and rate of fusion. Reported satisfactory clinical outcomes range from 16% to 95%.[2]

There is continued interest in and controversy about instrumented fusion. Posterior pedicle instrumentation was first used in Europe in the early 1960s.[5] In recent years, there has been an explosion of surgical and commercial interest in a wide variety of methods of instrumented fusion in both Europe and the United States. The aforementioned meta-analysis of published case series of degenerative spondylolisthesis[3] suggested that fusion with pedicle screws produced a higher fusion rate (93% vs. 86%) than fusion without instrumentation, which was not statistically significant, but that it did not produce any difference in clinical outcomes (86% vs. 90% satisfactory outcomes). There is less available scientific information about other methods of fusion, whether anterior or posterior. In recent years, there has been rapidly growing clinical, commercial, and public interest in other innovative technologies, such as intradiscal electrotherapy (IDET) and disc arthroplasty. In view of these various continued uncertainties, a systematic review of all randomized controlled trials (RCTs) of surgical treat-

ment of degenerative lumbar spondylosis remains appropriate.

■ **Objectives**

Our objective is to test the following null hypotheses:

1. Any form of surgical treatment for low back pain and/or associated leg symptoms secondary to degenerative lumbar spondylosis is no more effective than natural history, placebo, conservative treatment, or a rehabilitation program.
2. Decompression of spinal stenosis secondary to degenerative lumbar spondylosis is no more effective than natural history, placebo, conservative treatment, or a rehabilitation program.
3. There is no difference in outcome between different forms of surgical treatment for spinal stenosis.
4. Fusion for low back pain secondary to degenerative lumbar spondylosis is no more effective than natural history, placebo, conservative treatment, or a rehabilitation program.
5. There is no difference in outcome between different forms of surgical treatment for low back pain.

■ **Criteria for Considering Studies for This Review**

Types of Studies

All randomized and quasi-RCTs on the surgical treatment of degenerative lumbar spondylosis were performed.

Types of Participants

Patients older than 18 years with degenerative lumbar spondylosis participated in the study.

Types of Interventions

Laminectomy; laminotomy; anterior lumbar intervertebral body (ALIF), posterolateral, posterior lumbar intervertebral body (PLIF) fusion, alone or in combination, or other forms of instrumented fusion; IDET, disc arthroplasty; combinations of the preceding interventions were used.

Types of Outcome Measures

Patient-centered clinical outcomes are of primary interest to patients, although surgical outcomes are often of more interest to surgeons.[6]

Patient centered outcomes include: (1) proportion of patients with successful outcomes according to self-assessment, (2) improvement in pain measured on a validated pain scale, (3) improvement in function measured on a disability or quality of life scale, (4) occupational outcomes, and (5) economic data as available. Surgical outcomes include: (1) proportion of patients with successful outcomes according to clinician's assessment; (2) fusion rate; (3) progression of spondylolisthesis; (4) rate of repeat back surgery; (5) any other technical surgical outcomes; and (6) objective clinical measures of physical improvement or impairment, including change in spinal flexion, improvement in straight leg raise, alteration in muscle power, and change in neurologic signs.

■ **Search Strategy for Identification of Studies**

Relevant RCTs in all languages were identified up to March 2005 by: the Cochrane Central Register of Controlled Trials; computer searching of MEDLINE[7]; PubMed at http://www.ncbi.nlm.nih.gov/; hand searching of *Spine* and International Society for the Study of the Lumbar Spine abstracts from 1975; communication with members of the Cochrane Back Review Group and other international experts; personal bibliographies; and citation tracking from all articles identified by the aforementioned strategies.

■ **Methods of the Review**

Eligible trials were entered into RevMan 4.2® and sorted on the basis of the inclusion and exclusion criteria. For each included trial, assessment of methodological quality and data extraction were performed:

1. Both authors (J.N.A.G. and G.W.) selected the trials to be included in the review. Disagreement was resolved by discussion, followed, if necessary, by further discussion with an independent colleague.
2. The methodological quality was assessed and internal validity scored by both authors, assessing the risk of pre-allocation disclosure of assignment, intention-to-treat analysis, and blinding of outcome assessors.[8] The quality of concealment allocation was rated in three grades: A, clearly yes (some form of centralized randomization scheme or assignment system); B, unclear (assignment envelopes, a "list" or "table," evidence of possible randomization failure, such as markedly unequal control and trial groups, or trials stated to be random but with no description); and C, clearly no (alternation, case numbers, dates of birth, or any other such approach, allocation procedures that were transparent before assignment). Withdrawal, blinding of patients and observers, and intention-to-treat analyses were assessed according to standard Cochrane methodology and tabulated in the results tables.[9] The nature, accuracy, precision, observer variation, and timing of the outcome measures were also tabulated. Initially, any outcomes specified were noted. The data were then collated and outcome measures collected for later meta-analysis. In fact, only four categorical outcomes were consistently reported: the patient and surgeon's ratings of success, attainment of spinal fusion, and performance of a second surgical procedure. To pool the results, ratings of excellent and good were classified as "success," while fair and poor were classified as "failure." The pooled data are given in the analysis tables.
3. For each study, odds ratios (OR) and 95% confidence limits (95% CI) were calculated. Results from clinically comparable trials were pooled using random-effects models for dichotomous outcomes. It is noteworthy that in several instances, the test for homogeneity was significant, which casts doubt on the statistical validity of the pooling. Nevertheless, there is considerable clinical justification for pooling the trials in this way. In view of the clinical interest, these results are presented as the best available information at present, with the qualification that there may be considerable statistical weaknesses to some of the results. The evidence was rated strong, me-

dium, or limited according to the Cochrane Back Review Group levels of evidence.[9]

Description of Studies. A total of 31 RCTs have been included in this review as detailed later. Information regarding individual trials is presented in Table 1 (available for viewing online through ArticlePlus only).

Methodological Quality of Included Studies. Descriptions of randomization were poor in the earlier trials, but there now appears to be more awareness of the importance of the method of randomization. In 16 studies, there was a clear attempt at concealment of group allocation. In 7 trials, the method of allocation was not described. Four trials[10–13] were considered quasi-randomized because the patients were allocated by alternate assignment according to their date of admission to hospital or by odd and even file numbers. There were 6 trials that were clearly "open" to potential selection bias.[11–16]

Of the 31 trials, 18 had the recommended follow-up for surgical studies of at least 2 years. Most had a follow-up rate of at least 90%. One trial[17] gave different patient outcomes after best and worst case analyses. Blinding is difficult in surgical studies, but three of the recent trials were double blind, and several used an independent assessor. Most of the recent trials also provided patient-oriented, clinical outcomes.[6] The majority of trials gave technical surgical outcomes, such as fusion, spondylolisthesis progression, or the need for reoperation. Clinical outcomes were mainly crude ratings on a 3 to 4-point scale: 5 trials gave a surgeon's rating and 9 gave a patient's rating. Eleven gave direct information on back pain (Table 1, is available for viewing online through ArticlePlus only) and 9 on functional outcome measured on a validated assessment scale. These defects of trial design introduced considerable potential for bias, and many of the conclusions of this review are about surgical outcomes rather than patient-centered clinical outcomes. There is still a lack of long-term follow-up beyond 2 years, which is particularly important in procedures that aim to alter the long-term natural history or clinical progress of a degenerative condition. There is a general lack of data on occupational outcomes.

■ Results

Data from 31 RCTs of all forms of surgical treatment for degenerative lumbar spondylosis are included in this updated review. In the first edition of this review, 9 of the 16 trials identified were found on MEDLINE, 4 from personal bibliographies, and 4 from abstracts of meeting proceedings. The authors collected the new trials mainly from personal literature review or after notification by colleagues of the Cochrane Back Review Group. Three trials originally included have now been deleted from the review (Characteristic of Excluded Trials table) because, originally, they were abstracts of work in progress, and no data have been published over the intervening years.[18–20] Three further trials are included as ongoing studies. The majority of the trials compared two or more surgical techniques. From a surgical perspective, the trials now fall into three broad sections: (1) surgical treatment (decompression with or without fusion) for spinal stenosis and/or nerve root compression; (2) surgical treatment (fusion, IDET or disc arthroplasty) for back pain; and (3) comparison of different techniques of spinal fusion.

In the first section, 1 trial compared surgical treatment with conservative therapy, and one compared different techniques of decompression for spinal stenosis. Three trials compared decompression alone with decompression and some form of fusion. One trial compared outcomes following the use of an interspinous spacer with those after a nonoperative regime, including epidural injection. A further two trials of surgery for isthmic spondylolisthesis were included. The second section included two trials of fusion to relieve discogenic back pain compared with different forms of conservative treatment, preliminary results from three small trials of IDET, and two trials of disc arthroplasty. In the third section, 15 trials considered the role of instrumentation in fusion and 4 trials that of electrical stimulation (direct current and pulsed electromagnetic stimulation) in posterolateral fusion. Five trials included subgroups of participants and are included in more than 1 section.

Analysis of the included trials is complicated by the inclusion of participants with varied pathology and a lack of consistency in treatment methods. Only 5 of the trials[21–25] had a conservative treatment arm. It was not possible to analyze participants according to duration of symptoms, type of previous conservative treatment, or indications for surgery because few of the trials provided these data in usable form. Although many trials provided limited information on select complications, these were not comparable between trials. Three trials provided comparative information on operating time and blood loss, and three provided information on progression of spondylolisthesis. No other adverse effects could be reviewed. A cost analysis was performed in 1 trial,[23] although the methodological criticisms by Goosens and Evers[26] are noteworthy.

Techniques for Decompression of Spinal and Nerve Root Stenosis

The effectiveness of surgical decompression for spinal stenosis has been considered in 1 new trial.[22] In this trial, 19 patients with severe symptoms were selected for surgical treatment and 50 with moderate symptoms for conservative therapy. A further 31 patients were randomized between the two treatments. The overall results were broadly in line with those from meta-analyses of retrospective case series by Turner[27] and Ciol[1] *et al.* The results of conservative therapy were better than expected, but the investigators suggested that if surgery was deemed necessary, it might be "good" for up to four fifths of severely affected individuals. However, the small randomized portion of the study showed no statistically significant effect. At 10 years, 5 people of the 11 randomized to decompression had no, or minimal, pain compared with 4 of the 14 who were initially treated conservatively (6 were lost to follow-up).

Postacchini *et al*[11] considered techniques of decompression for spinal stenosis by comparing laminectomy

with multiple laminotomy. This study had several confounding factors. Of the 35 patients scheduled for laminotomy, 9 actually had undergone laminectomy for technical reasons, and several patients in each group also had undergone an intertransverse arthrodesis for degenerative spondylolisthesis. This trial did not show any difference in clinical outcomes or spondylolisthesis progression between the two treatment methods.

Three trials considered whether some form of posterolateral fusion, with or without instrumentation, was a useful adjunct to decompression alone.[10,12,14] They provided data on a total of 139 participants with 99% follow-up at 2 to 3 years. Pooling of the three trials showed no statistically significant difference in surgeons' ratings between decompression plus fusion or decompression alone (random OR 0.44; 95% CI 0.13, 1.48), so no definite conclusions can be drawn. One of these trials[12] considered fusion with and without instrumentation in patients with degenerative spinal stenosis with no evidence of instability. In the fusion arm of the trial, patients were allocated to either decompression plus arthrodesis of only the most stenotic segment or decompression of the whole area. The investigators concluded that in the absence of instability, arthrodesis was not necessary, provided the posterior elements were preserved during decompression.

The other two trials considered the role of adjunct fusion in spinal stenosis associated with single or 2-level degenerative spondylolisthesis. Herkowitz and Kurz[10] studied noninstrumented fusion alone, and showed that fusion produced significantly less self-reported back and leg pain, and significantly better surgeon ratings of outcome. Bridwell et al[14] studied both instrumented and noninstrumented fusion. Those patients with an instrumented fusion had a significantly higher fusion rate, less spondylolisthesis progression, and more improvement in walking ability. *Post hoc* analysis showed that achieving a solid fusion was associated with subjective improvement. However, there were methodological limitations to this trial. In particular, the control group was too small, and there were insufficient data for an intention-to-treat analysis to show any significant effect of performing fusion *per se versus* decompression alone.

Currently, there are no published RCTs of surgical decompression to relieve isolated nerve root stenosis, but there is 1 trial examining the effect of an interspinous spacer device[28] in elderly patients with 1 or 2-level central stenosis. Limited results at 1 year suggest better outcome estimated on the Zurich Claudication Questionnaire and less pain following device use. Trials of intraforaminal steroid injection are not included in this surgical review.

There are two trials of surgical treatment for isthmic spondylolisthesis. It may be debated whether this condition is within our definition of degenerative lumbar spondylosis, but for completeness, these trials have been included in this review. Moller and Hedlund[21] studied 111 adults with low back pain alone (one third) or with sciatica (two thirds) associated with isthmic spondylolisthesis. The primary aim of the trial was to compare the outcome of posterolateral fusion with conservative treatment in the form of an intensive exercise program. At 2 years, patients treated surgically had less pain and disability, and better self-rated and observer-rated outcomes. There was no significant difference in occupational outcomes. However, no separate data were presented for back pain, and it is not clear how much of these successful outcomes was related to relief of sciatica from foraminal stenosis, which is the generally accepted indication for surgery in this condition. Carragee[29] compared the results of fusion alone or fusion plus laminectomy and decompression for isthmic L5/S1 spondylolisthesis. Again, these patients had both back and leg pain, although without serious neurology. This trial was confounded by the fact that patients who did not smoke had fusion by bone grafting alone, while those who did smoke had their fusion supplemented by instrumentation. However, in neither group did the addition of decompression to the arthrodesis appear to improve clinical outcome.

Surgery for Back Pain without Neurologic Compromise

At the original Cochrane Review of degenerative lumbar spondylosis (1999) there were no published RCTs on the effectiveness of fusion for chronic back pain, compared with natural history, conservative treatment, or placebo. There are now two new trials. The Swedish trial of lumbar fusion *versus* physiotherapy treatment for chronic low back pain[23] included 294 individuals presenting at 19 spinal centers during a 6-year period. Strict inclusion criteria limited trial entry to those patients who had low back pain more pronounced than leg pain, lasting longer than 2 years, and no evidence of nerve root compression. Each patient had to have completed a course of conservative treatment that had failed to produce relief. Of the patients, 19% had undergone previous surgery. Individuals were randomized into four treatment groups. A total of 72 patients had conservative treatment, and 222 had 1 of three different fusion techniques.

There was a 98% follow-up at 2 years. A total of 25 subjects did not complete treatment according to random allocation, but these "group changers" were included in the original "intention-to-treat" analysis. At 2 years, independent assessors rated 46% of the surgical group as "excellent" or "good," compared with 18% of the conservative group ($P < 0.0001$). More patients who underwent surgery rated their results as "better" or "much better" (63% *vs.* 29%, $P < 0.0001$). The patients who underwent surgery had significantly more improvement in pain (visual analog scale [VAS]) and disability (Oswestry scale). The "net back to work rate" was significantly in favor of surgical treatment (36% *vs.* 13%, $P = 0.002$). There were no significant differences in any of these outcomes among the three surgical groups. The Swedish trial also provided one of the few cost-effective

analyses of spinal surgical treatment. The cost differences between the surgical and conservative groups were significant, mainly because more individuals went back to work in the surgical group.[23]

The major question about the Swedish trial was the nature of the conservative treatment used as the control intervention.[30] The investigator tried to ensure that each patient understood that "no treatment method, as far as was known, was superior to any other." Nevertheless, the control group essentially received more of the same "usual nonsurgical treatment" that had already failed, and the failure of which was one of the indications leading to consideration of surgery. In view of the likely negative patient expectations, it is hardly surprising that the results in the control group appear to have been poorer than most epidemiologic studies of natural history. Strictly speaking, this trial provided the first substantive evidence that fusion is more effective than continued, standard 1990s "usual care."

The Norwegian trials[24,25] compared posterolateral fusion with transpedicular screws and postoperative physiotherapy versus a modern "rehabilitation" type of program, consisting of an educational intervention[31] and a 3-week course of intensive exercise sessions, based on cognitive-behavioral principles. A total of 64 patients with low back pain lasting longer than 1 year plus disc degeneration at L4/5 and/or L5/S1,[24] and 60 more patients with chronic low back pain more than 1 year after previous discectomy[25] were randomized and reported on separately. There was a 97% follow-up at 1 year and intention-to-treat analysis. In both series, there were no significant differences in any of the main outcomes of independent observer rating, patient rating, pain, disability, or return to work. Radiating leg pain improved significantly more after surgery, whereas fear avoidance beliefs and forward flexion improved significantly more after conservative treatment. At 1-year follow-up, the conservative groups had significantly better muscle strength and endurance.[25] Despite the relatively small size of these trials (although the number randomized to conservative treatment is comparable to the Swedish trial, 57 compared to 72), the consistent results in both first time patients and those for whom surgery previously failed, and the lack of any trends make a type II error unlikely. In contrast to the Swedish trial, these results suggest that the outcomes of fusion are no better than those of a modern rehabilitation approach.

There are now results from three small RCTs of IDET, each using different protocols. The first trial[32] randomized 28 patients to either IDET or placebo. At 8 weeks, 1 patient was judged a success in those stimulated (n = 13) and 2 in the controls (n = 15). No more detailed or longer term results have been published. The second trial[33] reported on a highly select group of 64 patients, from a potential cohort of 4253, randomized to IDET or placebo. Results from 56 patients suggested that IDET resulted in a significantly higher improvement in pain and disability. The third trial[34] randomized 57 patients with a 2:1 ratio to IDET or placebo and had 96% follow-up. No patient in either arm met predefined criteria for clinically significant improvement in the Low Back Outcome Score or SF-36, or for a successful outcome. These trials are all small, so it is not possible to draw any firm conclusions about the effectiveness of IDET. Nevertheless, the extremely poor results of Barendse[32] and Freeman[34] et al cast serious doubt on the highly selective, positive results reported by Pauza et al.[33] IDET was also found to be ineffective in both arms of a randomized trial published by Ercelen et al[35] This trial was excluded from the review because it compared two durations of thermocoagulation rather than the intervention versus any form of control therapy.

There are three makes of artificial disc (i.e., the SB Charité [DePuy Spine, Inc., Raynham, MA], ProDisc [Spine Solutions, Inc., New York, NY], and Maverick currently undergoing Food and Drug Administration-approved multicenter RCTs for degenerative lumbar disc disease. McAfee[36] and Zigler[37] et al, respectively, summarized an earlier European experience of these two devices, which did not include any RCTs. McAfee et al[36] reported on the pilot feasibility study of the US RCT comparing the SB Charité (n = 41) and BAK anterior interbody fusion (n = 19) for single-level degenerative disc disease at L4–L5 or L5–S1. There was no significant difference in Oswestry Disability scores between the artificial disc and fusion groups at 2 years. During the review of this article, further data from an additional 244 participants (total 304, including 205 Charité, 99 BAK) have been published by Geisler et al.[38] Oswestry disability scores, VAS scores, and device failure rates are provided in the analysis tables. No significant differences were observed.

Zigler et al[37] (n = 39) and Delamarter et al[39] (n = 53) each reported 6-month results from single centers participating in the US RCT of ProDisc versus circumferential 360° fusion for 1 or 2-level degenerative lumbar disc disease between L3–S1. Zigler et al[37] compared 28 patients who received ProDisc and 11 who had fusion. Operating time, blood loss, and length of hospital stay were lower with disc replacement. Patients who underwent disc replacement had a trend toward better Oswestry Disability scores, but at 6 months, there were no significant differences in pain, disability, or patient satisfaction. In view of the small numbers, it is not possible to present graphically the results, make multiple statistical comparisons, or draw any firm conclusions. Delamarter et al[39] compared 35 patients who received the ProDisc and 18 who had fusion. Patients who underwent disc replacement had significantly faster improvement in VAS pain and Oswestry Disability scores at 6 weeks and 3 months, but by 6 months, there was no significant difference between disc replacement and fusion. Patients with disc replacement at L4–L5 preserved significantly better motion.

Techniques of fusion

There were 15 trials that addressed various questions about the role of instrumentation in fusion. Of these, four were subgroups from trials already described in the "Techniques for Decompression of Spinal and Nerve Root Stenosis" and "Surgery for Back Pain without Neurologic Compromise" sections.[12,14,21,23] This was a very heterogeneous group of studies, in terms of surgical pathology, the technique(s) of instrumentation, and questions addressed. Four trials included patients with back pain associated with mixed pathologies, including degenerative disc disease, degenerative spondylolisthesis, isthmic spondylolisthesis, or failed back surgery, and did not present separate results for each condition.[15,17,40,41] The Swedish study[23] focused on people with chronic low back pain caused by degenerative disc disease and excluded stenosis or spondylolisthesis, but 19% of the participants had back pain following previous surgery for disc herniation. Two trials had participants with degenerative spondylolisthesis and stenosis,[14,42] and three had participants with isthmic spondylolisthesis.[20,29,43] Only the recent Norwegian study[24] reported separately on participants with chronic low back pain caused by degenerative disc disease.

There were differences in surgical approach and instrumentation systems in most studies, and only three trials used the same pedicle screw system. There was also lack of uniformity in the outcome measures, with the most common being technical surgical outcomes, including fusion rates, progression of spondylolisthesis, and reoperation rates. The results from the trials are summarized in the "analysis tables" of the Cochrane Review. It is noteworthy that once again, the caveat that the test for homogeneity was significant in all these meta-analyses, so the results must be used with caution.

There were 8 trials that directly addressed the question of whether instrumentation improves the outcome of posterolateral fusion, with an average 95% patient follow-up at 16 months to 4.5 years (mean 28 months). These trials provide moderate evidence that in-

strumentation improves the fusion rate (Figure 1). Together, these trials provide conflicting evidence that instrumentation produces a statistically and clinically significant improvement in clinical outcomes (Figure 2). However, that is heavily dependent on the suspiciously good results of Bridwell et al[14] and Zdeblick.[15] If only the methodologically stronger trials since 1997 are considered, then any advantage appears to be marginal and nonsignificant (74% vs. 68%).

Four trials compared various combinations of anterior, posterior, or combined fusion. Schofferman et al[13] found no difference in clinical outcomes between ALIF plus pedicle screws plus instrumented posterolateral fusion (360°) versus ALIF plus pedicle screws without graft (270°). Health care costs increased with the complexity of surgery. Kitchel and Matteri[16] found no difference in outcomes with the addition of PLIF in degenerative spondylolisthesis (grade I/II) to a posterolateral instrumented fusion for patients older than 60 years but did find significantly longer surgery time, higher blood loss, and complication rate in this group. Christensen et al[41] reported that circumferential fusion using ALIF carbon fiber cages produced a higher fusion rate (90% vs. 80%) and lower reoperation rate (7% vs. 22%) than posterolateral fusion with Cotrel-Dubousset instrumentation. Circumferential fusion produced marginally less back and leg pain, although of borderline significance on multiple comparisons. Finally, Sasso et al[44] compared a cylindrical threaded titanium cage inserted anteriorly with a femoral ring allograft. Although the fusion rate was higher with the cage, disability and neurologic outcome scores were not significantly different. These conflicting results do not permit any conclusions about the relative effectiveness of anterior, posterior, or circumferential fusion.

There were four trials that assessed whether electrical stimulation could enhance fusion, although they all used different methods. Mooney[45] and Linovitz et al[46] used pulsed electromagnetic stimulation for 4 hours/day and 30 minutes/day, respectively. Goodwin et al[47] used ca-

Review: Surgery for degenerative lumbar spondylosis
Comparison: INSTRUMENTED POSTEROLATERAL FUSION vs GRAFT ONLY (mixed disease)
Outcome: Fusion at 2 yrs

Study or sub-category	Instrumented n/N	Graft only n/N	OR (random) 95% CI	Weight %	OR (random) 95% CI
Bridwell 1993	21/24	3/10		8.66	16.33 [2.66, 100.26]
McGuire 1993	10/13	10/14		9.07	1.33 [0.24, 7.56]
Zdeblick 1993	62/72	33/51		14.47	3.38 [1.40, 8.16]
Fischgrund 1997	29/35	15/33		12.87	5.80 [1.90, 17.68]
Thomsen 1997	42/62	54/64		14.62	0.39 [0.16, 0.92]
France 1999	22/29	18/28		12.63	1.75 [0.55, 5.51]
Moller 2000	29/37	24/37		13.43	1.96 [0.70, 5.52]
Fritzell 2001	54/62	48/67		14.25	2.67 [1.07, 6.66]
Total (95% CI)	**334**	**304**		**100.00**	**2.30 [1.10, 4.80]**

Total events: 269 (Instrumented), 205 (Graft only)
Test for heterogeneity: Chi² = 24.62, df = 7 (P = 0.0009), I² = 71.6%
Test for overall effect: Z = 2.22 (P = 0.03)

0.1   0.2   0.5   1   2   5   10
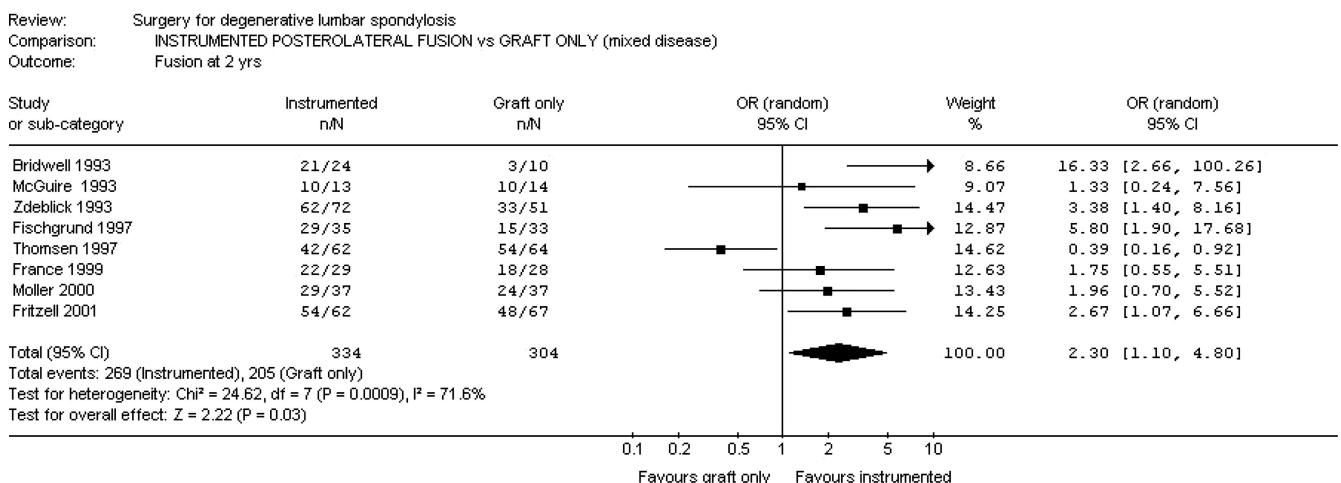Favours graft only   Favours instrumented

Figure 1. Instrumented posterolateral fusion versus graft only: a likelihood of fusion.

Review: Surgery for degenerative lumbar spondylosis
Comparison: INSTRUMENTED POSTEROLATERAL FUSION vs GRAFT ONLY (mixed disease)
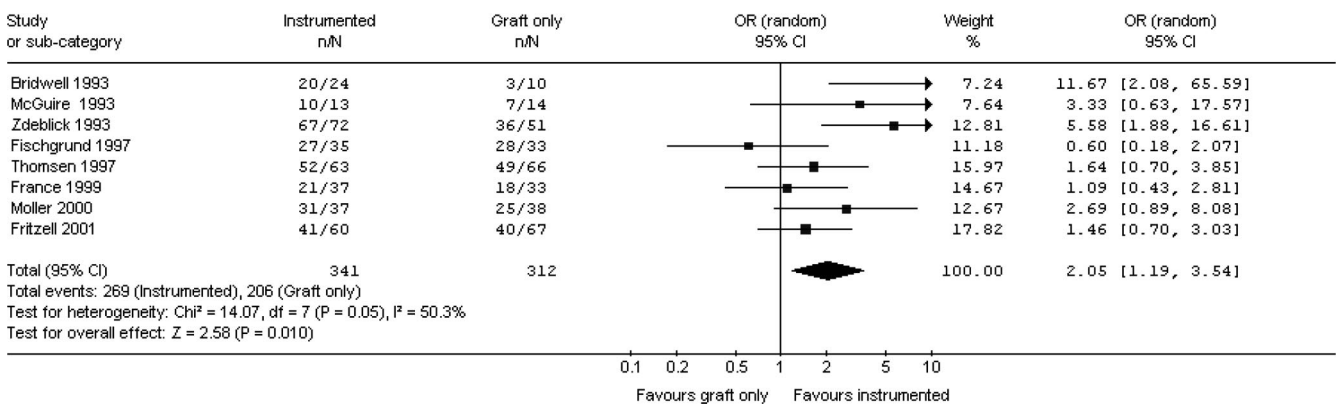Outcome: Good clinical outcome

Study or sub-category	Instrumented n/N	Graft only n/N	OR (random) 95% CI	Weight %	OR (random) 95% CI
Bridwell 1993	20/24	3/10		7.24	11.67 [2.08, 65.59]
McGuire 1993	10/13	7/14		7.64	3.33 [0.63, 17.57]
Zdeblick 1993	67/72	36/51		12.81	5.58 [1.88, 16.61]
Fischgrund 1997	27/35	28/33		11.18	0.60 [0.18, 2.07]
Thomsen 1997	52/63	49/66		15.97	1.64 [0.70, 3.85]
France 1999	21/37	18/33		14.67	1.09 [0.43, 2.81]
Moller 2000	31/37	25/38		12.67	2.69 [0.89, 8.08]
Fritzell 2001	41/60	40/67		17.82	1.46 [0.70, 3.03]
Total (95% CI)	341	312		100.00	2.05 [1.19, 3.54]

Total events: 269 (Instrumented), 206 (Graft only)
Test for heterogeneity: Chi² = 14.07, df = 7 (P = 0.05), I² = 50.3%
Test for overall effect: Z = 2.58 (P = 0.010)

0.1   0.2   0.5   1   2   5   10
Favours graft only   Favours instrumented

Figure 2. Instrumented posterolateral fusion *versus* graft only: a likelihood of good outcome.

pacitively coupled field stimulation 15−16 hours/day, and Jenis et al[48] tested both pulsed electromagnetic stimulation and implanted direct current. The anatomic technique of fusion varied. Jenis et al[48] tested instrumented and Linovitz et al[46] noninstrumented fusion, while Mooney[45] and Goodwin et al[47] tested both instrumented and noninstrumented fusion. Three trials in noninstrumented fusion showed a significant effect on the fusion rate (random OR 0.38; 95% CI 0.22, 0.64: favored stimulation). Two of the three trials in instrumented fusion showed positive results, though the third trial had negative results (random OR 0.59; 95% CI 0.15, 2.30: not significant). Although these results suggest that electrical stimulation does have a modest effect on enhancing fusion, it is not possible to assess the relative value of different methods of electrical stimulation. Jenis et al[48], Mooney,[45] and Goodwin et al[47] assessed clinical outcomes, but overall, there was no significant effect.

■ **Discussion**

There is now an increasing scientific database of 31 RCTs on surgical treatments for degenerative lumbar spondylosis. Four RCTs were presented in a single day at the 2003 meeting of the International Society for Study of the Lumbar Spine. Most of the recent trials are of higher quality than those reported earlier. However, most still compare different surgical techniques, and few address the more fundamental question of whether surgery provides effective relief of presenting symptoms. Many trials still report relatively short-term, technical, surgical outcomes rather than patient-centered outcomes of pain, disability, and capacity for work. The limited evidence on the long-term effects of either surgical decompression or fusion remains a matter of concern, given the magnitude of the clinical problem, and numbers and costs of surgical procedures being performed.

The trials on spinal stenosis and decompression permit limited conclusions. There is no clear evidence about the most effective technique of decompression for spinal stenosis or the extent of that decompression. There is limited evidence that adjunct fusion to supplement decompression for degenerative spondylolisthesis produces less progressive slip and better clinical outcomes than decompression alone. There is also limited evidence that fusion alone may be as effective as fusion combined with decompression for grade I or II isthmic spondylolisthesis with no significant neurology.

There are now two trials on the effectiveness of fusion compared with conservative treatment. The first (Swedish) trial[23] appeared to provide strong evidence in favor of fusion, but the more recent (Norwegian) trial[24,25] refutes this. The difference may lie in the treatment given to the control group. Fusion is more effective than continued, failed, standard 1990s "usual care"; it does not appear to be any more effective than a modern rehabilitation program. Clearly, there are still open questions about the scientific evidence on the clinical effectiveness of fusion. Further evidence is required, which hopefully will be provided by the multicentered RCTs of fusion that are presently underway in the United States and United Kingdom.

There are now 15 trials of instrumented fusion, but they are clinically and statistically very heterogeneous, and any attempt to combine and interpret the results must be cautious and tentative. These trials dealt with diverse pathologic conditions, with different criteria for surgery, and the results were not always presented separately for each subgroup. Most of the trials used different instrumentation systems. Many of these trials were of low methodological quality with inadequate randomization, lack of blinding, and potential for bias. The published results were mainly surgical outcomes, such as fusion and surgeon's ratings, rather than patient-centered outcomes. Some of the trials were published in abstract form only. Considering these limitations, instrumentation of a posterolateral fusion appears to lead to a higher fusion rate, although there are problems assessing fusion in the presence of metalwork, which few of these

trials considered.[49,50] Despite enhancing fusion, it appears that any improvement in clinical outcomes is marginal. It is not possible to draw any conclusions from this review about the relative morbidity or complications, except that instrumentation is obviously associated with unique complications. It is also not possible to draw any conclusions about the possible role of instrumented fusion for any particular pathologic condition or about the relative benefits of any particular instrumentation system.

Bono and Lee[51] recently completed a comprehensive review of a much wider range of randomized and non-randomized, prospective and retrospective studies of lumbar fusion, which provides a useful check on this more rigorous but more limited Cochrane Review. They also concluded that:

1. The surgical literature on lumbar fusion over the past 20 years is "incomplete, unreliable, haphazard." They made useful suggestions on how this should be improved in future studies.
2. Instrumentation appears to increase the overall fusion rate, but only slightly.
3. Instrumentation does not improve overall clinical outcomes, although there is currently insufficient evidence to judge particular subgroups of patients.

The recent trial[28] on an interspinous spacer device for lumbar spinal stenosis shows promising results, and further studies are clearly warranted. There are still only preliminary results available on disc replacement, which do not permit any firm conclusions. It is likely to be another 18 months before the full 2-year outcomes from all centers of the US RCTs are published.

Only four trials in this entire review[23–25,40] considered occupational status, and it is not possible to draw any conclusions about the efficacy of any of these surgical treatments on capacity for work. There is no good evidence on cost-effectiveness. There are other data on various aspects of surgical technique that we have not included in this review (*e.g.*, computer assistance on the placement of pedicle screws).[52] There is also immense scientific interest in the role of recombinant bone morphogenic protein[53,54] and gene therapy,[55] but we believe that these topics should be the subject of a separate Cochrane review.

■ Conclusions

There is now some evidence on various issues of surgical techniques of decompression and fusion for individuals with degenerative lumbar spondylosis. Presently, there is still insufficient evidence on the effectiveness of surgery on clinical outcomes to draw any firm conclusions. A need exists for more scientific evidence on the clinical efficacy and cost-effectiveness of surgical decompression and/or fusion for specific pathologic and clinical syndromes associated with degenerative lumbar spondylosis. This will require high quality RCTs, preferably comparing these surgical treatments with natural history, placebo, or conservative treatment. Surgeons should seek expert methodological advice when planning trials. This Cochrane review should be maintained and updated as further RCTs become available. The authors of this review will be pleased to receive information about any new RCTs of surgical treatment of degenerative lumbar spondylosis.

■ Key Points

● An updated Cochrane review identified 31 RCTs.
● There is conflicting evidence on the clinical effectiveness of fusion.
● Instrumentation produces a higher fusion rate, but any improvement in clinical outcomes is probably marginal.
● The limited available evidence on IDET suggests that it is ineffective.
● Preliminary data on disc arthroplasty do not permit firm conclusions.
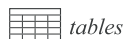
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Editorial Comment
Lumbar Discography—Where Are We Today?

ALF NACHEMSON, MD, PhD

IN A POSITION STATEMENT ON DISCOGRAPHY[34] the members of the executive committee of the North American Spine Society strongly support its use as a preoperative diagnostic test. They do so without forwarding any scientific studies to support their claim.

In the majority of patients the origin of back pain is unknown[30,45] and we are still awaiting results from basic science laboratories around the world to clarify this matter.[32] It is unfortunately also quite clear that our present-day treatment is mostly ineffective, at least judging from the epidemical increase in disability due to back pain in all industrialized societies.[9,31,39,45,46]

It also seems that the patients with back pain are subjected to too much treatment.[31,45] It has been proposed that our past pathological model is partly to blame, that is, the preoccupation with finding a pathological entity when none such exists leads us to applying unnecessary, unproven treatment modalities.[46] The lay-press attests to this, and it has been proposed that it is time to bury the time-honored "clinical freedom" because it is at best a disguise for ignorance, at worst an excuse for quackery.[16,32] Before embarking on more and more elaborate fusion operations—currently a multitude of plates and other instrumentations are tried—it is probably time to stop and think and ask ourselves if we are really doing any good.

If we read the literature on lumbar discography it becomes evident that there is no controversy as to the possibility of detecting with some probability the various stages of disc degeneration from a discogram.[1,17,18] It is also likely that discograms can show ruptures and that they can sometimes elicit pain that the patient says mimics what he had experienced before.[6,14,17,26] The intricate, multiple-level nervous supply to the outer part of the annulus fibrosus or the dorsal longitudinal ligament that can be reached by the injected irritants can be one of the reasons why this interpretation is difficult and sometimes false, as demonstrated by several authors.[14,21,28,52] Also, absolutely normal, previously pain-free people can get back pain from a discogram.[21,47] Weinstein et al,[51] in their experimental study, found chemical evidence of possible affects to the dorsal root ganglion by surgical manipulations of dogs' discs, including discography. Their results were derived from normal dogs, "probably not representative of true disc disease." They do, however, point to the possibility of a chemically sensitized dorsal root ganglion playing an important part in low-back pain syndromes.

Disc degeneration is very common, increasing with age, and ruptures certainly exist without pain.[8,18,22,25] Recent MRI studies[36] on 400 normal women demonstrated this fact very nicely. Many researchers have demonstrated that injections of irritants at many different sites in the motion segment also can elicit both back and leg pain in healthy volunteers.[5,19,21,28]

The initial hope expressed by Lindblom[26] in 1948 that lumbar discography eventually would replace myelography has not been fulfilled. Lindblom's notion[27] that, in particular, laterally located disc herniations could be seen by the discographic method was true to some extent, but better accuracy can be obtained today by a CT.[2,23] Furthermore, disc herniations can exist in asymptomatic subjects.[2,4,20] How often laterally situated disc herniations exist without pain is not known but the frequency is, for anatomic reasons, probably higher than the 22–30% described in the more medially located herniations.

Recent studies have demonstrated that the sensitivity, specificity and predictive value of the discogram for detection of disc herniation is less good than myelography, CT and MRI.[2,14,41,52] Jackson et al[23] demonstrated that discography alone had a sensitivity of 81% but a specificity of only 31%. On the other hand, when discography was combined with CT in a study where there was a two-level and sometimes two-sided surgical confirmation and blinded evaluation of the disco-CT and discography alone, they demonstrated the disco-CT to be slightly better than myelography and CT. Calculating the radiation necessary to perform all these studies gives values that seem rather high. In the study just mentioned the subjects evaluated received approximately 40 milliSievert. This thorough study was aimed, however, at the diagnosis of symptom-producing disc herniations and really did not prove anything with regard to diagnosing "degenerative disc disease."

In another recent multicenter disco-CT study, Vanharanta et al[48] claimed that intradiscal pathology plays a major role in nonspecific low-back pain syndromes. These authors did not calculate the sensitivity and specificity, however. From the facts given in their paper this seems acceptable only in those with disc hernias. The authors did not state their definition of the various groups—disc herniation, degenerative disc, lumbar syndrome, lumbar radicular syndrome—but nevertheless put forth the claim that in 56% of the lumbar syndrome patients and in 59% of the lumbar radicular syndrome patients CT-discography demonstrated both a disc lesion and a positive pain provocation, which would indicate "discogenic" pain, in patients where other diagnostic procedures had failed to detect the source of pain. It is obvious that such reasoning cannot be used to defend the value of discography, even when enhanced with CT.

In an interesting preliminary report on the role of external spinal skeletal fixation in the assessment of low-back disorders, Esses et al[10] compared preoperative testing with the AO external fixator with ordinary X-rays and discography in 34 patients with chronic low-back pain. While clinical improvement by rigid external fixation proved to be a good predictor for a later good result after a posterior fusion, such significantly was *not* the case for an abnormal discogram or pain reproduction by a discogram. Nor was there any signficant association with disc degeneration on plain radiograms and positive surgical outcome. In that particular report, reproduction of pain by discography was an even less sensitive predictor of surgical results than degenerative changes observed on routine radiograms.

Walsh et al[47] tried to improve pain rating at discography and compared 10 young volunteers with an inhomogeneous group of seven patients. Their method enabled them to state that the sensitivity of discography producing pain was nearly 100%. They admit, however, that specificity and validity are still unproven. The basic question still remains. We cannot at the present time state that pain from a degenerative disc caused by injection means

that that particular disc is the cause of the patient's problem. The prospective clinical study of Esses et al,[10] the only one of its kind in this field, although preliminary, nevertheless casts grave doubts on the value of discography for predicting outcome from a fusion operation.

In the past we have been notoriously poor in evaluating new diagnostic procedures.[3,13,33] Applying modern clinical statistics and calculating sensitivity, specificity and accuracy leaves the method of lumbar discography short of demonstrating usefulness. Therapy, including lumbar fusion, based on the discographic picture and/or pain response at injection also have been poorly evaluated, with few if any studies even having validated outcome measures or adequate follow-up by unbiased observers.[13,15,33,37] Two recent reviews[13,15] in the *Journal of Bone and Joint Surgery* on how orthopaedic clinical research must be performed have highlighted our deficiencies in this respect, also previously pointed out in an editorial comment in SPINE by Nachemson and LaRocca.[33] Discography was justified, originally, only on the basis of descriptive studies. The radiological appearance of the contrast material, thought to correspond to the shape of the nucleus pulposus, and the reproduction of "typical pain" on injection of known amounts and pressure of contrast were interpreted as being diagnostic of the disc degeneration responsible for the patient's symptoms.

Validation of diagnostic tests, however, requires the determination of the sensitivity and specificity of the test against an explicit and meaningful standard. The weakness inherent in most studies scrutinizing discography is the relative lack of studies on patients thought *not* to have disc degeneration. This makes it very difficult to estimate the specificity of discography, that is, the proportion of "healthy" subjects exhibiting negative tests. A test with less than 100% specificity, used to decide on operative management, will result in unnecessary surgery and its associated morbidity and cost.

The least credible standard is the presence or absence of symptoms prior to discography. Only Holt[21] and Walsh et al[47] have managed to supply a truly asymptomatic control group.

At the second level of credibility, presence or absence of pathologically confirmed disc degeneration at surgery serves as the standard against which discography is judged. In the study by Jackson et al,[23] sensitivity was acceptable, but specificity was low, leading to excessive surgery.

Colhoun et al,[7] in a nonconsecutive population of previously unoperated patients, tried to evaluate the outcome of a variety of spinal operations, mostly fusion procedures, against the preoperatively performed discography. The statistical analysis was performed against the pain response, but only "technically successful operations" were included. The 2-year follow-up by an unbiased observer revealed a satisfactory result in 88% of patients with a positive pain reproduction at discography. Disregarding the result of that test, however, they had a success rate of 82%. Since the study was not originally set up as a prospective trial of the value of discography, the validity cannot really be determined.

Using surgical outcome as standard against which discography is measured provides the third level of evidence. The Esses et al[10] study strongly suggests that positive discograms *do not* effectively predict therapeutic response.

The ideal study would scrutinize discography against some absolute knowledge of the cause and severity of each patient's symptoms. But because we lack a thorough understanding of neck and back pain, we have to accept long-term therapeutic response as the best standard currently available. Further studies like the one by Esses et al,[10] conducted by the techniques recommended by Walsh et al[47] must be performed before we will know the diagnostic validity of discography.

For those who still advocate lumbar discography and/or lumbar fusion we expect prospective, randomized trials to be performed. Probably the best way to do this is to randomize surgeons[15,38,40,43] and agree on the same type of patients to be diagnosed and treated, one way or the other. With our present updated knowledge this should perhaps be done using disco-CT[23,48] to elucidate whether the use of this new modality can enhance the results after a fusion operation.

It is, however, most likely that the discography saga is ended, after 40 years of controversy.[16,42] The new modality, magnetic resonance imaging (MRI), seems to be superior in visualizing disc hernias,[4] also laterally located. Staging of disc degeneration with visualization of ruptures seems possible with MRI.[44]

The benefit of surgery for low-back pain and sciatica at the present time is proven in a scientific manner only for disc herniations giving root pain.[49,50] Good retrospective studies also exist to prove effectiveness in cases with definite instability[12] and with moderate success rate, relieving leg pain only, in patients with spinal stenosis.[24] Surgery is not yet a proven modality for patients with root canal stenosis[35] or internal disc disruption.[8] Nor is it proven effective in patients with disc degeneration in whom lumbar discography can elicit pain. In the preliminary study by Esses et al[10] it was actually scientifically disproven.

Finally, we must remember that examination by discography of two to three discs with added CT exposes the patient to 15-20 milliSievert.[29] The drastic reduction of American tourism in certain parts of Europe following the Chernobyl accident, where subjects were exposed to 2 milliSieverts, attests to the fact that the public certainly is aware of the dangers of radiation—when informed.

In the Position Statement[34] a post-discography discitis rate of 0.1-0.2% was quoted. Judging from the recent publication by Fraser et al,[11] rates are rather in the 2-3% range!

Discographic studies should not continue, except for prospective studies performed in large spine centers, after the approval of human experimentation committees, where the intent is to find out if they can really help in treatment selection for the chronic low-back patient.

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Abnormal Magnetic-Resonance Scans of the Lumbar Spine in Asymptomatic Subjects

A Prospective Investigation*

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ABSTRACT: We performed magnetic resonance imaging on sixty-seven individuals who had never had low-back pain, sciatica, or neurogenic claudication. The scans were interpreted independently by three neuroradiologists who had no knowledge about the presence or absence of clinical symptoms in the subjects. About one-third of the subjects were found to have a substantial abnormality. Of those who were less than sixty years old, 20 per cent had a herniated nucleus pulposus and one had spinal stenosis. In the group that was sixty years old or older, the findings were abnormal on about 57 per cent of the scans: 36 per cent of the subjects had a herniated nucleus pulposus and 21 per cent had spinal stenosis. There was degeneration or bulging of a disc at at least one lumbar level in 35 per cent of the subjects between twenty and thirty-nine years old and in all but one of the sixty to eighty-year-old subjects. In view of these findings in asymptomatic subjects, we concluded that abnormalities on magnetic resonance images must be strictly correlated with age and any clinical signs and symptoms before operative treatment is contemplated.

Magnetic resonance imaging is being used increasingly for the diagnosis of conditions causing acute low-back pain and sciatica. Some investigators have proposed that magnetic resonance imaging should replace, rather than supplement, myelography[12]. Several have reported that the sensitivity of magnetic resonance imaging for the diagnosis of herniated nucleus pulposus and spinal stenosis is equivalent to or better than that of computerized tomography, even when computerized tomography is combined with myelography or discography[2,5-8]. Magnetic resonance imaging is sensitive enough to detect a partial or complete tear of the anulus fibrosus that is undetectable with other non-invasive imaging modalities[14].

Despite the high sensitivity of magnetic resonance imaging, there is still a question about whether the modality is acceptably specific, especially when it reveals abnormal findings in the absence of clinical signs and symptoms[9]. Specificity is ordinarily defined by percentages of false-positive and false-negative results, and it is determined most often in symptomatic patients. However, a considerable number of abnormalities are found on the magnetic resonance images of asymptomatic subjects. An abnormal finding on magnetic resonance imaging in an asymptomatic subject is not necessarily a false-positive result, since such a lesion cannot be correlated with an anatomical lesion in subjects who are not operated on. Thus, in this report on asymptomatic subjects, we use the term magnetic-resonance positive to allow inference about the specificity of the findings and to allow calculation of the prevalence of abnormal findings.

Three studies have demonstrated high incidences (24 to 37 per cent) of abnormal findings on discograms, myelograms, and computerized tomography scans of asymptomatic subjects[3,4,13]. To our knowledge, analogous data have not been generated for magnetic resonance imaging. The purpose of this investigation was to determine the prevalence of positive findings on magnetic resonance images of the lumbar spine in asymptomatic subjects.

Materials and Methods

Magnetic resonance imaging of the lumbar spine was performed on sixty-seven volunteers, who ranged in age from twenty to eighty years (average, forty-two years). There were thirty men and thirty-seven women. The subjects were recruited through advertising in several general newspapers, and the respondents, as well as their spouses (when eligible) were chosen to obtain the correct balance of sex and age for three groups (Fig. 1). The volunteers were screened with a standardized questionnaire, and only those who had no history of pain in the back, sciatica, or neurogenic claudication were included in the study. Any episode of non-radiating low-back discomfort that had lasted more than twenty-four hours or had necessitated time off from work was grounds for excluding the candidate from the study. Volunteers were also excluded if they had had sciatica (pain or sensory abnormalities in the buttocks or
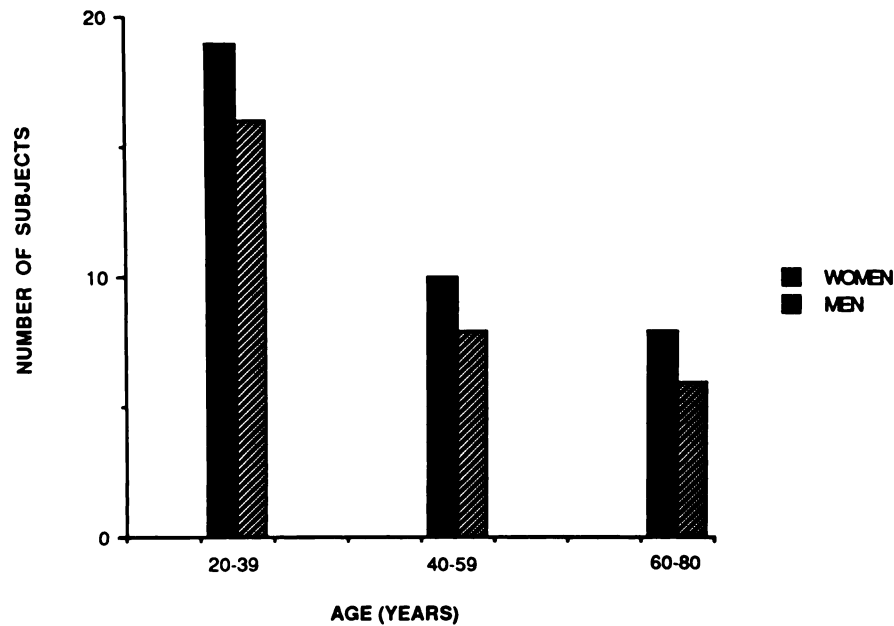
Fig. 1

Demographic data for sixty-seven asymptomatic volunteers.

lower limbs) or if walking caused pain or a sensory abnormality in a lower limb.

Once the subject was entered in the study, multiplanar magnetic-resonance imaging was done from the first lumbar to the first sacral vertebra with a 1.5-tesla imaging system (Signa, General Electric, Milwaukee, Wisconsin). A sagittal localizing series was performed with a repetition time of 400 milliseconds, an echo time of twenty milliseconds, a slice thickness of five millimeters with one-millimeter intervals, and a thirty-two to thirty-six-centimeter field of view. For the sagittal images (twenty-four-centimeter field of view), a multiple spin-echo technique was used, with a repetition time of 1000 milliseconds, to produce five-millimeter-thick slices at one-millimeter intervals after four excitations. Two echoes were generated; the first had an echo time of twenty milliseconds (T1 weighted) and the second, an echo time of seventy milliseconds (T2 weighted). For axial sequences, which were angled through the disc space, four-millimeter-thick slices at one-millimeter intervals were acquired with a repetition time of 600 milliseconds and an echo time of twenty milliseconds.

The sixty-seven studies of the asymptomatic subjects were mixed randomly with thirty-three scans that had been made with the same scanner on patients who had well defined clinical symptoms of either a herniated disc or spinal stenosis. Those symptoms correlated with an unequivocal abnormality on the magnetic resonance image, as previously interpreted by neuroradiologists who were not associated with the study. Thus, 100 scans were presented, in random sequence, to three of us who are neuroradiologists (D. O. D., T. S. D., and N. J. P.) and who had no information about the patients or the subjects. At the level of each disc, any important diagnoses (herniated nucleus pulposus and spinal stenosis) were identified, as were findings of less-

certain importance (bulging and degeneration of a disc). In addition to rating the severity of the abnormality, the neuroradiologist rated his certainty about the diagnosis (definite, probable, or possible).

Since precise radiographic definitions of lesions in the lumbar discs remain subject to variations between readers, this study was designed to yield a spectrum of independent interpretations from three expert neuroradiologists. Herniated nucleus pulposus was considered to be an extrusion, mainly focal, of disc material beyond the osseous confines of the vertebral body, resulting in displacement of epidural fat, nerve root, or thecal sac. A bulge was defined as a diffuse, usually non-focal protrusion of non-osseous material beyond the normal disc space. The basic criterion for a diagnosis of stenosis of the spinal canal was non-discogenic loss of signal in the epidural fat with compression of neural tissues within the canal. Degeneration of the disc

TABLE I

CORRELATION OF AGE WITH ABNORMAL MAGNETIC-RESONANCE IMAGES OF THE LUMBAR SPINE IN SIXTY-SEVEN ASYMPTOMATIC SUBJECTS

	Percentage of Subjects Who Had an Abnormal Finding		
	20-39 Yrs. Old (N = 35)	40-59 Yrs. Old (N = 18)	60-80 Yrs. Old (N = 14)
All abnormal findings			
Reader 1	26	28	57
Reader 2	20	22	64
Reader 3	20	17	50
Average*	22 (7)	22 (3)	57 (7)
Herniated discs	21	22	36
Spinal stenosis	1	0	21

* Figures in parentheses represent the number of subjects in each age group for which the interpretations of all three readers were in complete agreement.
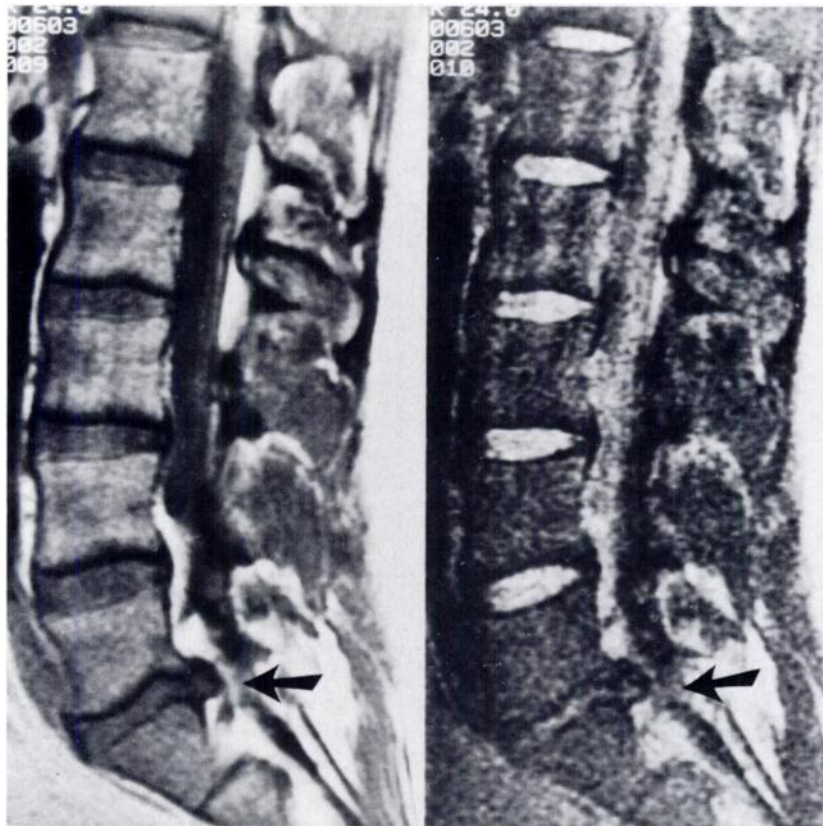
FIG. 2

Magnetic resonance image interpreted by three neuroradiologists as showing herniation of the disc between the fifth lumbar and first sacral vertebrae in a thirty-three-year-old subject who had never had low-back pain or sciatica.

was considered to be present when there was loss of height of the disc space and a decreased signal on T2-weighted sequences.

At the level of each disc, each neuroradiologist scored the findings of the magnetic resonance image quantitatively and objectively and assessed the importance of any abnormal finding subjectively. The results from each reader were averaged, and the diagnosis and the severity of the lesion were tabulated according to the subject's age. Only the findings that the interpreters had labeled as probably or definitely abnormal were recorded as abnormal findings. The over-all number of abnormal magnetic-resonance images included only those that were considered to demonstrate very substantial abnormalities. Findings that were graded as being less important to the diagnosis were tabulated separately. The consistency of interpretation among the neuroradiologists was also assessed. Finally, the percentage of asymptomatic subjects who had abnormal findings was calculated, thus establishing the prevalence of abnormal magnetic-resonance images of the lumbar discs of asymptomatic subjects.

Results

The three neuroradiologists independently interpreted the magnetic resonance images as being substantially abnormal for about 28 per cent (nineteen) of the sixty-seven asymptomatic subjects. Herniated nucleus pulposus was

noted in about 24 per cent (sixteen subjects) and stenosis of the spinal canal, in about 4 per cent (three subjects). Three more subjects had evidence of herniated nucleus pulposus on the magnetic resonance image, but the average of the readings of the three neuroradiologists resulted in a rating of "less than probable". Therefore, these subjects were not included in the group that had an abnormal scan.

The prevalence of abnormal findings was the same in the asymptomatic men and women, but it varied according to the ages of the subjects (Table I). In the twenty to thirty-nine-year-old and forty to fifty-nine-year-old groups, the prevalence of abnormal scans averaged about 20 per cent (seven of thirty-five and four of eighteen, respectively). In the sixty to eighty-year-old group, however, it averaged about 57 per cent (eight of fourteen). The most common important abnormalities in the oldest group were herniated nucleus pulposus (about 36 per cent, or five of fourteen) and stenosis (about 21 per cent, or three of fourteen), whereas all but one of the subjects who were less than sixty years old and had an abnormality had a herniated disc.

Figure 2 shows a magnetic resonance image of a thirty-three-year-old subject who never had back pain. All three interpreters thought that the scan showed a substantially herniated disc between the fifth lumbar and first sacral vertebrae. Most of the herniated discs were between the fourth and fifth lumbar or the fifth lumbar and first sacral levels (Fig. 3).
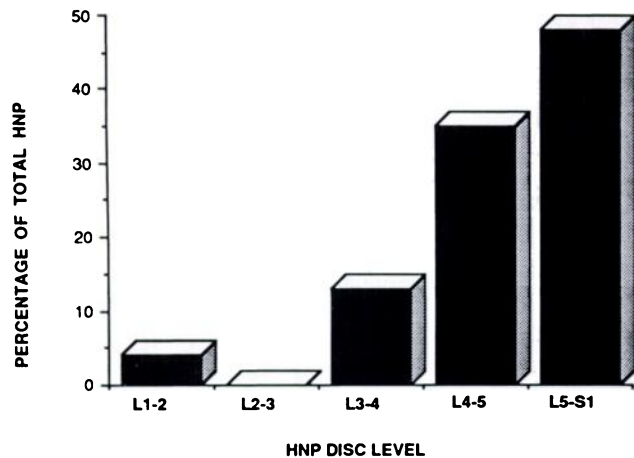
FIG. 3

Distribution of herniated nucleus pulposus (HNP) as seen on magnetic resonance images of the lumbar spine in asymptomatic individuals. Twenty-nine levels in twenty-one volunteers were involved.

At least one bulging disc was seen in about 54 per cent (nineteen) of thirty-five subjects who were less than sixty years old and in 79 per cent (eleven) of the fourteen subjects who were sixty years old or older. Similarly, at least one degenerated disc was noted in 34 per cent (twelve) of the thirty-five subjects in the youngest group and in all but one of the subjects in the oldest group (Fig. 4). In the subjects who were less than sixty years old, the degeneration involved an average of two levels, whereas in each of the subjects who were sixty years old or older, it involved an average of three levels. Approximately half of the degenerated discs also bulged, and this prevalence did not vary with age. In contrast, the proportion of bulging discs that were also degenerated increased from about one-third in the subjects who were less than sixty years old to about two-thirds in the older group.

In all but one of the thirty-three symptomatic patients, the findings on the magnetic resonance image correlated with the operative diagnosis. In the exceptional patient, who had spinal stenosis, one of the involved levels was not identified by two of the three readers.

The three neuroradiologists agreed regarding the presence or absence of abnormal findings on the magnetic resonance image at 99 per cent of the 500 disc levels (five in each subject) from both the symptomatic patients and the asymptomatic subjects. The subjective assessments of the severity of the findings varied somewhat, but over-all the three readers agreed completely on the exact diagnosis at 86 per cent of the levels, two agreed on the diagnosis at 98 per cent, and there was no consensus regarding the diagnosis at only 2 per cent of the levels. With regard to the 335 disc levels of the asymptomatic subjects alone, all three neuroradiologists agreed on the diagnosis at 90 per cent of the levels, and two agreed on the diagnosis at 99 per cent. When there was disagreement, it usually did not involve the presence or absence of an abnormality but rather the precise score of its severity and importance.

Discussion

Substantial percentages of individuals who never had low-back pain or sciatica but had abnormal myelograms (24 per cent), computerized tomography scans (36 per cent), or discograms (37 per cent) have been reported[3,4,13]. In the present study, about 30 per cent of an asymptomatic population had a major abnormality on a magnetic resonance image of the lumbar spine. The finding that an asymptomatic individual has more than a one-in-four chance of having an abnormal magnetic-resonance image emphasizes the danger of predicating a decision to operate on the basis of any diagnostic tests in isolation, without clinical information. A diagnosis that is based on magnetic resonance imaging,
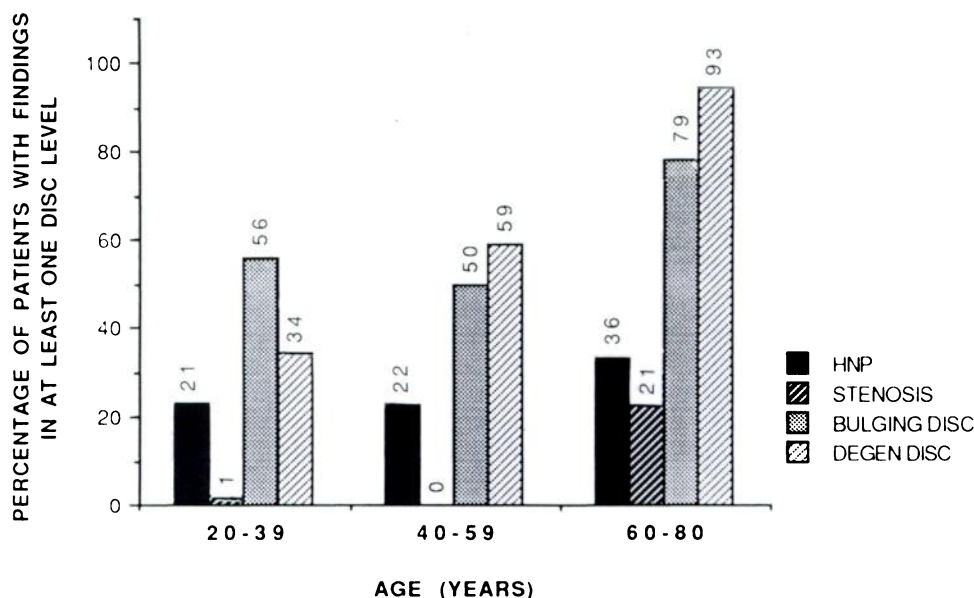

AGE (YEARS)

FIG. 4

Incidences of herniated nucleus pulposus (HNP), spinal stenosis, a bulging disc, and a degenerated disc on the magnetic resonance images of sixty-seven asymptomatic individuals.

in the absence of objective clinical findings, may not be the cause of the patient's pain, and an attempt at operative correction could be the first step toward disaster.

Comparison of the results of the present study with those of investigations of other types of imaging in asymptomatic subjects must be undertaken with caution. As we have noted, many abnormal findings are age-dependent. The study of discograms by Holt and the study of myelograms by Hitselberger and Witten differed from our study with regard to the mean age of the subjects. In fact, the results of the other two studies were not analyzed according to age. In contrast, Wiesel et al. studied computerized tomography scans in an asymptomatic population in which the distribution of age was comparable with that in ours. For the subjects who were less than forty years old, the incidences of abnormalities were similar in the two studies, but for the subjects who were forty or older, our data suggested that magnetic resonance imaging may yield fewer positive findings than computerized tomography does (approximately 35 per cent compared with approximately 50 per cent). Magnetic resonance imaging may be even more superior than the studies suggested because the computerized tomography was done at the fourth and fifth lumbar and the fifth lumbar and first sacral levels only, while the magnetic resonance images demonstrated herniated discs at the third and fourth lumbar levels as well. In fact, 13 per cent (four) of all twenty-nine herniated discs in our asymptomatic subjects were at these levels.

As with computerized tomography, subjects who were sixty years old or older were found to have a far higher percentage of abnormal magnetic-resonance scans than did those who were younger than sixty. Thus, an abnormal magnetic-resonance image in a younger patient is more likely to be a true indication of the cause of the complaints. For individuals who are sixty years old or older, it is less likely that the lesions demonstrated by magnetic resonance imaging are of clinical importance.

The interpretations of the three neuroradiologists in our study varied substantially less than those of the investigators of the computerized tomography scans[13]. In our study, the neuroradiologists agreed completely about 60 per cent of the scans, whereas the investigators did so about only 11 per cent of the computerized tomography scans. As noted earlier, the disagreements in our study mainly concerned the severity of the findings. Accordingly, one might infer that magnetic resonance imaging is better than computerized tomography for assessing the size and importance of lesions and of neural compression. However, that inference could be validated only if the same team of radiologists interpreted both computerized tomography scans and magnetic resonance images for the same group of patients.

The sensitivity of magnetic resonance imaging also enabled us to study the incidence and distribution of bulging and degenerated discs. In addition to the surprisingly high prevalence of those findings in asymptomatic subjects of all ages (twenty years old or older), the interrelationships of the two findings differed from what had been expected.

Although many authors have considered bulging of a disc to be caused by degeneration[5,6], in our asymptomatic subjects only half of the degenerated discs bulged, and only half of the bulging discs were also degenerated. In addition, in the older subjects, the prevalence of degeneration was more increased than that of bulging. These relationships may suggest that factors other than degeneration result in bulging, or possibly that the T2-weighted magnetic-resonance-imaging sequences do not detect all lesions that are indicative of degenerated discs[15].

In analyzing the reliability of data like ours, it is important to consider the selection of subjects as related to the design of the study. For the asymptomatic subjects in this study, the distribution of age and sex (Fig. 1) was similar to the typical spectrum for patients who have low-back pain[1,10,11]. Our three groups contained approximately equal numbers of men and women (by design) and most subjects were less than sixty years old. In addition, in our study, the distribution of the levels of the herniated discs was similar to that in a large study of patients who were treated for herniation of a lumbar disc[11].

Another important aspect of our selection of subjects was the exclusion of those who had any history of back pain, sciatica, or neurogenic claudication. It is possible, especially with older patients, that an episode of pain in the back might be forgotten, but we tried to minimize this error by using a standardized questionnaire that elicited the necessary information with several different avenues of questioning. Subjects whose reliability was questionable or who had problems with memory were excluded from the study.

We designed the prospective study to maximize the reliability of the neuroradiologists' estimates of the abnormalities on the magnetic resonance images. The asymptomatic volunteers were examined with a complete and standardized imaging protocol that was identical to the one used for the symptomatic patients. Precautions were taken so that the scans of the asymptomatic subjects could not be distinguished on a technical basis from those of the symptomatic patients. We randomized the sequence in which the scans were read so that the neuroradiologists' interpretation would be blind and unbiased by knowledge of the clinical situation. The forced-choice design of the score sheet necessitated evaluation of each disc level for the four objective findings and was intended to minimize inadvertent underreporting of findings. Finally, our three neuroradiologists differed in training, experience, and type of practice (private or academic), so that the spectrum of interpretation for each scan would be as wide as possible.

In conclusion, the high incidence of bulging and degenerated lumbar intervertebral discs seen on the magnetic resonance images of asymptomatic subjects confirms observations that have been made with computerized tomography and myelography studies that these findings are part of a normal, or at least common, aging process. The finding of an abnormal lumbar disc on a magnetic resonance image is most reliable in symptomatic patients who are less than sixty years old. It is less reliable in older patients. In this

study, the prevalence of abnormal magnetic-resonance images for asymptomatic subjects who were less than forty years old was comparable with that reported by Wiesel et al. for computerized tomography scans. Finally, the finding of substantial abnormalities of the lumbar spine in about 28 per cent of asymptomatic subjects emphasizes the dangers of predicating a decision to operate on the basis of diagnostic tests — even when a state-of-the-art modality is used — without precise correlation with clinical signs and symptoms.

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Surgical Treatment of Lumbar Disk Disorders

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THE BENEFIT OF SURGICAL TREATMENT FOR SOME DIS-eases affecting the lumbar spine is not controversial in many clinical circumstances, such as major trauma with gross instability, unstable spondylolisthesis, persistent or complicated spinal infections, and some spinal tumors with progressive neurologic loss. More commonly a patient may contemplate surgical treatment for complications of common degenerative conditions affecting the lumbar disk. In general, 2 clinical syndromes are associated with these degenerative conditions, and the clinical course and efficacy of interventions for each is very different. The first is primary back pain with little or no component of radicular symptoms due to nerve root irritation. The second is primary radicular pain, which usually has some component of back pain.

Surgical treatment for primary back pain associated with disk changes ("discogenic pain") is the more controversial and less successful.[1,2] When examination of the lumbar spine reveals only common degenerative changes, the relationship of these findings to a patient's back pain is unclear. Disk degeneration, anular fissures, small protrusions, and facet arthritis are commonly found in individuals with little or no back pain.[3-6] Furthermore, many studies have shown that serious disability in this group is associated with abnormal psychological profiles, multiple chronic pain processes, and compensation issues.[7,8] Conversely, longitudinal studies have found that the severity of chronic pain illness in this group appears to correlate much less well with presence or extent of degenerative findings than with these psychosocial or generalized neurophysiological comorbid conditions.[4,5] Not surprisingly, the surgical treatment of this poorly defined discogenic pain illness has been somewhat disappointing.[1,9] Randomized trials of lumbar fusion compared with various nonsurgical strategies have shown neither consistently good outcomes with surgery nor clear benefit over nonsurgical treat-ments.[10-12] In the randomized controlled trial (RCT) with the best surgical results, the improvement in pain intensity score was only 2 points (on a 10-point scale), and the disability improvement by Oswestry Disability Index was only 10 to 12 points (on a 100-point scale).[11] Furthermore, clinical outcomes appear to steadily deteriorate after 6 months. In a large population-based study, approximately 18% of patients who had spinal fusion for degenerative conditions experienced procedure-related complications; 20% of these patients went on to reoperation over the next 5 years.[13]

In contrast, for primary lumbar radicular pain syndromes or sciatica, the common clinical perception has been that surgical treatment is more effective and more reasonably considered. In working-age persons, by far the most common cause of sciatica has been lumbar disk herniation.[14] In most instances, imaging studies show clear pathologic disk herniation and root compression. The question of misdiagnosis, a serious issue in primary back pain syndromes in which imaging and provocative tests have poor validity, is much less of a problem in the presence of sciatic tension signs, neurologic symptoms, and concordant imaging studies. Fortunately, sciatica is usually a short-lived condition, and many of those affected experience only minor impairment and often do not seek medical attention. However, in some persons the radicular pain associated with disk herniation can be severe, intolerable, and, when persisting, gravely debilitating. How to treat patients seeking care for this problem is controversial.

In a landmark 1983 RCT, Weber[15] showed that, among patients with more or less tolerable sciatica and without serious motor weakness, a laminectomy and disk removal appeared to be more effective than nonoperative care over at least the first year. Both groups had a somewhat slow convalescence. However, the comparatively large surgical exposure and operative morbidity that were characteristic of spinal surgery 30 years ago seem excessive when compared with those of today's surgical interventions, which are characterized by small

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incisions, minimal blood loss, and early hospital discharge. In most cases, a simple laminotomy and diskectomy can be performed in about 1 hour on an outpatient basis, with negligible anesthetic risk. In fact, more recent data[16] show the postoperative convalescence after a modern uncomplicated limited diskectomy may be only a few weeks compared with a few months in the study by Weber. In contrast to spinal fusion surgery for discogenic pain, observational studies of modern laminotomy and limited diskectomy for disk herniation have frequently shown rapid pain relief and functional improvement in 70% or more of patients.[16,17]

Similarly, the relatively passive approach with expectant care used in the study by Weber[15] may seem overly cautious today. Modern aggressive rehabilitative techniques also may be more effective, with observational studies showing frequent and relatively full recovery over 4 to 6 months despite severe sciatica.[18] Comparing modern techniques, a recent but relatively small (N=56) RCT that included patients with between 6 and 12 weeks of sciatica and disk herniation but only moderate sciatica severity (mean Oswestry Disability Index, 39), more rapid improvement in leg pain and disability occurred during the first 6 to 12 weeks in the surgery group, with these effects diminishing over time.[19] Similarly, in an RCT involving 169 patients, Butterman[17] reported better short-term (up to 6 months after surgery) outcomes with surgical treatment of disk herniation compared with epidural steroid injection. In these RCTs, the differences in outcomes between the surgical and nonsurgical groups becomes much smaller and is possibly negligible with 2 or more years of follow-up.[15,17,19]

In this issue of *JAMA*, the results of 2 studies[20,21] from the Spine Patient Outcomes Research Trial (SPORT) on lumbar disk surgery for persistent radicular pain are reported. These include a multicenter RCT of surgical vs nonoperative care (n=501)[18] and a companion observational cohort of patients who declined randomization and selected either surgery or continued nonoperative care (n=743).[19] These 2 studies represent a colossal research effort and provide a fascinating snapshot of both modern patient preferences and clinical outcomes for this common clinical problem.

The SPORT investigation included patients with definitive symptoms, signs, and imaging of disk herniation and sciatica. Patients had experienced at least 6 weeks of radicular pain at the time of enrollment. It is noteworthy, however, that about 20% to 25% of the enrolled patients had a current sciatica episode of more than 6 months. In addition, patients reported a wide range of pain and disability at baseline. In SPORT, surgical candidates were offered enrollment in either the randomized trial or the concurrent observational cohort. Those entering the RCT seem to have been truly ambivalent about what care they preferred. Even in the group randomized to surgery, only 50% had proceeded to surgery 3 months later. Examining which patients elected surgery in either study shows an interesting pattern: these patients were younger, had lower income and educational levels, reported more severe perceived disability and pain, and felt their situation was deteriorating.

The surgery appears to have been well monitored and relatively benign. Less than 5% of the surgery group had any complication, and most adverse events appear to have been minor. Reoperation not associated with another disk herniation was also infrequent (<5%). In the RCT, an intent-to-treat analysis at follow-up revealed only small differences in outcomes at 1 and 2 years. But in a study in which only half of those in the surgery group underwent the procedure 3 months after entry, these finding are difficult to evaluate. Nonetheless, it is clear that both surgical and nonoperative treatment were associated with clinically significant improvements over time and that differences between treatments, as has been shown in previous work, decreased with time.

Several other studies have shown an earlier comparative benefit with surgical treatment,[17,19,22] and this effect also is evident in the SPORT study. The group electing surgery in the observational cohort had an improvement on the Oswestry Disability Index of nearly 40 points (on this scale, the minimal clinically important difference is 10-15 points[23]), from severe disability to nearly normal by 6 weeks after surgery. This degree of improvement is as substantial as that reported for any musculoskeletal intervention. After 1 and 2 years, there were no significant differences in outcome between groups in the RCT, whereas in the observational cohort there were both clinically important and statistically significant differences in self-reported outcome for patients having surgery.

Regardless of the intervention received, most patients seemed satisfied with their care and, given the high crossover rate, most received the intervention they preferred. Previous work has shown that the nature of the disk herniation can predict outcome and response to treatment.[16] Similarly, compensation issues and psychological profiles also influence outcomes and clinical course.[24] But patient preference and necessity may be even more potent guides to clinical care. In that patients' subjective symptoms improved after both surgical and nonoperative interventions, the results of the SPORT trial appear to support the decision-making of many of the study participants. However, it is unclear whether similar improvements would be found if patients had been restricted to their assigned treatment groups. If the main benefit from surgery is that patients perceive a more rapid resolution of disabling pain, the question for patients may be how badly they feel and how urgently they wish to achieve relief in the next 2 to 4 months.

Consequently, whether to choose a surgical approach to sciatica due to disk herniation depends strongly on the individual patient's situation beyond the commonly considered medical and surgical comorbid conditions. For example, for a self-employed carpenter with little cash reserves, for a mother with toddlers and no local resources for help, or for a salesperson working on commission, the apparently slower recovery without surgery (as demonstrated in the SPORT clinical trial and observational cohort) may represent a hardship be-

yond physical pain. While curtailing activity can lessen sciatica if the patient can afford to do so, these individuals may be unable to meet important daily necessities over an extended illness; they may lose their ability to care for family, to earn a living, or to keep a competitive job. The long-term resolution of radicular pain in 1 year's time will be little comfort if socioeconomic losses have seriously disrupted the patient's family, depleted lifelong savings, or led to losing a job. In these circumstances, the surgical option may be very attractive despite the expense of surgery, the documented small risks of complications, or the potential for reoperation. The data from the SPORT study emphasize the reasonable expectations of surgical outcome for disk herniation and sciatica, how accurate the selection of patients can be with modern imaging, and how the fear of a failed back surgery (a very real possibility following fusion for discogenic pain [50%-60%])[9-12] is quite uncommon even in a large multicenter study.

On the other hand, many patients in the SPORT study clearly improved without surgical intervention. These findings suggest that in most cases there is no clear reason to advocate strongly for surgery apart from patient preference. For the patient with emotional, family, and economic resources to handle mild or moderate sciatica, surgery may have little to offer. In fact, this was the profile of many patients who opted against surgery in the SPORT trial: older participants with higher income and higher education but with milder pain and disability. Furthermore, the SPORT data clearly show that the risk of serious problems (neurologic deterioration, cauda equina syndrome, or progression of spinal instability) when receiving nonoperative care is extremely small. The fear of many patients and surgeons that not removing a large disk herniation will likely have catastrophic neurologic consequences is simply not borne out. Thus, these data help both clinicians and patients make better informed decisions based each patient's needs and expectations.

Several important questions remain. The cost-effectiveness of surgery for lumbar disk herniation must be established. A Swedish case-control study suggested favorable cost-utility, but these results need corroboration.[25] The effect of early surgical decompression in the face of severe paresis is poorly understood. In the SPORT study, motor loss was infrequent and no surgery was performed soon after herniation. Common clinical practice is to consider decompression when paresis is functionally disabling, but few data support this approach. Similarly, cauda equina syndrome due to disk herniation causing loss of bowel and bladder function is uncommon and usually is treated surgically, even though strong evidence regarding efficacy or timing is lacking. Technical advances allow less extensive procedures to decompress the nerve roots, and whether these approaches will lead to better outcomes or increase complications is unclear. Similarly, pharmacologic treatment aimed at local inflammatory processes is being investigated. For now, however, the SPORT clinical trial and observational cohort have provided important and timely information regarding the relative advantages of current practice alternatives for patients with radicular pain due to lumbar disk herniation.

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Does Minor Trauma Cause Serious Low Back Illness?

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and Eric Hurwitz, PhD

Study Design. Prospective, 5-year, cohort study of working subjects.

Objectives. To assess whether the occurrence of common minor trauma events affects the risk of developing serious low back pain (LBP) and LBP disability in subjects with and without degenerative changes to the lumbar spine.

Summary of Background Data. Although some theories suggest that minor traumatic events in combination with preexisting degenerative changes commonly cause significant structural injury to spinal segments and serious LBP illness, no prospective data exist on the relationship of minor trauma, detailed structural changes, and outcome measures of serious LBP episodes and occupational disability.

Methods. Two hundred subjects without clinical LBP problems were recruited, and underwent baseline clinical and imaging studies. Every 6 months, subjects completed a scripted, algorithm-based interview assessing interval back pain episodes, severity, medical treatment, occupational disability, and the subject's perceived relation of this LBP episode to any preceding event. If a serious LBP episode clinically required a new magnetic resonance examination, the follow-up imaging was obtained and compared to baseline for interval changes.

Results. There was no association of minor trauma to adverse LBP events. For each 6-month study interval, the risk of developing a serious LBP episode was 2.1% unassociated with minor trauma and 2.4% following minor trauma ($P = 0.59$). Neither the frequency of minor trauma events nor the reported severity of the event correlated with adverse outcomes. Subjects with advanced structural findings were not more likely to become symptomatic with minor trauma events than with spontaneously evolving LBP episodes. Follow-up magnetic resonance imaging evaluating new serious LBP illness rarely revealed new clinically significant findings. Age and sex-adjusted prediction models, including abnormal psychometric testing, smoking, and compensation issues, accurately identified 80% of serious LBP events and 93% of LBP disability events.

Conclusions. In this study cohort, minor trauma does not appear to increase the risk of serious LBP episodes or disability. The vast majority of incident-adverse LBP events may be predicted not by structural findings or minor trauma but by a small set of demographic and behavioral variables.

Key words: low back pain, psychological factors, disability, psychosocial, minor trauma, compensation, depression, chronic pain. **Spine 2006;31:2942–2949**

Through most of the history of western medicine, common low back problems have been regarded as more or less spontaneous events or rheumatic conditions, quite apart from traumatic injuries.[1] In fact, modern clinical and population studies of subjects developing serious low back pain (LBP) illness demonstrate significant genetic,[2–4] psychological, and social predisposing factors,[5–8] and a high degree of comorbidity[9,10] with other nonspinal chronic pain conditions (range 60% to 70%) and mental disorders (35%).[11] Despite these historical and modern observations, a strongly held opinion has gained currency in the last century that "low back injury" commonly occurs in the absence of clear boney or ligamentous injury.[1,12,13] This opinion holds that minor trauma, while unlikely to injure a normal spinal segment, does cause serious structural injury to already degenerative components. The purported vulnerable structural component in this scenario is usually the degenerative intervertebral disc.[1,12,13]

It is difficult to examine scientifically the proposition that minor traumatic events in combination with preexisting degenerative changes are materially causative of serious persistent LBP troubles. While benign and transient LBP episodes are common, serious LBP events with major medical or occupational impact are less so. Because the significant outcome is uncommon in the general population, large cohort studies and long follow-up periods are required to detect sufficient events for appropriate analysis in unselected subjects. Detailed imaging of the lumbar spine of a large cohort documenting the "preinjury" structural state would also be needed; and, to test this hypothesis, a "postinjury" magnetic resonance imaging (MRI) when serious LBP illness develops would be necessary.[14] A study design would also require detailed close-interval assessment of all minor trauma events occurring in the cohort over time. To date, this close monitoring of a well-defined cohort after detailed baseline structural assessment had not been performed.

In this study, we have recruited a medium-sized (200 subjects) cohort of working persons, without any history of serious LBP problems but with both an increased risk at baseline of spinal degenerative disease and comorbid factors (neurophysiological and psychosocial) predisposing to the development of chronic disabling LBP problems. This cohort was examined in detail at baseline, lumbar degeneration documented by radiograph

and MRI, and then followed for 5 years with detailed interval histories of LBP episodes and minor trauma events taken every 6 months. New MRIs of the lumbar spine were examined in subjects developing persistent clinical LBP and compared to baseline studies. The risk of developing LBP with and without interval minor trauma, and with and without preexisting degenerative findings could be assessed and analyzed with predictive models.

Our intention was that by recruiting this relatively high-risk cohort, we would more closely simulate the subset from the general population with comorbid chronic nonlumbar pain and psychological profiles, as identified by Von Korff,[11] Burton,[10] and Pincus[7] et al, who develop serious LBP illness. In this high-risk cohort, we could reasonably expect to observe sufficient serious events over a 5-year follow-up period to discern the relative effects of minor trauma, lumbar degenerative findings, and other risk factors on the subsequent development of serious LBP episode and disability.

■ Methods

Study Design. This study was a prospective cohort designed to investigate the effect of minor trauma episodes on the subsequent development of LBP episodes in working subjects with an increased risk of developing LBP troubles.

All recruited subjects had known risk factors for degenerative lumbar disc disease, but no history of clinical LBP episodes. In addition, the subject recruitment strategy was to recruit 50% of subjects with a history of chronic nonlumbar pain, as this group is known to have a high incidences of both psychological distress and presumed increased neurophysiological effects of chronic pain.

All subjects were to be examined for structural pathology of the spine by physical examination, plain radiography, and MRI of the lumbar spine. Outcome measures were serious LBP episodes and occupational disability.

Primary Hypothesis. Minor trauma is an independent risk factor of subsequent disabling LBP episodes among persons without LBP histories but with known risk factors for degenerative disc disease.

A secondary hypothesis was considered that the effects of psychological and structural factors are not independent risk factors of subsequent disabling LBP.

Subject Recruitment. Consecutive patients seen for cervical disc disease at the Stanford University Hospital were assessed for concurrent LBP symptoms as part of a study of cervical disc herniations.[15–17] As described in previous publications, patients were screened, and subjects without low back symptoms or those who described LBP symptoms as mild and not associated with any functional loss or medical treatment, were recruited. For this cohort, only working subjects were recruited, excluding some subjects in the original group who were occupationally disabled at baseline, to complete the full cohort of 200 subjects. In addition, the International Association for the Study of Pain definition was used to identify potential subjects who had any chronic nonlumbar pain syndrome (e.g., chronic cervical pain syndrome, any chronic regional pain syndrome). A stratification ratio of 1:1 was used to recruit subjects with

and without chronic nonlumbar pain, on a consecutive case basis (i.e., 1 subject with chronic pain [nonlumbar] was selected for admission to the study for each "pain free" subject admitted). It should be reiterated, as stated above, that this group had successfully completed 2 stages of the previous cervical spine study, and would be predicted to have a higher follow-up rate and protocol compliance than a nonselected cohort.

Approval was obtained from the institutional review board and the Administrative Panel of Human Subjects in Medical Research according to U.S. Department of Health and Human Services regulations at Stanford University School of Medicine. Informed consent according to University and U.S. Department of Health and Human Services guidelines was obtained from all prospective participants at the time of the original screening.

Potential subjects were excluded by the following criteria: structural spinal abnormalities (spondylolisthesis, scoliosis, Scheuermann kyphosis, compression fracture, etc.) found on screening; subjects unable to undergo MRI scanning because of ferromagnetic implants, severe claustrophobia, or inability to tolerate positioning for either MRI; or not working more than 20 hours/week at the time of screening.

Screening for Previous Low Back Problems. A screening questionnaire and the Oswestry Disability Index (ODI) for previous or current low back troubles were administered 6–9 months before the subsequent questionnaires in the present study. Patients were asked to evaluate the severity of any LBP using numerical rating scales for "maximum" and "usual" 0–10 pain over the last week. All subjects were confirmed to have reported being either asymptomatic or minimally symptomatic (<2/10) for all LBP history for screening complaints for at least 2 years before the study. A repeat screening for LBP problems was conducted again before the study start date and has been previously described.[15–17] For all subjects, they must have indicated never having sought medical attention for LBP troubles, never having restricted occupational or recreational activities due to LBP problems, a numerical rating scale score <2/10, and an ODI score of 15 or less on 2 repeated tests: 1 administered 6–9 months before and another within 2 weeks before the study start date.

Baseline Physical Examination and Imaging. A physical examination was performed, documenting low back range of motion, the presence of any deformity or tenderness of the thoracolumbar spine, lower extremity neurologic examination, and sciatic and femoral root tension signs. All subjects meeting the entry criteria above were examined with plain radiographs and a lumbar spine MRI. Details of the MRI protocol have been previously described. Examiners blind to the clinical and demographic data graded degree of disc degeneration, anular disruption, and endplate status, and followed previous reports methodology.[9,18–20] When there was no agreement, a third examiner read the film in question, and a modal score was used. There was agreement on disc degeneration grade in 81% of first 2 readings, 72% of high intensity zone/anular disruption, 77% of endplate changes, and 79% disc herniations readings. In the event of a disagreement, the third reader agreed with one of the primary readers in all occurrences of disagreement. Canal stenosis was graded mild to severe by subjective assessment and included all causes of stenosis (congenital, spondylotic, or associated with disc pathology). Canal stenosis was arbitrarily graded moderate (touching or displacing nerves) or severe

(compressing and distorting nerve). As previously described, baseline imaging of these asymptomatic or minimally symptomatic volunteers were graded in a mixed batch with MRI of 42 clinically symptomatic control subjects undergoing routine radiographic evaluation in the Orthopedic Spine Clinic. Clinical control subjects with spinal deformity were excluded.

Standardized Questionnaires

Pain Intensity. Numerical rating scale scores of LBP intensity were scored on a 10 cm, 11-point scale, with instructions indicating 0 as "no LB pain" and 10 as the "worst imaginable pain."

Functional Assessment. Modified Oswestry Low Back Disability Questionnaire (ODI) was completed as a measure of subjective functional assessment. The ODI contains 10 items, each scored from 0 to 5, and the final score is expressed as a percent score (range 0–100). A higher percent indicates a greater amount of disability.[21]

Psychometric Studies. A Modified Zung Depression Test and Modified Somatic Pain Questionnaire were administered to each subject. From these measures, a classification of subject indicating psychological distress was made according to Main et al.[22]

Follow-up Interval Assessment. Subjects were contacted every 6 months after baseline measures were complete. Independent research assistants (T.V.T., G.N., and B.Y.) who were blinded to patient baseline data and were not involved in the study design conducted a scripted telephone interview. The interview was conducted by telephone, including an interval medical history, interval lumbar imaging studies history, occupational history, medication usage, and accident or injury history. Subjects were asked specifically about "Major Injuries" (defined as LBP episodes associated with high-energy trauma resulting in serious visceral injury, proximal long bone, or pelvic or spinal fracture or dislocation) and "Minor Injuries to the Low Back" (defined as any perceived injury to the low back area with a back pain intensity >2/10 for at least 48 hours but not meeting the major injury definition and with specific instructions that this included such minor episodes as "injuries" occurring during lifting, sports, road traffic accidents, or slipping or minor falls.)

If a minor trauma was reported, an interview algorithm was used to describe the nature of the incident, including: mechanism (lifting, fall, road traffic accident, sports injury, others); severity of the incident (weight lifted, awkwardness of lifting/twisting, height of fall, speed of traffic collision); associated injuries; perception of fault if a traffic accident; whether reported as a work injury; and whether a civil claim had been made.

Follow-up Imaging. Subjects reporting interval lumbar imaging with MR were identified, those images retrieved, saved on optical discs, and the images were reviewed at the conclusion of the study. These follow-up examinations were graded in the same manner as the original MRIs. The graders were blinded to both interval and baseline data. The new "symptomatic" MRIs were mixed, 1 (new interval study) to 2 (controls), with MRIs from both "asymptomatic" studies and clinically symptomatic control subjects. Not all interval symptomatic subjects were imaged at our facility (i.e., some subjects had new "outside" MRI films). For this reason, "outside" films from new control subjects were added to the film review batch so that examiners

at the final review would not be unblinded by the presence of "nonuniversity radiology" films as indicating new interval symptomatic examinations.

Outcomes Data. Primary outcomes measures were: (1) "serious back pain episodes" with a pain intensity defined by a numerical rating scale ≥6 for at least 1 week, and (2) disability from usual occupation due to LBP troubles. Secondary outcome measures were: (1) disability duration ≤1 month; (2) disability duration >1 month; (3) medical visits primarily for LBP evaluation and treatment, including chiropractor, physiotherapy, and interventional injection treatment, and surgical intervention; and (4) MRI changes in subjects with serious LBP events or disability when required in the course of medical assessment.

Statistical Methods. Descriptive statistics were used to summarize patient sociodemographic and MRI characteristics measured at baseline, and adverse LBP events reported during follow-up. Means, standard deviations, and medians were calculated for continuous variables; frequency distributions were generated for categorical variables. Incidence rates of LBP events according to trauma status (no trauma, minor trauma, major trauma) were computed for the 5-year follow-up period. Estimated effects of baseline structural findings on subsequent LBP were adjusted for age and sex. Logistic regression was used to estimate the effects of: (1): minor trauma versus no minor trauma and (2) possible clinical/structural predictors of adverse LBP events. In addition to the presence or absence of minor trauma and age and sex, initial prediction models also included as covariates chronic non-LBP, previous compensation dispute, current smoking status, psychometric variables, disc degeneration grade, presence of anular disruption, canal stenosis, and moderate or severe endplate changes. Variables representing the joint (combined) effects of chronic non-LBP, current smoking, and abnormal psychological findings were included in the final prediction models. The logistic model results were used to estimate odds ratios (ORs) and 95% confidence limits. The StatView statistical program (SAS Institute Inc., Cary, NC) was used for all analyses.

Power Analysis. Current literature indicates that subjects with the selected risk factors have approximately 2% to 4% per year risk of LBP disability and 20% risk of a lesser LBP episode.[5,20,23–25] The risk of minor trauma as described in the literature indicates 20% to 40% risk of minor trauma episodes per year.[5] Statistical effects demonstrated in these reports indicate that a moderate effect (for minor disabling episodes) and a strong effect (for nondisabling LBP events) of minor trauma would be detected with 500 person-years of observation, assuming 80% power and alpha = 0.05. A conservative study design, therefore, required the recruitment of 200 subjects with a targeted 5-year follow-up (1000 man-years of observation) measured at twice-yearly intervals (2000 interval observations).

■ Results

The characteristics of subjects at baseline are given in Table 1. Chronic nonlumbar pain was strongly associated with abnormal psychometric scores, smoking, and previously disputed compensation claims.

Five-year follow-up was completed in all subjects. There were 23 missed interval observations (1.2%). One

Table 1. Distributions of Baseline Characteristics of Subjects, by Nonlumbar Pain Status

	All Subjects	Chronic Nonlumbar Pain	No Pain	P
No.	200	100	100	
Age (ys)	39.4	38.2	40.8	0.34
Males	59.5%	62	57	0.45
Baseline ODI	5.5	5.9	5.0	0.10
Normal DRAM	100	29	71	<0.0001
Previous disputed compensation claim	23	21	2	<0.0001
Smoking	27.5%	44	11	<0.0001
Heavy work	28.0%	25	31	0.34
DDD grades 3–5	76.5%	72	81	0.13
Anular fissure (HIZ)	19.5%	19	20	0.86
Endplate changes (moderate-severe)	21.5%	18	25	0.23
Spinal stenosis (moderate-severe)	13%	11	15	0.40

DDD indicates degenerative disc disease; HIZ, high intensity zone.

subject completed the final interview 3 months before the 60-month mark. Four subjects completed the final interview more than 30 days beyond the 5-year end point (63, 66, 67, and 67 months, respectively).

Major Trauma

There were 16 major trauma events in 16 subjects: 8 of these (50%) were associated with LBP ≥6/10 for at least 1 week. Four of 16 subjects had short-term occupational disability associated at least in part with back pain. For a 6-month interval, the OR of a serious LBP episode associated with major trauma was 4.53 (95% confidence interval [CI] 1.51–13.57; P = 0.0004) compared to subjects having an episode of minor trauma and 4.84 (95% CI = 1.64–14.33; P = 0.0003) compared to those reporting no trauma event of any kind.

Minor Trauma and Adverse Events

There were 118 minor trauma events with a LBP intensity report of ≥6/10 for at least 1 week (serious LBP episode) and 652 minor trauma events with a LBP intensity report of >2/10 for 48 hours. As expected, serious LBP events were more commonly reported in the chronic pain (77 events) group than those in the pain-free group (41 events) (OR = 4.81; 95% CI 2.6–8.8), as were disability events after minor trauma (4 events in the chronic pain cohort vs. 12; OR = 4.57; 95% CI 1.5–14.2).

The incidence of minor trauma with LBP events was 0.62 events per person-year, and minor trauma with serious LBP episodes was 0.12 events per person-year. The range of minor trauma events ranged from 0 to 18 over 5 years: the distribution of LBP episodes and outcomes are given in Table 2. There was no association of minor trauma to adverse LBP events. The proportion of subjects experiencing a serious LBP event was not higher with 1 or more minor trauma events (range 2.8% to 4.9%/y) compared to none (6.0%/y). There was also no appreciable trend toward more adverse events in subjects reporting a greater number (≥5) of minor trauma events.

Table 2. Frequency Distribution of Minor Trauma Events

No. Events in 5-y Period	No. Subjects (%)	LBP ≥6/10 Events (any)	LBP ≥6/10 Events With Minor Trauma	Medical Care for Event	Disability
0	30 (15)	58	0	14	9
1	24 (12)	55	19	12	7
2	36 (18)	49	26	9	5
3	43 (21.5)	53	29	11	7
4	36 (18)	57	25	15	9
≥5	31 (15.5)	51	19	12	7

Type and Severity of Minor Trauma and Adverse Outcomes

There were 126 falls, 122 road traffic accidents, 193 sports injuries, 196 lifting injuries, and 15 miscellaneous minor trauma events. The serious LBP events, number receiving medical attention, and disability episodes with the minor-trauma types are given in Table 3.

The relative severity of minor trauma was classified for motor vehicle accidents (speed of reported collision), falls (distance fallen), and lifting injury (weight involved).

For subjects reporting the cause of the motor vehicle accident was their own fault, or no one's fault (n = 96), there were 2 (2.1%) episodes (at relatively high speeds, 30 and 35 mph) of serious LBP and no disability. In 26 subjects claiming back pain when they perceived others at fault for the collision, 5 (19%) reported serious LBP events. Of these, 1 was reported at over 30 mph, 4 were less than 20 mph, and 2 less than 10 mph. The risk of serious LBP was significantly greater when the subject perceived others at fault for the incident (P = 0.001), and serious LBP events were more likely at low speed (<20 mph) when others were perceived as responsible for the accident (P = 0.001).

For LBP with minor trauma reported after falls (n = 126), there were 30 serious LBP events (4 with occupational or personal injury claims and 26 without). Compensation issues was associated with risk of reporting a serious injury with smaller falling distance. All 4 falls associated with compensation issues were for falls from standing or less than 3 feet. Of the 26 serious LBP events after a fall but not associated with a compensation claim, 6 were with a reported fall of <3 feet and 20 >3 ft (P = 0.01). There was 1 long-term disability claim, in the compensation group.

Table 3. Frequency Distribution of Minor Trauma-Type and Adverse LBP Events (n = 625)

	LBP >2/10 for 48 Hours (%)	LBP ≥6 for 1 Week (%)	Medical Attention	Disability
Falls	126 (20.2)	30 (25.4)	4	1
Road traffic accident	122 (19.5)	20 (17.0)	15	3
Sports/exercise	193 (30.1)	31 (26.3)	4	2
Lifting	196 (31.6)	34 (28.8)	10	10
Other	15 (2.4)	3 (2.5)	0	0
Total	625 (100)	118 (100)	33	16

Table 4. Frequency Distribution of Lifting Events Associated With LBP Episodes

Weight Involved (lb)	Any LBP Episode* After Lifting		Serious LBP Episode† After Lifting	
	Total (%)	Occupation/PI	Total (%)	Occupation/PI
<30	33 (16.8)	20	6 (17.6)	4
30 to <60	28 (14.3)	10	7 (20.6)	4
60 to <90	76 (38.8)	7	13 (38.2)	1
≥90	59 (30.1)	2	8 (23.5)	0

*LBP >2/10 intensity × 48° after the event.
†LBP >6/10 intensity × 1 week after event.
PI indicates personal injury claim.

Lifting events were the most common associated event with new LBP episodes related to minor trauma (196 total events, 0.20 events per person-year) and disability. Most LBP events after lifting occurred when relatively heavy weights were involved (>60 lb, >27.3 kg). Of the 196 events, 39 resulted in workers' compensation claims or personal injury claims. Most events, 178 of 196 (91%) were reported to be associated with lifting in an awkward position (33/39 WC/PI claims, 85%; 145/157 noncompensation events, 92%; $P = 0.76$). The distribution of LBP events and serious LBP episodes for different weight ranges is given in Table 4. Of 61 events with weights involving <60 lb, 30 (49.2%) involved compensation issues; of 135 involved with weights lifted ≥60 lb, 9 (6.7%) involved compensation issues ($P < 0.0001$). Similarly, serious LBP episodes after lifting were reported in 34 subjects. Of these, 13 events involved weights <60 lb (8 of 13 [61.5%] with compensation issues) and 21 with weights ≥60 lb (1 [4.8%] with compensation issues) ($P = 0.04$). There were 10 subjects with disability after a lifting event with LBP (5.1%), 6 with weights <60 lb (all with compensation issues), and 4 with weights ≥60 lb (none with compensation issues).

Adverse Events Reported Without Minor Trauma

There were 228 events of serious LBP lasting 1 or more weeks, which were unassociated with any preceding major or minor traumatic event. Of these, 102 were associated with routine activities of daily living, and 126 had no association whatsoever. These events resulted in short-term work loss (≤1 month) in 18 cases and long-term disability in 12 patients. For each 6-month study interval, the risk of developing a serious LBP episode was 2.1% unassociated with minor trauma and 2.4% following minor trauma ($P = 0.59$). The risk of disability when an LBP event arose with or without a preceding minor trauma event was not different. For a serious LBP episode associated with minor trauma, there was a 15.7% risk of disability that was similar to the risk (15.2%) of disability unassociated with trauma ($P = 0.62$).

Baseline Structural Findings and Adverse Events

Serious LBP events were not significantly more common in subjects with disc degeneration or anular fissures, whether the subjects had minor trauma or not (Table 5).

Table 5. Estimated Age and Sex-Adjusted Effects (OR; 95% CIs) of Baseline Structural Findings on Subsequent Serious LBP, by Trauma Status

	Severe LBP Event	
	Minor Trauma (n = 118) OR (95% CI)	No Trauma (n = 228) OR (95% CI)
DDD (grades 3, 4, 5)	1.28 (0.69–2.20)	1.33 (0.79–2.40)
Anular fissure/HIZ	0.98 (0.45–1.52)	1.00 (0.56–1.64)
Disc protrusion	1.29 (0.70–2.37)	1.47 (0.54–4.22)
Endplate changes (moderate-severe)	2.42 (0.85–5.95)	2.66 (0.75–5.99)
Canal stenosis (moderate-severe)	2.94 (0.72–7.76)	2.86 (0.84–7.96)

LBP >6/10 intensity × 1 week after event.
DDD indicates degenerative disc disease; HIZ, high intensity zone.

Similarly, there were 10 of 47 (21%) subjects with no degeneration who had a disability event, whereas 34 of 153 (22%) with disc degeneration had disability events. There was a trend toward more serious LBP events in subjects with grade 5 disc degeneration (with collapse) (OR 4.40; $P = 0.08$).

Moderate-to-severe endplate changes (OR = 2.5; $P = 0.1$) and canal stenosis (OR = 2.9; $P = 0.09$) were weakly associated with serious LBP episodes. These events did not appear to be more common after minor trauma in subjects with these findings than when arising spontaneously. (Table 4). There was no increased disability in subjects with endplate changes compared to those without. There were 9 disability episodes in 26 subjects with moderate-to-severe stenosis at baseline (34.6%), compared to 35 disability episodes in 174 subjects without stenosis (20.1%), indicating a trend in the presence of canal stenosis (OR 1.70; $P = 0.11$).

Prediction Model

Chronic nonlumbar pain, smoking, and abnormal psychological findings were found in preliminary analysis to be highly correlated with each other and adverse LBP outcomes. Consequently, variables representing their joint (combined) effects were created and included in the final prediction models. Adjusting for age and sex, an abnormal psychometric profile and smoking correctly identified 72 of 118 (61%) serious LBP events (OR = 3.97; 95% CI 2.19–7.22; $P = 0.004$). Adding a history of disputed compensation claim correctly identified 94 of 118 (80%) of the serious LBP event (OR = 10.6; 95% CI 5.50–20.68). Disability was predicted by an abnormal psychological profile and previously disputed compensation claim, correctly identifying 41 of 44 (93%) disability events (OR = 8.34; 95% CI 4.31–16.16; $P < 0.0001$). Prediction was not improved by adding minor trauma to the models.

Analyzing the pain-free cohort independently, again adjusting for age and sex, subjects with normal psychometric testing and no history of a disputed compensation claim were highly unlikely to have either: a serious LBP

Table 6. Interval New or Progressive Magnetic Resonance Imaging Findings in Subject With and Without Minor Trauma

Interval Change	Minor Trauma (n = 38)	No Minor Trauma (n = 29)
No. new disc protrusions	1	1
No. new disc extrusions	0	1
No. new spondylolisthesis	0	1
No. advanced DDD grade 1	2	2
No. advanced DDD grade 2	1	1
No. endplate changes (mild to >moderate)	1	1
No. advance stenosis grades	0	1

DDD indicates degenerative disc disease.

event after minor trauma (OR = 0.26; 95% CI 0.06–0.49; $P = 0.02$); a serious LBP without any trauma (OR = 0.30; 95% CI 0.10–0.90; $P = 0.04$); or disability after minor trauma (OR = 0.014; 95% CI 0.04–0.97; $P = 0.05$). In this group (*i.e.*, subjects with no comorbid pain issues, normal psychometric findings, and no history of disputed compensation issues), moderate-to-severe endplate changes and canal stenosis effects became significant in predicting serious LBP events (OR 2.88; 955 CI 1.06–5.67).

Progression of Structural Findings

There were 69 new lumbar MRIs performed in 53 subjects for evaluation of clinical LBP episodes. Two scans could not be retrieved from an outside facility, and 67 MRI were reviewed after the final 5-year interval. Sixteen subjects had 2 follow-up studies. None of the subjects with 2 follow-up studies had new, progressive findings or additional findings noted on the second scan. Eight of the 67 scans (11.9%) showed progression of previous findings (9) or new findings (4) (Table 6).

Of the 21 subjects with disability lasting more than 1 month, there were only 3 (14%) new findings: 1 subject had a new spondylolisthesis, progression of endplate changes and advanced stenosis; 1 had an extruded disc herniation with root compression; and 1 subject had an advance of 1 grade of degenerative disc disease scoring (grade 3–4). Subjects with compensation claims (n = 46) were more likely to have a MRI after a minor trauma (30 of 38 scans); 28 (93%) of those scans in compensation cases showed no new or progressive findings. The most clinically important findings (new disc extrusion, new spondylolisthesis, and progression to severe stenosis) both occurred without preceding minor trauma, and both were not associated with compensation claims.

■ Discussion

The association of LBP with major trauma, infection, and neoplasm is well documented. Similarly, the association of benign LBP events with certain activities such as heavy labor or the start of conditioning training in military recruits is well recognized. The association of serious LBP illness and disability with minor trauma events is more controversial.[1] The rise of the concept of serious back "injury" resulting from relatively low-force events in persons with degenerative changes has attained popularity, but whether the "minor trauma" itself had much to do with either long-term serious effects or new structural damage has not been validated.

In the absence of major trauma or serious structural disease (tumor, infection, gross instability), chronic LBP has been shown in previous studies to be correlated with psychosocial issues, and a high comorbidity of other chronic pain processes and mental health issues.[5,6,8,10,26–28] Attempts to correlate structural changes in the spine by MRI with serious LBP illness is difficult because of the high prevalence of common degenerative findings in healthy subjects.[18,19,29] Studies following healthy subjects with baseline MRI changes for new LBP events have failed to show a strong effect. Following 131 veterans after MRI, Jarvik *et al*[14] found depression was an important predictor of new LBP and saw only infrequent new MRI findings. Similarly, following 46 asymptomatic subjects after MRI, Boos *et al*[9] found psychological aspects of work and other nonstructural variables to predict most strongly work incapacity due to LBP events. Neither of these studies examined the relation of new LBP events to specific injury.

The attribution of serious LBP illness to minor trauma events is commonly made in medical-legal arenas. Much of the evidence debated in these forums compares biomechanical modeling and prediction of structural injury, on the one hand, *versus* the epidemiological determined predictors of serious LBP illness on the other. To our knowledge, no study has prospectively assessed the incidence of minor trauma events associated with LBP in a large cohort with defined baseline MRI and clinical variables over an extended period.

In the 5-year observation of this study's cohort of 200 subjects, minor short-lived backache associated with minor trauma was very common, and these appeared most commonly when lifting in an awkward manner or with sports or exercise activities. However, serious LBP episodes were most frequently seen arising spontaneously or with usual daily activities rather than involving trauma of any sort. Furthermore, contrary to the popular paradigm that minor trauma events commonly lead to serious LBP episodes because of preexisting degenerative conditions, the data here show that baseline disc degeneration, disc protrusion, and anular disruption did not significantly increase the risk of serious LBP events with any type of minor trauma. Even the minor trauma events causing LBP involving relatively greater forces (traffic accidents at greater than 30 mph, falls from heights >3 ft, or lifting injury with awkward posture and greater than 60 lb) resulted in work loss in less than 3% of 169 episodes. It is interesting that traumatic episodes associated with the least relative forces described were highly correlated with compensation claims or the perception of others being at fault for an accident.

As in previous studies cited, prediction of serious LBP episodes and disability, when adjusted for age and sex, was strongly predicted by baseline measures of psychological distress, smoking, and a history of disputed compensation. There were nonsignificant trends between baseline MRI findings (moderate-severe canal stenosis, moderate-severe endplate changes, and severe loss of disc height) and adverse outcomes. This effect was best demonstrated in subjects with no chronic pain or psychosocial comorbidities.

It is also interesting that despite concern for new structural pathology in subjects who became seriously symptomatic, MRI looking for new pathology was rarely clinically helpful. Follow-up MRI evaluating new serious LBP illness did not reveal any new structural changes in 61 of 67 examinations (88%). Only 2 subjects had new clinically relevant findings (3%). In the absence of the baseline examinations, it is likely, in our opinion, that many of the preexisting benign findings would have been considered to be causative of the recent LBP episode. This is the first study to survey systematically these follow-up examinations taken soon after new LBP episodes and compare these to baseline imaging. These findings are consistent with the recent work and prediction of Jarvik et al.[14]

. This study has certain design limitations. A select sample was used instead of a full population or random sampling of a large population. The cohort was composed only of subjects who had also successfully completed a prior cervical spine protocol, and this selection apparently provided a more stable clinical population for follow-up and protocol compliance. The inclusion of 50% subjects with chronic pain issues, while simulating the chronic back pain population in psychosocial comorbidities, may also have diluted the effect of structural findings. While this strategy may have increased the relevance of the findings to subjects at high risk for serious LBP illness, the design concomitantly limits to generalizability to the general (low risk) population. In addition, the study of 200 subjects, even for a 5-year period, will have a limited power to detect and poor precision for estimating small effects (e.g., effects of uncommon structural findings). Finally, the predictive models used need to be replicated and validated in subsequent cohorts.

There is potential confounding by unmeasured factors (i.e., work life, job satisfaction, factors predictive of incident LBP that may be associated with trauma). In this study, the minor trauma events could not be independently measured for forces applied and other parameters, which may be quantified in the laboratory. While there was no clear trend toward more severe symptoms with the gross estimates of minor trauma severity used in our analysis, there are likely certain spinal loading events within our definition of minor trauma that can be expected to cause clinically relevant structural failure. The results of this study would suggest that these events are relatively uncommon.

The strengths of this study include a relatively large sample size of subjects with MRI, uniform LBP histories, careful baseline examinations, and close interval follow-up. Although there were some missed interval evaluations, no subjects were lost to follow-up for more than 1 data set, and there was 100% completion of the study at 5 years. Validated outcome measures were used. Nearly all (98%) follow-up MRIs performed to evaluate clinical LBP problems were retrieved and compared to baseline studies in a blinded fashion. In addition, the sampling strategy succeeding in recruiting a study cohort with a wide range of significant degenerative changes as well as a diverse mix of psychometric profiles. This mixture of normal (about 25%) to severe (about 25%) MRI findings would not have been possible in a population sample of this age group, which would have had much milder degeneration. Similarly, the spectrum subjects with other pain issues (50%) and psychological distress (50%) provided an excellent diversity in the sample. This diversity of dependent variables was important to allow the statistical analysis of possible effects. Nonetheless, a large population sample followed with a similar protocol may have detected variables with smaller effect sizes not noted in this study.

Despite the methodological constraints above, this study is the first to address the issue of minor trauma and adverse LBP events prospectively in the context of disc degeneration and psychosocial comorbidities. While the popular perception exists that minor loading events may commonly "harm" the spine, our data suggest this is rare, and most persons experience these minor events commonly and have excellent resilience. Conversely, chronic pain, emotional issues, and the perception of fault and entitlement appear to affect adversely symptoms, despite this native structural resilience. We are continuing to follow this cohort for the long-term evolution of LBP and spinal degenerative findings. Ongoing imaging and clinical surveys will hopefully increase our understanding of the natural history of LBP in this clinically important subgroup of at-risk individuals.

■ Conclusions

Among persons with known risk factors for degenerative lumbar disc disease but with no history of serious LBP, minor trauma did not appear to increase the risk of serious LBP episodes or disability. MRI after serious LBP episodes and minor trauma rarely demonstrated significant new findings. The vast majority of incident-adverse LBP events may be predicted not by structural findings or minor trauma but by a small set of demographic and behavioral variables.

■ Key Points

- Among persons with known risk factors for degenerative lumbar disc disease but with no history of serious LBP, minor trauma does not appear to increase the risk of serious LBP episodes or disability.
- MRI after serious LBP episodes and minor trauma rarely demonstrated significant new findings.

> • The vast majority of incident-adverse LBP events may be predicted not by structural findings or minor trauma but by a small set of demographic and behavioral variables.

Acknowledgments

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Lumbar Spinal Fusion

Number   7.01.542
Effective Date April 14, 2015
Revision Date(s) 04/14/15; 01/13/15; 07/14/14; 04/08/13; 10/09/12; 09/11/12; 03/11/11
Replaces   7.01.141 (not adopted)

Policy

[TOP]

Lumbar spinal fusion may be considered **medically necessary** for any one of the following conditions:

1. Spinal stenosis with both of the following:
    a. Any one of the following
        1. Associated spondylolisthesis demonstrated on plain x-rays OR spinal instability demonstrated with 4 mm in the sagittal plane measured on functional flexion/extension films; OR
        2. Spinal instability is anticipated due to need for bilateral or wide decompression with facetectomy or resection of pars interarticularis; imaging studies must document encroachment on the nerve root channel (neural foramen); AND
    b. Either of the following:
        1. Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 month of conservative care and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging, OR
        2. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
2. Severe, progressive idiopathic scoliosis with either of the following:
    a. Cobb angle greater than 40 degrees
    b. Spinal cord compression with neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 month of conservative care
3. Severe degenerative scoliosis (i.e., lumbar or thoracolumbar) with a minimum Cobb angle of 30 degrees, or significant sagittal imbalance (e.g., sagittal vertical axis > 5 cm), and with any one of the following:
    a. Documented progression of deformity with persistent axial (nonradiating) pain and impairment or loss of function unresponsive to at least 1 year of conservative therapy
    b. Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 1 year of conservative nonsurgical care
    c. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
4. Isthmic spondylolisthesis, when all of the following are present:
    a. Congenital (Wiltse type I) or acquired pars defect (Wiltse II), documented on x-ray, and:
    b. Persistent back pain (with or without neurogenic symptoms), with impairment or loss of function
    c. Either unresponsive to at least 3 months of conservative nonsurgical care or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
5. Recurrent, same level, disc herniation, at least 3 months after previous disc surgery, when all of the following are present:
    a. Recurrent neurogenic symptoms (radicular pain or claudication) or evidence of nerve-root

irritation, as demonstrated by a positive nerve-root tension sign or positive femoral tension sign or a corresponding neurologic deficit
   b. Impairment or loss of function
   c. Unresponsive to at least 3 months of conservative nonsurgical care or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
   d. Neural structure compression or instability documented by imaging at a level and side corresponding to the clinical symptoms
6. Pseudarthrosis, documented radiologically, when all of the following are present:
   a. No less than 6 months after initial fusion with persistent axial back pain, with or without neurogenic symptoms, or with severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
   b. Impairment or loss of function, in a patient who had experienced significant interval relief of prior symptoms
7. Instability due to fracture, dislocation, infection, abscess, or tumor when extensive surgery is required that could create an unstable spine
8. Iatrogenic or degenerative flatback syndrome with significant sagittal imbalance; when fusion is performed with spinal osteotomy or interbody spacers
9. Adjacent level disease when all of the following are present:
   a. Persistent back pain (radicular pain or neurogenic claudication) with impairment or loss of function that is unresponsive to at least 3 months of conservative therapy
   b. Eccentric disc space collapse, spondylolisthesis, acute single level scoliosis, or lateral listhesis on imaging
   c. Symptoms and functional measures correlate with imaging findings
   d. The previous fusion resulted in significant relief for at least 6 months

Lumbar spinal fusion is considered **investigational** if the sole indication is any one of the following conditions:

- Disc herniation
- Chronic nonspecific low back pain without radiculopathy
- Degenerative disc disease
- Initial discectomy/laminectomy for neural structure decompression
- Facet syndrome

Smoking within the previous 6 weeks is a contraindication for lumbar spinal fusion.

Lumbar spinal fusion is considered **not medically necessary** for any indication not addressed above.

Multiple level lumbar spinal fusion is considered **not medically necessary** when the criteria listed above are not met for all levels that will be fused.

Related Policies

7.01.85   Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

7.01.87   Artificial Intervertebral Disc: Lumbar Spine

7.01.130   Axial Lumbosacral Interbody Fusion

7.01.138   Interspinous Fixation (Fusion) Devices

Policy Guidelines

Smoking within the previous 6 weeks is a contraindication for lumbar spinal fusion.

Conservative nonsurgical therapy for the duration specified should include the following:

- Use of prescription strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
- Analgesics should include anti-inflammatory medications with or without adjunctive medications such as nerve membrane stabilizers or muscle relaxants (if not contraindicated) AND
- Participation in at least 6 weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
- Evaluation and appropriate management of associated cognitive, behavioral or addiction issues when present
- Documentation of patient compliance with preceding criteria.

"Severely restricted functional ability" should generally include loss of function and/or documentation of inability or significantly decreased ability to perform normal daily activities of work, school or at-home duties.

Persistent debilitating pain is defined as:

- Significant level of pain on a daily basis defined on a visual analog scale (VAS) as greater than 4; AND
- Pain on a daily basis that has a documented impact on activities of daily living in spite of optimal conservative nonsurgical therapy as outlined above and appropriate for the patient.

The minimal **documents necessary** to accurately and expeditiously complete reviews for spinal fusion are:

- Specific procedures requested with CPT/ICD-9 codes and disc levels indicated
- Office notes, including a current history and physical exam
- Detailed documentation of extent and response to conservative therapy, including outcomes of any procedural interventions, medication use and physical therapy/physiatrist notes
- Documentation of current smoking status, and evidence of 6 weeks of non-smoking status prior to scheduled surgery (unless emergent)
- Most recent radiology reports for MRI`s, CT`s, etc. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, the radiologist report will supersede
- Flexion-extension films for spinal fusion requests based upon instability
- The requesting surgeon should have personally evaluated the individual at least twice before requesting surgery (except in cases of malignancy, trauma, infection or rapidly progressive neurologic symptoms)

Description

Summary

Lumbar spinal fusion (arthrodesis) is a surgical technique that involves fusion of 2 or more lumbar vertebrae using local bone, autologous bone taken from the iliac crest of the patient, allogeneic donor bone, or bone graft substitutes. There are numerous potential indications for lumbar spinal fusion. A number of these indications are controversial, for example when lumbar spinal fusion is performed in combination with discectomy for either herniated discs or degenerative disc disease, or in combination with decompression of the spinal canal for spinal stenosis when there is no suggestion of instability.

The literature was examined on the use of fusion for the following indications:

- Spinal Stenosis with Spinal Instability. Findings from the SPORT trial, in which 95% of patients in the surgical group underwent decompression with fusion, and a smaller study that specifically assessed the addition of fusion to decompression, support that fusion in patients with spinal stenosis associated with spondylolisthesis improves outcomes and therefore may be considered medically necessary for this indication.
- Idiopathic Scoliosis. Long-term follow-up of a large case series and guidelines from the Scoliosis Research Society provide support that fusion can reduce curve progression in patients with curves

greater than 40°. Therefore, lumbar spinal fusion may be considered medically necessary for this population.

- Degenerative Scoliosis. No randomized controlled trials (RCT) were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study found superior outcomes in patients treated with fusion compared with nonoperative controls. Based on this evidence, clinical input, and the strong rationale for its efficacy, spinal fusion may be considered medically necessary for adults with degenerative scoliosis.
- Isthmic Spondylolisthesis. One RCT was identified that compared fusion versus an exercise program in patients with symptomatic isthmic spondylolisthesis. Results of this trial support that fusion may be considered medically necessary for this condition.
- Spinal Fracture. Results of 1 small randomized trial indicate that spinal fusion for patients with spinal fracture without instability or neural compression may result in worse outcomes than nonsurgical management, and therefore spinal fusion is considered not medically necessary for this indication.
- Herniated Discs. Current evidence, which includes the large SPORT RCT, supports surgical treatment with discectomy for lumbar disc herniation. Evidence is insufficient to conclude that the addition of fusion to discectomy improves outcomes in patients with lumbar disc herniation without instability. As a result, lumbar spinal fusion is considered investigational for this indication.
- Nonspecific Chronic Low Back Pain. Meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with nonspecific chronic low back pain (CLBP) that is unresponsive to conservative management. While some trials have reported a benefit, others have not. Due to the uncertainty as to whether outcomes are improved, spinal fusion is considered investigational for this population.

Background

Fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction (see *Appendix*). Anterior (ALIF) or posterior lumbar interbody fusion (PLIF) are traditionally performed with an open approach (long incision with wide retraction of the musculature), but can also be performed through minimally invasive/minimal access procedures. Minimally invasive approaches that use specialized retractors include lateral transpsoas interbody fusion/lateral interbody fusion (e.g., lateral transpsoas interbody fusion [LTIF], extreme lateral interbody fusion [XLIF], direct lateral lumbar interbody fusion [DLIF]), and transforaminal interbody fusion (TLIF). Posterolateral fusion (PLF) fuses the transverse processes alone and should be differentiated from the interbody procedures (e.g., PLIF) just described. Interbody cages, instrumentation such as plates, pedicle screws, or rods, and osteoinductive agents such as recombinant human bone morphogenetic protein (rhBMP) may be used to stabilize the spine during the months that fusion is taking place and to improve fusion success rates.

The objective of interbody fusion is to permanently immobilize the functional spinal unit (2 adjacent vertebrae and the disc between them) that is believed to be causing pain and/or neurologic impingement. An alternative or supplemental approach is fusion of the transverse processes. Lumbar fusion is most commonly accepted when it is used to stabilize an unstable spine or to correct deformity. For example, lumbar spondylolisthesis is an acquired anterior displacement (slip) of 1 vertebra over the subjacent vertebra that is associated with degenerative changes. Patients who do not have neurologic deficits will typically do well with conservative care. However, patients who present with sensory changes, muscle weakness or cauda equina syndrome are more likely to develop progressive functional decline without surgery. Scoliosis, an abnormal lateral and rotational curvature of the vertebral column, can result in severe deformity that is associated with back pain in adulthood and may lead to compromised respiratory function if it is not corrected. Scoliosis with severe deformity is also an accepted indication for spinal fusion.

Lumbar spinal fusion is more controversial when the conditions previously described are not present. For example, fusion is frequently performed in combination with discectomy or laminectomy when these procedures do not result in instability of the spine. Fusion has also been performed for degenerative disc disease (DDD). DDD is a universal age-related condition consisting of morphologic changes in the lumbar motion segment. As many degenerative changes seen on imaging are asymptomatic, and invasive provocative discography has variable accuracy in the ability to localize the pain generator, identifying the source of low back pain can be difficult. A large number of fusion operations are also performed for non-specific low back pain that is not responsive to nonsurgical measures (e.g., nonsteroidal anti-inflammatory drugs [NSAIDs], analgesics, and physical therapy), when definite indications for fusion are not present. Across the United States, there is wide variation in the rates of lumbar spinal fusion, and many experts consider lumbar fusion to be overused, indicating a need for better standardization and uniformity in the application of this procedure.

Regulatory Status

Lumbar spinal fusion is a surgical procedure and does not require approval by the U.S. Food and Drug Administration (FDA). A variety of instrumentation used in lumbar spinal fusion is cleared for marketing by the FDA. Infuse (rhBMP-2) and OP-1 (rhBMP-7) are approved by the FDA for specified indications

Scope

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Benefit Application

N/A

Rationale

This policy was created in March 2011 with a regular literature search of the MEDLINE database. The most recent literature review was performed through September 30, 2014. Below is a summary of key studies to date.

Spinal Stenosis with Spondylolisthesis

A consensus statement from the North American Spine Society (NASS) defines degenerative lumbar spinal stenosis as a condition in which there is diminished space available for the neural and vascular elements in the lumbar spine secondary to degenerative changes in the spinal canal. (1) When symptomatic, this causes a variable clinical syndrome of gluteal and/or lower extremity pain and/or muscle fatigue which may occur with or without back pain.

The NASS defines lumbar degenerative spondylolisthesis as an acquired anterior displacement of one vertebra over the subjacent vertebra, associated with degenerative changes, but without an associated disruption or defect in the vertebral ring. (2) Most patients with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits do well with conservative care. Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery.

Weinstein et al. reported findings from the multicenter controlled trial (Spine Patient Outcomes Research Trial [SPORT]) that compared surgical and nonsurgical treatment for lumbar degenerative spondylolisthesis. (3, 4) All patients had neurogenic claudication or radicular leg pain associated with neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis shown on lateral radiographs with symptoms persisting for at least 12 weeks. There were 304 patients in a randomized cohort and 303 patients in an observational cohort. About 40% of the randomized cohort crossed over in each direction by 2 years of follow-up. At the 4-year follow-up time point, 54% of patients randomized to nonoperative care had undergone surgery. Five percent of the surgically-treated patients received decompression only and 95% underwent decompression with fusion. Analysis by treatment received was used due to the high percentage of crossovers. This analysis, controlled for baseline factors, showed a significant advantage for surgery at up to 4 years of follow-up for all primary and secondary outcome measures.

A 1991 study by Herkowitz et al. evaluated decompression, with or without fusion, in 50 patients with spondylolisthesis and spinal stenosis. (5) All patients had failed a trial of non-operative treatment. This quasi-

randomized prospective study used alternating assignment to the 2 treatment groups. At a mean follow-up of 3 years (range, 2.4 to 4.0), the patients who had posterolateral lumbar fusion (PLF) together with decompression had significantly improved outcomes, as measured by overall outcomes and numeric rating scales, compared to the group of patients who underwent decompression alone.

Section Summary
Findings from the SPORT trial, in which 95% of patients in the surgical group underwent decompression with fusion, and the smaller study by Herkowitz et al. that specifically assessed the addition of fusion to decompression, support that the use of lumbar spinal fusion improves outcomes in patients with spinal stenosis associated with spondylolisthesis.

Adolescent Idiopathic Scoliosis
Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, or secondary), the severity of the condition (degrees of curve), and the remaining growth expected for the patient at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high risk of curve progression. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, in the United States surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more. (6)

In 2001, Danielsson and Nachemson reported long-term follow-up on 283 consecutive patients who had been treated with a brace or with surgical treatment for adolescent idiopathic scoliosis in Sweden. (7) Lumbar curves of less than 60° were treated with a brace worn for an average of 2.7 years. Curves of 60°or more were treated with fusion using bone grafts from the iliac crest. An average of 9.5 vertebrae were fused. Clinical and radiologic follow-up was obtained in 89% of patients at a mean of 22 years (range, 20-28). Curve progression was 3.5° for surgically-treated curves and 7.9°for brace-treated curves. Five patients (4%) treated surgically and 39 (36%) treated with bracing had an increase in the Cobb angle of more than 10°.

Section Summary
Long-term follow-up of a large case series supports guidelines from the Scoliosis Research Society that fusion can reduce curve progression in patients with curves greater than 40°. This is likely to result in reduced morbidity for treated patients.

Adult Symptomatic Lumbar Scoliosis
In 2009, Bridwell et al. reported a prospective multicenter cohort study that compared operative versus nonoperative treatment of adult symptomatic lumbar scoliosis (defined as a minimum Cobb angle of 30°) in 160 consecutively enrolled patients. (8) Operative versus nonoperative treatment was decided by the patient and medical team. Nonoperative treatment included observation (21%), medications (26%), medications plus physical therapy and/or injections (40%), and other treatment without medications (13%). For analysis, the patients were matched using propensity scores that included baseline Cobb angle, Oswestry Disability Index (ODI), Scoliosis Research Society subscore, and a numerical rating scale for back and leg pain. The percentage of patients who returned for follow-up at 2 years was higher for operative than non-operative patients (95% vs. 45%), though the baseline measures for patients who were lost-to-follow-up was similar to those who were followed for 2 years. At the 2-year follow-up, non-operative treatment had not improved quality of life or any other outcome measures, while the operative group showed significant improvement in all outcomes.

Section Summary
No randomized controlled trials were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study, which may be subject to selection bias from the patient choice of treatment, reported superior outcomes in patients treated with fusion compared to non-operative controls.

Isthmic Spondylolisthesis
In 2000, Moller and Hedlund reported a study of 111 patients with adult isthmic spondylolisthesis who were randomly assigned to posterolateral fusion (with or without instrumentation, n=77) or to an exercise program

(n=34). (9) Inclusion criteria for the study were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and a severely restricted functional ability. The mean age of patients was 39 years, with a mean age at onset of symptoms of 26 years. At 1- and 2-year follow-up, functional outcome (assessed by the Disability Rating Index) had improved in the surgery group but not in the exercise group. Pain scores improved in both groups, but were significantly better in the surgically treated group compared to the exercise group.

Section Summary
One RCT was identified that compared fusion vs. an exercise program for patients with symptomatic isthmic spondylolisthesis. Results of this trial support that the use of fusion for this condition improves functional status compared to conservative treatment.

Spinal Fracture
A 2006 qualitative systematic review compared operative and nonoperative treatment for thoracolumbar burst fractures in patients without neurological deficit. (10) Two RCTs were identified, one by Wood et al. in 2003 (described below) and a second small study by Alany et al. with 20 patients.

The study by Wood et al. randomized 53 consecutive patients with a stable burst fracture and no neurological deficit or loss of structural integrity to fusion with instrumentation or to non-operative treatment with application of a body cast or orthosis for approximately 16 weeks. (11) At an average follow-up of 44 months (24 month minimum) the patients completed assessments of pain and function. At follow-up the 2 groups were similar in the average fracture kyphosis, canal compromise and return to work. Patients treated nonoperatively reported less disability on the ODI and SF-36 physical function, lower pain scores, and had fewer complications.

Section Summary
Results of this small randomized trial indicate that spinal fusion may be associated with worse outcomes compared to conservative care in patients with spinal fracture without instability or neural compression.

Lumbar Disc Herniation with Radiculopathy
Weinstein et al. also reported on randomized (n=501) and observational (n=743) cohorts of patients from the SPORT trial with lumbar disc herniation and radiculopathy who received either discectomy or nonoperative care. (12, 13) There was no mention of any patient undergoing fusion following discectomy. Specific inclusion criteria at enrollment were radicular pain (below the knee for lower lumbar herniations, into the anterior thigh for upper lumbar herniations) and evidence of nerve-root irritation with a positive nerve-root tension sign (straight leg raise–positive between 30° and 70° or positive femoral tension sign) or a corresponding neurologic deficit (asymmetrical depressed reflex, decreased sensation in a dermatomal distribution, or weakness in a myotomal distribution). Additionally, all participants were surgical candidates who had undergone advanced vertebral imaging (97% magnetic resonance imaging, 3% computed tomography) showing disk herniation (protrusion, extrusion, or sequestered fragment) at a level and side corresponding to the clinical symptoms. Patients with multiple herniations were included if only one of the herniations was considered symptomatic (i.e., if only one was planned to be operated on). Exclusion criteria included prior lumbar surgery, cauda equina syndrome, scoliosis greater than 15°, segmental instability (>10°angular motion or >4-mm translation), vertebral fractures, spine infection or tumor, inflammatory spondyloarthropathy, pregnancy, comorbid conditions contraindicating surgery, or inability/unwillingness to have surgery within 6 months. In the randomized cohort, 50% of patients assigned to discectomy and 30% of patients assigned to non-operative treatment received surgery in the first 3 months. Intent-to-treat analysis for the randomized cohort found a small advantage for patients assigned to discectomy with no significant differences between the 2 groups for the primary outcome measures. Analysis by treatment-received found significant advantages for discectomy. In the observational cohort, the 528 patients who chose surgery had greater improvement in the primary outcome measures of bodily pain, physical function, and ODI compared to the 191 patients who received usual non-operative care. All groups improved over time.

Section Summary
Current evidence, which includes a large RCT, supports that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy. However, there is no evidence to support that the addition of spinal fusion to discectomy improves outcomes in patients with the sole indication of lumbar disc herniation without instability.

Tobacco Use and Spinal Fusion

Tobacco use has been recognized as a contributor to poor healing and is associated with an increased risk of non-union by several researchers. Deyo, et al, found an increased risk of major complications in their 2010 study of adults who underwent lumbar fusion for spinal stenosis. (14) As early as 1986, (Brown et al) noted a higher rate of pseudoarthosis in individuals who used tobacco and underwent spinal fusion. (15) Anderson, et al (2001) found that fusion mass was decreased in smokers, and that smokers had a lower bone density over all. (16) They also found that smoking cessation increases fusion rates to close to those of non-smokers. Tobacco use has also been associated with less pain relief, poorer functional improvement in rehabilitation, and poorer rates of satisfaction (17) Others have reported that smoking cessation correlates with outcomes that are similar to those seen in non-smokers (18).

The American Academy of Orthopedic Surgeons (AAOS) strongly recommends avoiding use and exposure to tobacco products because of the negative impact on the musculoskeletal system including the bones, muscle, tendons and ligaments (19, 20). Lumbar fusion is usually an elective surgery; and ideally individuals should be in the best physical condition prior to undergoing surgery. The guidelines recommend smoking cessation for 4-8 weeks prior to surgery. The International Society of Advancement for Spine Surgery also recommends that while undergoing conservative care prior to surgery smokers should be encouraged to stop smoking as smoking aggravates low back pain, is a risk factor for multiple systemic health problems, and increases the risk from poor outcomes of spine surgery (21).

Chronic Low Back Pain without Radiculopathy

Nonspecific chronic low back pain (CLBP) is persistent low back pain that is not attributable to a recognizable, known specific pathology such as infection, tumor, osteoporosis, fracture, structural deformity (e.g., spondylolisthesis, scoliosis), inflammatory disorder, radiculitis, or cauda equine syndrome. Surgical interventions, including fusion and disc arthroplasty, have been applied with the belief that abnormal intersegmental movement or degenerative pathology may be the cause of CLBP. (22)

A systematic review from 2013 assessed the number of studies that had been published up until that time on surgical fusion for CLBP. (23) As of September 2012, 4 RCTs with a total of 981 patients had been published comparing surgical versus nonsurgical approaches to CLBP. In contrast, 33 RCTs with a total of 3,790 patients had compared variations of surgical techniques.

Another systematic review from 2013 compared lumbar fusion vs. conservative treatment in patients with CLBP. (24) Meta-analysis of 4 trials (described next) with a total of 666 patients reported a reduction in the ODI that was -2.91 in favor of lumbar fusion. However, this did not attain statistical significance or the minimal clinically significant difference in ODI of 10 points. There was evidence of publication bias that favored placebo. The review concluded that there is strong evidence that lumbar fusion does not lead to a clinically significant reduction in perceived disability compared to conservative treatment in patients with CLBP and degenerative spinal disease. The review also concluded that it is unlikely that further research on the subject would alter this conclusion.

In 2012, the Agency for Healthcare Research and Quality (AHRQ) posted for public comment a draft of an updated technology assessment on spinal fusion for treating painful lumbar degenerated discs or joints. (25) As of September, 2014, AHRQ lists the report as in the final production phase. (26) The draft, which reviewed 4 of the studies described below, concluded that the evidence was minimally sufficient to conclude that fusion was associated with improved back pain and function at 2 years compared with physical therapy, but that the clinical significance of these findings was uncertain. This technology assessment is being finalized for publication.

One of the studies that compared surgical versus nonsurgical treatment for CLBP was a 2001 multi-center trial by the Swedish Lumbar Spine Study Group. (27) In this study, 294 patients with CLBP for at least 2 years, sick leave or disability for at least 1 year (mean, 3 years), and radiologic evidence of disc degeneration, were randomized into 1 of 3 types of spinal fusion or to physical therapy supplemented by other nonsurgical treatment. Patients were excluded if they had specific radiologic findings such as spondylolisthesis, new or old fractures, infection, inflammatory process, or neoplasm. With intent-to-treat analysis, the surgical group showed a greater reduction in back pain (33% vs. 7%), disability according to the ODI (25% vs. 6% reduction), Million visual analog score (VAS, 28% vs. 8%) and General Function Score (GFS, 31% vs. 4%). Significantly more surgical patients were back to work (36% vs. 13%) and more reported their outcome as better or much better (63% vs. 29%).

A 2005 trial from the English Spine Stabilisation Trial Group was a pragmatic multi-center randomized trial that compared spinal fusion with an intensive (approximately 75 hours) physical and cognitive-behavioral rehabilitation program. (28) Patients (n=349) who had back pain for at least 1 year and were considered candidates for surgical stabilization of the spine by the treating physician were randomized if the clinician and patient were uncertain which of the study treatment strategies were best. Radiological findings were not part of the inclusion criteria. By the 2-year follow-up, 48 (28%) of patients who were randomized to rehabilitation had undergone surgery. Results for 1 of the 2 primary outcome measures (ODI) showed a modest but significantly greater improvement (4.1 points) in the surgery group. There were no significant differences between the groups for the walking test or for any of the secondary outcome measures.

In 2010, Brox and colleagues reported 4-year follow-up from 2 randomized trials that compared surgery versus cognitive intervention and exercises in 124 patients with disc degeneration. (29) One of the studies enrolled patients with CLBP and radiographic evidence of disc degeneration, the other enrolled patients with chronic back pain after previous surgery for disc herniation. The criteria for symptomatic DDD were based on imaging without other diagnostic tests to identify the source of the CLBP. The combined 4-year follow-up rate was 92% in the surgical group and 86% in the non-surgical group. In the non-surgical group, 24% had undergone surgery by 4 years. In the surgical group, 15 (25%) had re-operation for persistent complaints or deterioration of the condition. In the intention-to-treat analysis, there was no significant difference between the groups in the ODI or in the percentage of patients who were on disability at 4 years. For the secondary outcomes, the only treatment effect identified was a reduction of fear-avoidance beliefs favoring cognitive intervention and exercises. Interpretation of this study is limited by the high percentage of cross-overs from non-surgical to surgical treatment.

A smaller trial that is frequently cited is a 2011 study by Ohtori et al. (30) In this study, patients with discogenic low back pain for at least 2 years (without radiculopathy) were selected following demonstration of disc degeneration at 1 level based on MRI, pain provocation on discography, and pain relief following intradiscal injection of anesthetic. Forty-six patients did not agree to undergo discography or intradiscal anesthetic injection, and 11 patients were excluded because of negative results. A majority of the patients (70%) were categorized with a bulging disc and the remaining had evidence of disc degeneration on MRI. The 41 patients included in the study were divided into a walking and stretching group (over a period of 2 years, n=20), or discectomy and fusion (n=21). The approach was anterior lumbar interbody fusion (ALIF, n=15) or alternatively posterolateral fusion (PLF, n=6) if the anterior approach was technically difficult due to blood vessel anatomy. At 2 years of follow-up, there was improvement for all groups on the visual analog score (VAS), Japanese Orthopedic Association Score (JOAS), and the ODI. The 2 surgical groups scored significantly better compared to the minimal treatment group on all measures, with some advantage of ALIF over PLF. For example, VAS improved from 7.7 to 4.7 in the minimal treatment group, from 7.4 to 1.3 in the ALIF group, and from 6.5 to 3.5 in the PLF group. A limitation of this study is the minimal treatment provided to the control group.

Section Summary
The results of trials comparing fusion to non-surgical management in this population are mixed. A meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with CLBP that is not attributable to a recognizable, known specific pathology such as, infection, tumor, osteoporosis, fracture, structural deformity (e.g. spondylolisthesis, scoliosis), inflammatory disorder, radiculitis, or cauda equina syndrome. The strongest benefits of surgery were reported in a study of patients who had been on sick leave or disability for more than 1 year, while no advantage of surgery was found when the patients or surgeon were unsure of whether surgery or conservative therapy would be the best treatment strategy. Interpretation of these studies is limited by the high percentage of patients who cross over to surgery, variances in the type of spinal fusion (e.g., posterolateral versus interbody), and uncertainty in establishing whether the source of CLBP is from DDD.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from the North American Spine Society and American Association of Neurological Surgeons, and the Congress of Neurological Surgeons, with 3 additional reviewers identified through

a third physician specialty society and 2 academic medical centers. The input addressed specific criteria to determine the medical necessity of lumbar spinal fusion. This input has been incorporated into the policy.

Summary of Evidence

Lumbar spinal fusion (arthrodesis) is a surgical technique that involves fusion of two or more lumbar vertebrae using local bone, autologous bone taken from the iliac crest of the patient, or allogeneic donor bone. The literature was examined on the use of fusion for the following indications:

- *Spinal Stenosis with spinal instability.* Findings from the SPORT trial, in which 95% of patients in the surgical group underwent decompression with fusion, and a smaller study that specifically assessed the addition of fusion to decompression, support that fusion in patients with spinal stenosis associated with spondylolisthesis improves outcomes and therefore may be considered medically necessary for this indication.
- *Idiopathic Scoliosis.* Long-term follow-up of a large case series and guidelines from the Scoliosis Research Society provide support that fusion can reduce curve progression in patients with curves greater than 40 degrees. Therefore, lumbar spinal fusion may be considered medically necessary for this population.
- *Degenerative Scoliosis.* No RCTs were identified on the treatment of adult symptomatic lumbar scoliosis with fusion. A cohort study found superior outcomes in patients treated with fusion compared to non-operative controls. Based on this evidence, clinical input, and the strong rationale for its efficacy, spinal fusion may be considered medically necessary for adults with degenerative scoliosis.
- *Isthmic Spondylolisthesis.* One RCT was identified that compared fusion versus an exercise program in patients with symptomatic isthmic spondylolisthesis. Results of this trial support that fusion may be considered medically necessary for this condition.
- *Spinal Fracture.* Results of 1 small RCT indicate that spinal fusion for patients with spinal fracture without instability or neural compression may result in worse outcomes than nonsurgical management, and therefore spinal fusion is considered not medically necessary for this indication.
- *Herniated Discs.* Current evidence, which includes the large SPORT RCT, supports surgical treatment with discectomy for lumbar disc herniation. Evidence is insufficient to conclude that the addition of fusion to discectomy improves outcomes in patients with lumbar disc herniation without instability. As a result, lumbar spinal fusion is considered investigational for this indication.
- *Non-specific Chronic Low Back Pain.* Meta-analysis of results from 4 RCTs found no clinically significant advantage of lumbar fusion over conservative therapy in patients with non-specific chronic low back pain that is unresponsive to conservative management. While some trials have reported a benefit, others have not. Due to the uncertainty as to whether outcomes are improved, spinal fusion is considered investigational for this population.

Practice Guidelines and Position Statements

In 2014, North American Spine Society (NASS) published policy recommendations for lumbar fusion. (31) Specific criteria were described for infection, tumor, traumatic injuries, deformity (e.g. scoliosis), stenosis, disc herniations, synovial facet cysts, discogenic low back pain, and pseudoarthrosis. NASS describes situations where lumbar fusion would not be indicated as disc herniation in the absence of instability or spondylolisthesis; stenosis in the absence of instability, foraminal stenosis or spondylolisthesis; and discogenic low back pain that does not meet the recommended criteria.

The 2008 guidelines from North American Spine Society (NASS) addressed the diagnosis and treatment of degenerative lumbar spondylolisthesis. (2, 32)

- NASS gave a grade B recommendation for surgical decompression with fusion for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone, and a grade C recommendation for decompression and fusion as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

The 2011 guidelines from NASS the addressed multidisciplinary spine care for adults with a chief complaint of degenerative lumbar spinal stenosis. (1, 33)

- The guidelines indicate that the nature of the pain and associated patient characteristics should be more

typical of a diagnosis of spinal stenosis than herniated disc. The evidence review addressed whether the addition of lumbar fusion to surgical decompression improves surgical outcomes in the treatment of spinal stenosis compared to treatment by decompression alone. The NASS gave a grade B recommendation (fair evidence) for decompression alone for patients with leg predominant symptoms without instability

The 2012 guidelines from NASS addressed multidisciplinary spine care for the diagnosis and treatment of lumbar disc herniation with radiculopathy. (34, 35)

- The guidelines indicate that there is insufficient evidence to make a recommendation for or against fusion for specific patient populations with lumbar disc herniation with radiculopathy whose symptoms warrant surgery. The best evidence available suggests that outcomes are equivalent in patients with radiculopathy due to lumbar disc herniation whether or not a fusion is performed. Grade of Recommendation: I (Insufficient Evidence)

The 2014 guidelines from the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) addressed fusion procedures for the lumbar spine. (36) The 2014 guidelines state that there is no evidence that conflicts with the recommendations formulated in the 2004 guidelines for fusion procedures for the lumbar spine.

- One- or two-level degenerative disease without stenosis or spondylolisthesis (part 7): AANS/CNS recommends that lumbar fusion be performed for patients whose low-back pain is refractory to conservative treatment (physical therapy or other nonoperative measures) and is due to 1- or 2- level degenerative disc disease without stenosis or spondylolisthesis (grade B, based on multiple Level II studies). (37) A grade C recommendation was given that discoblock "(a procedure that involves injecting the disc with an anesthetic agent instead of a contrast agent in an effort to eliminate as opposed to reproducing a patient's pain)" be considered as a diagnostic option during the evaluation of a patient presenting with chronic low-back pain (single level II study), but that the potential for acceleration of the degenerative process be included in the discussion of potential risks (part 6). (38)
- Disc herniation and radiculopathy (part 8): Lumbar spinal fusion is not recommended as routine treatment following primary disc excision in patients with a herniated lumbar disc causing radiculopathy. (grade C, level IV evidence). Lumbar spinal fusion is recommended as a potential option in patients with herniated discs who have evidence of significant chronic axial back pain, work as manual laborers, have severe degenerative changes, or have instability associated with radiculopathy caused by herniated lumbar disc (grade C, level IV evidence). Reoperative discectomy combined with fusion is recommended as a treatment option in patients with a recurrent disc herniation associated with lumbar instability, deformity, or chronic axial low-back pain (grade C, level III evidence). (39)
- Stenosis and spondylolisthesis (part 9): Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with degenerative spondylolisthesis in patients who desire surgical treatment (grade B, level II evidence). There was insufficient evidence to recommend a standard fusion technique. (40)
- Stenosis without spondylolisthesis (part 10): Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention (grade B, level II/III evidence). In the absence of deformity or instability, lumbar fusion is not recommended as it has not been shown to improve outcomes in patients with isolated stenosis (grade C, level IV evidence) (41)
- AANS/CNS also provided recommendations on (36):
  - Assessment of functional outcome following lumbar fusion (part 2),
  - Assessment of economic outcome (part 3),
  - Radiographic assessment of fusion status (part 4),
  - Correlation between radiographic outcome and function (part 5),
  - Interbody techniques for lumbar fusion (part 11),
  - Pedicle screw fixation as an adjunct to posterolateral fusion (part 12),
  - Injection therapies (part 13),
  - Brace therapy (part 14),
  - Electrophysiological monitoring (part 15),
  - Bone growth extenders and substitutes (part 16), and
  - Bone growth stimulators (part 17).

A 2011 American College of Occupational and Environmental Medicine update of their guidelines on low back disorders state that for third lumbar discectomy on the save disc, spinal fusion at the time of discectomy as an

option has a recommendation of inconclusive/insufficient evidence (I). (42)

A 2009 clinical practice guideline from the American Pain Society (APS) describes the following recommendations: (43)

- In patients with nonradicular low back pain who do not respond to usual, noninterdisciplinary interventions, it is recommended that clinicians consider intensive interdisciplinary rehabilitation with a cognitive/behavioral emphasis" (strong recommendation, high-quality evidence)
- In patients with nonradicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option" (weak recommendation, moderate-quality evidence)
- It is recommended that shared decision-making regarding surgery for nonspecific low back pain include a specific discussion about intensive interdisciplinary rehabilitation as a similarly effective option, the small to moderate average benefit from surgery versus non-interdisciplinary nonsurgical therapy, and the fact that the majority of such patients who undergo surgery do not experience an optimal outcome. This recommendation is based on evidence that fusion surgery is superior to nonsurgical therapy without interdisciplinary rehabilitation, but no more effective than intensive interdisciplinary rehabilitation.
- There is insufficient evidence to determine if laminectomy with fusion is more effective than laminectomy without fusion.

In 2009, the United Kingdom's National Institute for Health and Clinical Excellence (NICE) provided clinical guidelines on early management of persistent non-specific low back pain. (44)

- NICE recommends that practitioners consider referral for spinal fusion for people who have completed an optimal package of care that includes a combined physical and psychological treatment program and still have severe non-specific low back pain for which they would consider surgery.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (USPSTF) has not addressed lumbar fusion.

Medicare National Coverage
In 2006, the Medicare Evidence Development and Coverage Advisory Committee was convened to provide recommendations on the quality and strength of evidence for the benefits and risks of spinal fusion surgery for chronic low back pain from lumbar degenerative disc disease. (45) Included in the meeting materials was a technology assessment that was commissioned by Agency for Healthcare Research and Quality to evaluate spinal fusion for treatment of degenerative disease affecting the lumbar spine.

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Coding

Codes	Number	Description
CPT	0309T	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar, L4-L5 interspace (List separately in addition to code for primary procedure)
	22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
	22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression; thoracic or lumbar, each additional vertebral segment
	22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
	22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
	22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
	22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)
	22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
	22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
	22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)
	22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
	22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (List separately in addition to code for primary procedure)
	22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
	22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
	22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
	22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
	22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
	22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
	62290	Injection procedure for discography, each level; lumbar
	63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted

Appendix

Procedures used for lumbar interbody fusion differ primarily in the direction of approach to the spine, i.e., from the front (anterior), from the back (posterior or transforaminal) or from the side (lateral). An alternative approach to interbody fusion is arthrodesis of the transverse processes alone (posterolateral) which does not fuse the adjoining vertebral bodies. Circumferential fusion fuses both the adjacent vertebral bodies and the transverse processes, typically using both an anterior and posterior approach to the spine.

Open and Minimally Invasive Approaches to Lumbar Interbody Fusion (LIF)

Procedure	Access	Approach	Visualization
Anterior (ALIF)	Open, MI, or laparoscopic	Transperitoneal or retroperitoneal	Direct, endoscopic or laparoscopic with fluoroscopic guidance
Posterior (PLIF)	Open or MI	Incision centered over spine with laminectomy/laminotomy and retraction of nerve	Direct, endoscopic or microscopic, with fluoroscopic guidance
Transforaminal (TLIF)	Open or MI	Offset from spine, through the intervertebral foramen via unilateral facetectomy	Direct, endoscopic or microscopic, with fluoroscopic guidance
Lateral Extreme lateral (XLIF) Direct lateral (DLIF)	MI	Retroperitoneal through transpsoas	Direct, with neurologic monitoring and fluoroscopic guidance

Anterior Lumbar Interbody Fusion (ALIF)
Anterior access provides direct visualization of the disc space, potentially allowing a more complete discectomy and better fusion than lateral or posterior approaches. An anterior approach avoids trauma to the paraspinal musculature, epidural scarring, traction on nerve roots, and dural tears. However, the retraction of the great vessels, peritoneal contents, and superior hypogastric sympathetic plexus with a peritoneal or retroperitoneal approach place these structures at risk of iatrogenic injury. Access to the posterior space for the treatment of nerve compression is also limited. Laparoscopic ALIF has also been investigated.

Posterior Lumbar Interbody Fusion (PLIF)
PLIF can be performed through either a traditional open procedure with a midline incision or with a minimally invasive approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision to facilitate wide muscle retraction and laminectomy. In minimally invasive PLIF, tubular retractors may be used to open smaller central bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, hypertrophic ligamentum flavum), as well as stabilization of the spine through interbody fusion.

Transforaminal Lumbar Interbody Fusion (TLIF)
TLIF is differentiated from the more traditional bilateral PLIF by a unilateral approach to the disc space through the intervertebral foramen. In minimally invasive TLIF, a single incision about 2-3 cm in length is made approximately 3 cm lateral to the midline. A tubular retractor is docked on the facet joint complex and a facetectomy with partial laminectomy is performed. Less dural retraction is needed with access through the

foramen via unilateral facetectomy, and contralateral scar formation is eliminated. TLIF provides access to the posterior elements along with the intervertebral disc space.

Lateral Interbody Fusion (e.g., extreme lateral interbody fusion [XLIF] or direct lateral interbody fusion [DLIF])

Lateral interbody fusion uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas. In comparison with ALIF, the lateral approach does not risk injury to the peritoneum or great vessels. However, exposure to the spine may be more limited, and dissection of the psoas major places the nerves of the lumbar plexus at risk. Electromyographic monitoring and dissection predominantly within the anterior psoas major may be utilized to reduce the risk of nerve root injury. These various factors decrease the ability to perform a complete discectomy and address pathology of the posterior elements.

Circumferential Fusion

Circumferential fusion is 360 degree fusion that joins vertebrae by their entire bodies and transverse processes, typically through an anterior and posterior approach.

Posterolateral Fusion (PLF)

PLF is a procedure where the transverse processes of the involved segments are decorticated and covered with a mixture of bone autograft or allograft.

History

Date	Reason
03/08/11	Add to Surgery Section - New Policy held for provider notification. The effective and publication date will be 9/1/2011.
05/18/11	Policy Published - The policy was published on the internal and external sites with an effective date of September 1, 2011.
12/2/11	Related Policies updated; 7.01.115 removed.
01/11/12	Codes 22633 and 22634 added.
09/11/12	Replace policy - Policy statements extensively revised for clarification. Instability clarified by adding 4 mm of translational instability. Spinal stenosis criteria clarified. Pseudoarthrosis criteria clarified by adding lucency around the hardware per x-ray or CT scan. Failure of 6 months of nonsurgical care removed from all policy statements. Added reference 16.
10/09/12	Replace policy - Added definitions for truncal imbalance. Added clarity to spondylolisthesis statement – It is measured in the sagittal plane on functional flexion and extension views on upright x-ray. MRI and CT removed from bullet. Added references 17 and 18.
12/19/12	Update Related Policies – Add 7.01.85.
01/10/13	Coding update. CPT codes 22586 and 0309T, effective 1/1/13, added to policy.
04/08/13	Clarification only. "Acute" added to describe spinal fracture within the Policy section. Literature reviewed.
12/06/13	Update Related Policies. Add 7.01.138.
01/21/14	Update Related Policies. Add 7.01.551.
07/14/14	Annual review. Policy updated with literature review through October 23, 2013; considered medically necessary under specified conditions. Policy rewritten and reorganized.
01/13/15	Annual Review. Policy updated with literature review through September 2014; no change in policy statements. References 18 and 28-34 added. The following codes were removed from the policy as they do not facilitate adjudication: ICD-9 & ICD-10 diagnosis; CPT 20930-20938, 22840-22847 & 22851.
02/03/15	Update Related Policies. Add 7.01.130.
04/14/15	Interim Update. Policy updated within the Policy Guidelines section to state that smoking within the previous 6 weeks (previously stated 3 months) is a contraindication for lumbar spinal fusion; supportive Rationale added within said section and references 14-21 added (others renumbered). An additional bullet has been added within the same section within the minimal documentation requirement to document proof of smoking cessation for 6 weeks prior to surgery.

Lumbar Fusion (Re-review) draft evidence report

Presented by Dr. Gary Franklin, Medical Director, WA State Department of Labor and Industries

1. Page ES-4. It may be important to point out the average duration of the intensive multidisciplinary programs is 3-4 weeks. The 15 weeks is an outlier and perhaps older information.

2. Page ES-9. General treatment success and specific a priori definition of %improvement in specific measures of pain and function are very different ways of measuring outcomes. The more general impression of success is nothing like the degree of improvement on a validated instrument. For example, the new WA state opioid guideline defines clinically meaningful improvement as being 30% in pain and in function on validated brief instruments. This is basically what Carraggee did in the study you cited. Similarly, on Page-31, the "better vs much better" and "excellent vs good" outcome measures are not the same as pre-specified proportions of improvement on validated instruments. Can you treat these two types of improvement differentially in the report?

3. Page ES-19 and Page-33. Regarding surgical complications or adverse events, there is a study published recently on complications following lumbar fusion for low back pain and/or radiculopathy (Verla et al 2015. J Clinical Neuroscience. 22:342), which is not included in the evidence report. This is a rather large study (n=1498) using a multi-institutional, prospective spine outcomes registry. Complications occurred in 7.68% of the patients included in the study. The most common complications were cerebrospinal fluid leak (49.18%), bleeding requiring transfusion (13.11%), nerve root injury (9.83%) and surgical site infections (9.28%).

4. Page ES-32 and Page-47. "…ranged from $27,480 for decompression alone to $67,773 to complex fusion to $92,766 for complex fusion". The sentence is difficult to understand, and a typo is suspected. A suggested revision would be: "…ranged from $27,480 for decompression alone to $67,773 *for simple* fusion to $92,766 for complex fusion".

5. Page ES-32 and Page-48. "The difference in quality-adjusted survival between groups was 0.068 in favor of surgery". This statement is rather confusing here, especially to readers who are not very familiar with the concepts of "utility" and "quality-adjusted survival". It could be incorrectly interpreted as "fusion is superior to rehabilitation" in this context. In addition to the fact that the difference was not statistically significant (CI: -0.02 to 0.156, P=0.13), it reflects a difference in utility (quality of life of the two groups) existed at baseline prior to the interventions. Removal of the statement is recommended to avoid any confusion.

6. Page-13. Blue Cross Blue Shield of North Carolina was the first to do a more restrictive fusion policy. URL:

http://www.bcbsnc.com/assets/services/public/pdfs/medicalpolicy/lumbar_spine_fusion_surgery.pdf. In addition, the WA Dept of Labor and Industries has long had a guideline on lumbar fusion, which was updated following the 2007 HTA decision. URL:
http://www.lni.wa.gov/ClaimsIns/Files/OMD/MedTreat/LumbarFusion.pdf

7. Regarding reoperation rates, the two large population-based retrospective cohort studies done in WA state were consistent even though the two cohorts were separated by 8 years-both showed 22-23% reoperation within 2 years of fusion-this data should be added to the adverse event section (Franklin GM, et al. Spine 1994: 17: 1897-1904; Juratli et al, Spine 2006:31: 2715-23).

8. One adverse outcome the evidence report mentioned only briefly in the introduction section is the so called Failed Back Surgery Syndrome. This is persistent pain after spine surgery that can be worse than the pain that led to the surgery. Some publications have found a high prevalence of epidural fibrosis among patients following spine surgery. (see eg, Bosscher HA, Heavner JE. Incidence and severity of epidural fibrosis after back surgery: an endoscopic study. Pain Pract 2010: 10: 18-24.)

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September 17, 2015

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Re: AANS/CNS Comments on Draft Technical Assessment for Washington State HTA Re-review of Lumbar Spinal Fusion

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, and the Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to provide comments regarding the draft evidence assessment prepared for the Washington State Healthcare Authority (WCA) Health Technology Assessment (HTA) program re-review of coverage policy for lumbar spinal fusion for degenerative disc disease (DDD). We have provided the following remarks based on our study of the draft report. We add these comments to those that we submitted in our letter May 20, 2015 regarding the draft Key Questions used for the report. We look forward to publication of the final report and to the discussion by the Health Technology Clinical Committee (HTCC) on November 20, 2015.

Cited Literature Does Not Warrant a Policy Change

The document prepared by the Institute for Clinical and Economic Review (ICER) is a thorough review of the literature. However, as we stated when the HTA program first suggested that the 2008 HTA Lumbar Fusion for DDD coverage policy be revisited, we do not believe that there is a substantial change in evidence for this procedure and we do not support a change to the current policy, which was based on significant stakeholder input and a robust review by the HTCC. Nevertheless, we would like to provide the following commentary on various aspects of the ICER report.

Clarification that the Scope for the Report is for Uncomplicated DDD Only

The key questions for the report are specific to the treatment of chronic low back pain and uncomplicated DDD. As such, the title of the draft report is slightly misleading as it gives the impression that it pertains to all lumbar fusions, and not the specific disease entity of chronic low back pain and uncomplicated DDD. ICER should clarify this in the title of the

final report. The focus of the HTCC meeting discussion should be limited to the specific topic of chronic low back pain and uncomplicated DDD.

Heterogeneous Patient Population

As is the case with any review of the literature, it is very difficult to find studies that precisely provide information on the desired subject matter, as the diagnosis of chronic low back pain and uncomplicated DDD might not apply to the subjects enrolled in the clinical trials for Key Question #1. Brox et al, Fritzell et al, and Fairbanks et al. all included patients with previous surgeries. The duration of symptoms in all of these studies was 8 years. Some of these patients with prior surgery who did not improve may have entered the trial with a diagnosis of failed back syndrome, and possible neuropathic symptoms. Average symptoms were present for 8 years.   In the sport trial data, surgery was associated with significantly better outcomes when symptom duration was less than 12 months. (Radclif et al 2011, Spine (Phila Pa 1976). 2011 Dec 1; 36(25): 2197–2210. PMCID: PMC3236684).   In this sense, the studies used to answer Key Question # 1 might not completely reflect what the HTA program is attempting to study. It is possible that patients in these reported clinical trials may have benefitted to a greater extent from surgery if they were referred to spine surgeons at an earlier date.

Limitations of Studies from Outside the United States

Furthermore, the core studies used in the review have many well-known limitations as they are from outside the United States (US)—from the United Kingdom, Norway, and Sweden specifically. This introduces a serious population selection bias compared to our US and Washington state populations. Because these groups differ substantially to the US population, we do not feel that we can draw valid conclusions on how to manage our patients from this data.   This issue was raised at the November 2007 HTCC meeting and it was clear that significant differences in culture and alternative treatments exist between the United States and Europe.

Patient Safety Data

Regarding the section on complications from spine surgery, it is important to note mention of Goz et al's study using the NIS data to evaluate three different primary interbody fusion cohorts (923,038 fusions) over nine years. In this study, patients with uncomplicated DDD represented a majority of patients for each fusion group. A recent article by Gologorski et al (J Neurosurg Spine. 2014 Dec;21(6):984-93. doi: 10.3171/2014.8.SPINE131113) demonstrates that primary ICD-9-CM codes extracted from large administrative databases (NIS in particular) do not accurately reflect the surgeon's indication. As such, we cannot extrapolate on complication rates of lumbar fusion using datasets that might not even correctly portray the patients with diagnosis of interest.

We feel that it would be important to include results from Level 1 data on the purest of LBP populations-–artificial disk replacement versus fusion. Data from the fusion arm is not represented adequately in the ICER report. Including this data would provide valuable high quality context for important quality of life and function as well as safety data. In addition,

this data frequently comes from the US. We suggest the use of the Washington state Surgical Care Outcomes Assessment Programs (SCOAP) data base as a realistic patient safety assessment as it contains helpful real time data on complications. Furthermore it may be helpful to examine other high quality data registries such as the AANS/CNS National Neurosurgery Quality and Outcomes Database (N2QOD).

Cost Effectiveness Data

Incremental cost effectiveness of lumbar fusion when compared to non-operative treatments needs to be assessed on a long term basis. Numerous studies will demonstrate costly treatments in the fusion group. However, the true cost effectiveness of surgery is not realized until several years after fusion surgery. Further long term data will need to be collected to demonstrate long term cost effectiveness and long lasting effect of spine fusion despite the known risks of spine surgery. Andersen et al recently report that spinal fusion surgery in older patients does not generate excess hospital-based health care use in the longer term as compared with the background population.(Eur Spine J. 2013 May;22(5):977-84. doi: 10.1007/s00586-012-2479-5. Epub 2012 Aug 21. PMID: 22907726).
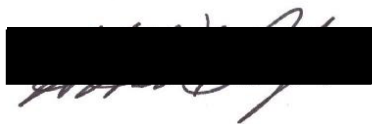
Cognitive Based Therapy for Uncomplicated DDD

We also feel that cognitive based therapy (CBT) is not a standard treatment alternative to fusion surgery. First of all, there is no clear definition to CBT. In addition, extreme selection bias exists with regard to which CBT therapy would apply to which patients. The Cochrane review concluded that CBT was useful for treatment of chronic pain , but different types of studies and analyses are needed to identify which components of CBT work for which type of patient on which outcomes and why (Williams, Cochrane 2012). Rather than asking if CBT or fusion is the better treatment modality, we really need to ask who needs either or both treatments and whether access to this kind of treatment specifically for uncomplicated DDD exists in the state of Washington or anywhere else in the US.
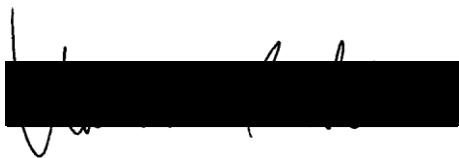
Conclusion

Thank you for your time and attention. We look forward to the November 20, 2015 meeting of the HTCC. We ask that a neurosurgeon with an active practice in spine surgery be included as the invited physician expert for the meeting and we can help identify appropriate neurosurgeons in the state of Washington to serve. As we have during our participation with the HCA HTA in the review of many neurosurgical procedures over the last eight years, we share the agency's dedication to the best possible healthcare for citizens of the state of Washington.

Sincerely,

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American Association of Neurological Surgeons

Nathan R. Selden, MD, PhD, President
Congress of Neurological Surgeons

Praveen Mummaneni, Chairman
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