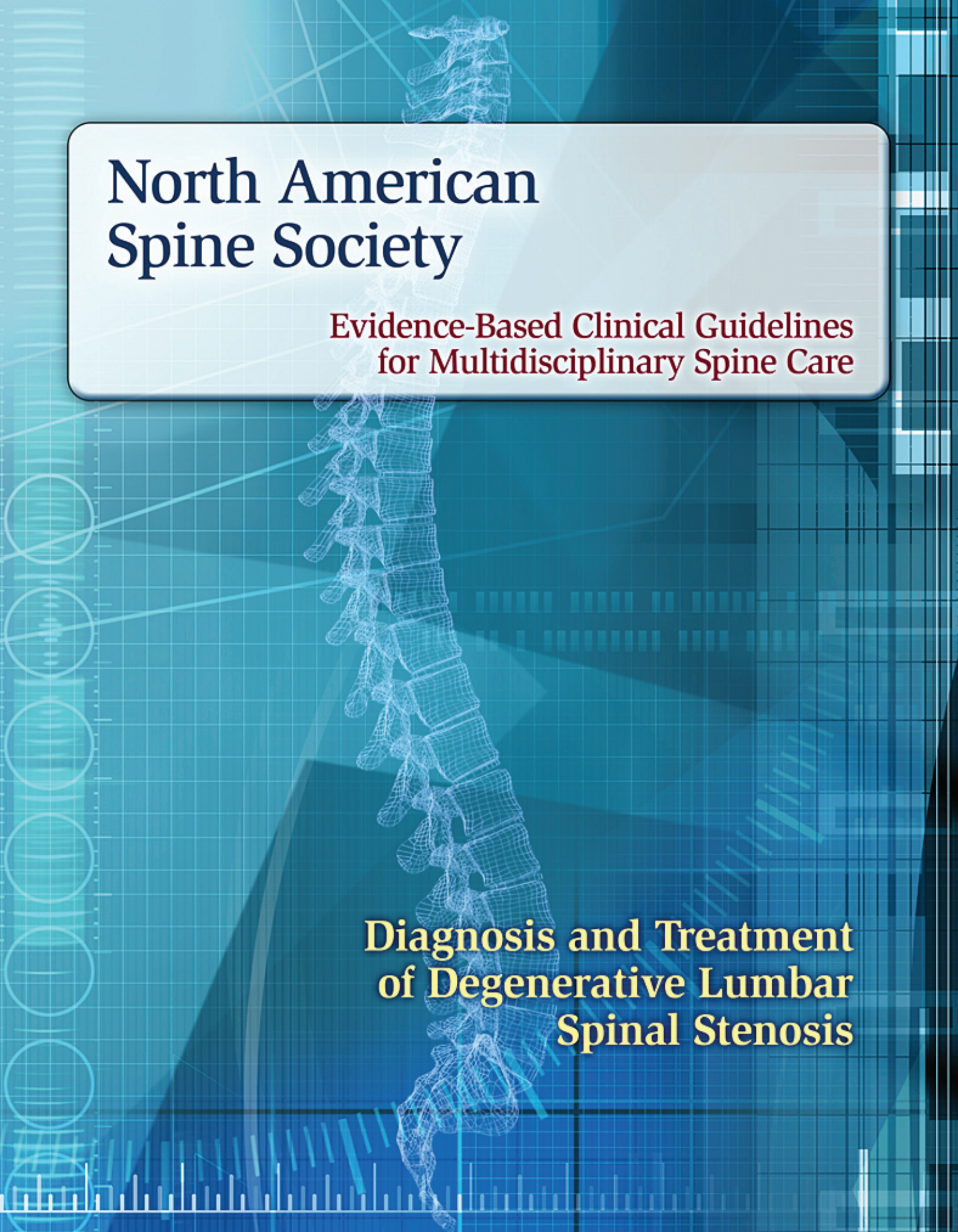
North American Spine Society

Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care



Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis

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Financial Statement

This clinical guideline was developed and funded in its entirety by the North American Spine Society (NASS). All participating authors have submitted a disclosure form relative to potential conflicts of interest which is kept on file at NASS.

Comments

Comments regarding the guideline may be submitted to the North American Spine Society and will be considered in development of future revisions of the work.

North American Spine Society
Clinical Guidelines for Multidisciplinary Spine Care
Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis

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I. INTRODUCTION

Objective

The objective of the North American Spine Society (NASS) *Clinical Guideline for the Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis* is to provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of degenerative lumbar spinal stenosis. The guideline is intended to reflect contemporary treatment concepts for symptomatic degenerative lumbar spinal stenosis as reflected in the highest quality clinical literature available on this subject as of April 2006. The goals of the guideline recommendations are to assist in delivering optimum, efficacious treatment and functional recovery from this spinal disorder.

Scope, Purpose and Intended User

This document was developed by the North American Spine Society Clinical Guidelines Committee as an educational tool to assist practitioners who treat patients with degenerative lumbar spinal stenosis. The goal is to provide a tool that assists practitioners in improving the quality and efficiency of care delivered to patients with degenerative lumbar spinal stenosis. The NASS *Clinical Guideline for the Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis* provides a definition and explanation of the natural history of degenerative lumbar spinal stenosis, outlines a reasonable evaluation of patients suspected to have degenerative lumbar spinal stenosis and outlines treatment options for adult patients with a diagnosis of degenerative lumbar spinal stenosis.

THIS GUIDELINE DOES NOT REPRESENT A "STANDARD OF CARE," nor is it intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside this guideline will sometimes be necessary. This guideline should not be seen as prescribing the type, frequency or duration of intervention. Treatment should be based on the individual patient's need and doctor's professional judgment. This document is designed to function as a guideline and should not be used as the sole reason for denial of treatment and services. This guideline is not intended to expand or restrict a health care provider's scope of practice or to supersede applicable ethical standards or provisions of law.

Patient Population

The patient population for this guideline encompasses adults (18 years or older) with a chief complaint of neurogenic claudication without associated spondylolisthesis. Furthermore, the nature of the pain and associated patient characteristics (eg, age) should be more typical of a diagnosis of spinal stenosis than herniated disc.

II. GUIDELINE DEVELOPMENT METHODOLOGY

Through objective evaluation of the evidence and transparency in the process of making recommendations, it is NASS' goal to develop evidence-based clinical practice guidelines for the diagnosis and treatment of adult patients with various spinal conditions. These guidelines are developed for educational purposes to assist practitioners in their clinical decision-making processes. It is anticipated that where evidence is very strong in support of recommendations, these recommendations will be operationalized into performance measures.

Multidisciplinary Collaboration
With the goal of ensuring the best possible care for adult patients suffering with back pain, NASS is committed to multidisciplinary involvement in the process of guideline and performance measure development. To this end, NASS has ensured that representatives from medical, interventional and surgical spine specialties have participated in the development and review of all NASS guidelines. It is also important that primary care providers and musculoskeletal specialists who care for patients with spinal complaints are represented in the development and review of guidelines that address treatment by first contact physicians, and NASS has involved these providers in the development process as well. To ensure broad-based representation, NASS has invited and welcomes input from other societies and specialties.

Evidence Analysis Training of All NASS Guideline Developers
NASS has initiated, in conjunction with the University of Alberta's Centre for Health Evidence, an online training program geared toward educating guideline developers about evidence analysis and guideline development. All participants in guideline development for NASS have completed the training prior to participating in the guideline development program at NASS. This training includes a series of readings and exercises, or interactivities, to prepare guideline developers for systematically evaluating literature and developing evidence-based guidelines. The online course takes approximately 15-30 hours to complete and participants have been awarded CME credit upon completion of the course.

Disclosure of Potential Conflicts of Interest
All participants involved in guideline development have disclosed potential conflicts of interest to their colleagues and their potential conflicts have been documented for future reference. They will not be published in any guideline, but kept on file for reference, if needed. Participants have been asked to update their disclosures regularly throughout the guideline development process.

Levels of Evidence and Grades of Recommendation
NASS has adopted standardized levels of evidence *(Appendix B)* and grades of recommendation *(Appendix C)* to assist practitioners in easily understanding the strength of the evidence and recommendations within the guidelines. The levels of evidence range from Level I (high quality randomized controlled trial) to Level V (expert consensus). Grades of recommendation indicate the strength of the recommendations made in the guideline based on the quality of the literature.

Grades of Recommendation:

A: Good evidence (Level I studies with consistent findings) for or against recommending intervention.

B: Fair evidence (Level II or III studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

The levels of evidence and grades of recommendation implemented in this guideline have also been adopted by the *Journal of Bone and Joint Surgery*, the American Academy of Orthopaedic Surgeons, *Clinical Orthopaedics and Related Research*, the journal *Spine* and the Pediatric Orthopaedic Society of North America.

In evaluating studies as to levels of evidence for this guideline, the study design was interpreted as establishing only a *potential* level of evidence. As an example, a therapeutic study designed as a randomized controlled trial would be considered a *potential* Level I study. The study would then be further analyzed as to how well the study design was implemented and significant shortcomings in the execution of the study would be used to downgrade the levels of evidence for the study's conclusions. In the example cited previously, reasons to downgrade the results of a potential Level I randomized controlled trial to a Level II study would include, among other possibilities, an underpowered study (patient sample too small, variance too high), inadequate randomization or masking of the group assignments and lack of validated outcome measures.

In addition, a number of studies were reviewed several times in answering different questions within this guideline. How a given question was asked might influence how a study was evalu-

ated and interpreted as to its level of evidence in answering that particular question. For example, a randomized control trial reviewed to evaluate the differences between the outcomes of surgically treated versus untreated patients with lumbar spinal stenosis might be a well designed and implemented Level I therapeutic study. This same study, however, might be classified as giving Level II prognostic evidence if the data for the untreated controls were extracted and evaluated prognostically.

Guideline Development Process

❖ Step 1: Identification of Clinical Questions

Trained guideline participants were asked to submit a list of clinical questions that the guideline should address. The lists were compiled into a master list, which was then circulated to each member with a request that they independently rank the questions in order of importance for consideration in the guideline. The most highly ranked questions, as determined by the participants, served to focus the guideline.

❖ Step 2: Identification of Work Groups

Multidisciplinary teams were assigned to work groups and assigned specific clinical questions to address. Because NASS is comprised of surgical, medical and interventional specialists, it is imperative to the guideline development process that a cross-section of NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized.

❖ Step 3: Identification of Search Terms and Parameters

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol *(Appendix D)* which has been followed to identify literature for evaluation in guideline development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the appendices *(Appendix E)*.

❖ Step 4: Completion of the Literature Search

After each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

Following these protocols ensures that NASS recommendations (1) are based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and

(3) represent the current best research evidence available. NASS maintains a search history in EndNote,™ for future use or reference.

❖ Step 5: Review of Search Results/Identification of Literature to Review

Work group members reviewed all abstracts yielded from the literature search and identified the literature they would review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members identified the *best research evidence available* to answer the targeted clinical questions. That is, if Level I, II and/or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.

❖ Step 6: Evidence Analysis

Members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence. In order to systematically control for potential biases, at least two work group members reviewed each article selected and independently assigned levels of evidence to the literature using the NASS levels of evidence. Any discrepancies in scoring have been addressed by two or more reviewers. The consensus level (the level upon which two thirds of reviewers were in agreement) was then assigned to the article.

As a final step in the evidence analysis process, members identified and documented gaps in the evidence to educate guideline readers about where evidence is lacking and help guide further needed research by NASS and other societies.

❖ Step 7: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus

Work groups held face-to-face meetings to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this guideline very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 ("extremely inappropriate") to 9 ("extremely appropriate"). Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8 or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, work group members developed the guideline content, addressing the literature which supports the recommendations.

❖ Step 8: Submission of the Draft Guidelines for Review/Comment

Guidelines were submitted to the full Clinical Guidelines Committee, the Clinical Care Council Director and the Advisory Panel for review and comment. The Advisory Panel is comprised of representatives from physical medicine and rehab, pain medicine/management, orthopedic surgery, neurosurgery, anesthesiology, rheumatology, psychology/psychiatry and family practice. Revisions to recommendations were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

❖ Step 9: Submission for Board Approval

After any evidence-based revisions were incorporated, the drafts were prepared for NASS Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence.

❖ Step 10: Submission for Endorsement, Publication and National Guideline Clearinghouse (NGC) Inclusion

Following NASS Board approval, the guidelines were slated for publication, submitted for endorsement to all appropriate societies and submitted for inclusion in the National Guidelines Clearinghouse (NGC). No revisions were made at this point in the process, but comments have been and will be saved for the next iteration.

❖ Step 11: Identification and Development of Performance Measures

The recommendations will be reviewed by a group experienced in performance measure development (eg, the AMA Physician's Consortium for Performance Improvement) to identify those recommendations rigorous enough for measure development. All relevant medical specialties involved in the guideline development and at the Consortium will be invited to collaborate in the development of evidence-based performance measures related to spine care.

This guideline will be pilot-tested among spine care specialists and primary care physicians for one year following publication. Findings of the pilot test will be considered to inform future guideline development.

❖ Step 12: Review and Revision Process

The guideline recommendations will be reviewed every three years by an EBM-trained multidisciplinary team and revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the guideline.

Use of Acronyms
Throughout the guideline, readers will see many acronyms with which they may not be familiar. A glossary of acronyms is available in *Appendix A*.

Nomenclature for Medical/Interventional Treatment
Throughout the guideline, readers will see that what has traditionally been referred to as "nonoperative," "nonsurgical" or "conservative" care is now referred to as "medical/interventional care." The term medical/interventional is meant to encompass pharmacological treatment, physical therapy, exercise therapy, manipulative therapy, modalities, various types of external stimulators and injections.

III. DEFINITION AND NATURAL HISTORY OF DEGENERATIVE LUMBAR SPINAL STENOSIS

What is the best working definition of degenerative lumbar spinal stenosis?

Lumbar spinal stenosis describes a clinical syndrome of buttock or lower extremity pain, which may occur with or without back pain, associated with diminished space available for the neural and vascular elements in the lumbar spine. Symptomatic lumbar spinal stenosis has certain characteristic provocative and palliative features. Provocative features include exercise or positionally-induced neurogenic claudication. Palliative features commonly include symptomatic relief with forward flexion, sitting and/or recumbency.

Workgroup Consensus Statement

What is the natural history of degenerative lumbar spinal stenosis?

The natural history of patients with clinically mild to moderate degenerative lumbar stenosis can be favorable in about one third to one half of patients.

Level of Evidence: II

In order to perform a systematic review of the literature regarding the natural history of patients with lumbar stenosis, a definition of lumbar stenosis was developed by consensus following a global review of the literature and definitive texts, and used as the standard for comparison of treatment groups. In order for a study to be considered relevant to the discussion, the patient population needed to fit this definition of lumbar stenosis which includes both clinical and radiographic features. The Levels of Evidence for Primary Research Questions grading scale *(Appendix B)* was used to rate the level of evidence provided by each article with a relevant patient population. The diagnosis of lumbar stenosis was examined for its utility as a prognostic factor. The central question asked was: "What happens to patients with lumbar stenosis who do not receive treatment?"

One study was determined to provide Level II medical evidence and four studies were determined to provide Level IV medical evidence. These are discussed below. Several prominent articles were discarded because of methodological flaws or issues with patient populations. A brief description of these papers is included as well. When the same data were presented in multiple reports, the primary reference was selected for review.

Amundsen and Weber[1] reported the outcomes observed in a group of 18 patients which served as the control arm for a prospective study of surgical treatment of lumbar stenosis. These patients had moderate symptoms of stenosis and were determined to be surgical candidates. An additional nonrandomized 50 patients with mild symptoms were also followed prospectively. All patients were followed for 10 years. These authors assessed subjective, patient-rated outcomes; opinion of examining physician; pain (Visual Analog Scale), working ability and walking ability; level of physical activity at leisure; and change in physical findings. Claudication was defined by median walking distance using a four-tiered classification system.

These authors reported that of the 18 patients with moderate symptoms, 56% (10 of 18) were worse at six months. At the 10-year mark, of the patients randomized to medical/interventional treatment (the control group), nine had crossed over to the surgical group. Seventy-five percent (6 of 8) reported moderate to severe pain and 25% (2 of 8) had light to mild pain. Of the original 50 patients with mild disease, 56% (15 of 27) had moderate to severe pain and 44% (12 of 27) had light to mild pain at 10 years. Significant crossover of patients occurred in both groups. Of patients randomized to medical/interventional treatment, 56% (10 of 18) crossed over to the surgical group. The authors did not note an association between radiographic findings and ultimate outcome. As a prospective, cohort study with less than 80% follow-up, this study provides Level II prognostic evidence for the natural history of patients with lumbar stenosis.

Hurri et al [17] retrospectively reviewed the outcomes of 75 patients with radiographically diagnosed lumbar spinal stenosis. Functional myelography was used to diagnose moderate and severe spinal stenosis. CT and MRI were not available in the timeframe of the study's index collection period. Severe encroachment was defined as less than 7.0 mm sagittal diameter. A medical/interventional treatment was applied to 18 of the patients. The authors did not discuss the details of this treatment. All patients were followed for 12 years. Outcome assessment used a structured questionnaire and the Oswestry Disability Index (ODI) to assess the low back disability in this case series.

Major subjective complaints were numbness elicited by walking, back pain, deficient sensation and leg weakness. Greater degrees of radiographic stenosis resulted in poorer outcomes. The outcomes in the medical/interventional treatment group showed that 44% (8 of 18) of the patients reported at least slight improvement. Eleven percent (2 of 18) of the patients worsened over time.

This paper is limited by the nonstandardized treatment and failure to stratify outcomes such as claudication, neurologic function and pain. The only reported outcome that allowed subgroup analysis of the medical/interventional group was ODI. The strengths of this study include its long follow-up and use of the ODI as an outcome measure. As a case series, this study provides Level IV evidence for the natural history of patients with lumbar stenosis.

As part of a retrospective comparison to the results of surgery, Johnsson et al[20] documented the outcomes of 19 untreated patients with lumbar spinal stenosis who were followed for an average of 31 months. No treatment was selected for those patients who were deemed unfit for surgery for medical reasons or who simply declined an operation. All patients had myelographically documented moderate to severe narrowing of the spinal canal with a mean anteroposterior diameter of 8.6 mm. Sixteen patients had neurogenic claudication, two had radicular symptoms and one had mixed claudicant-radicular symptoms. Outcomes measured were pain (assessed by a tiered system), walking capacity and patient reports of clinical symptoms as improved, unchanged or worse.

At final follow-up, walking capacity was minimally improved. Pain was rated as mild in four patients (21%), moderate in 14 patients (74%) and severe in one patient. Of the 16 patients with neurogenic claudication, approximately 31% (6 of 16) reported that their clinical symptoms improved at final follow-up. Both patients with only radicular symptoms reported improvement; the one patient with mixed symptoms reported no improvement. The authors concluded that 30% of untreated patients were improved and 60% were unchanged. In critique of this study, the population was identified retrospectively based on a final outcome of not having undergone surgery. With this inherent bias, it is not possible to determine how many patients had initially refused surgery but eventually underwent an operation. In addition, the investigators did not employ a disease-specific validated outcomes instrument. This case series provides Level IV prognostic evidence regarding the natural history of patients with lumbar stenosis.

Herno et al[16] retrospectively reviewed 54 patients with myelogram-documented spinal stenosis managed without surgery. These patients were selected individually to represent "matched pair controls" for a corresponding group of patients who were treated with surgical decompression. Patients were evaluated using the Oswestry questionnaire at an average of 4.3 years after the index myelogram. The "functional status" of the patients was evaluated by clinical examination and observation of activities of daily living, including rising from a chair, walking, walking on tiptoes and on the heels, crouching, undressing and getting on the examination table. The functional status of each patient was rated as either good or poor. The functional status in the medical/interventional group was described as "very good." The authors concluded that medical/interventional treatment is a reasonable option for those patients with moderate radiological stenosis.

The initial clinical status of these patients at the time of the index myelogram was unknown. The study was judged to provide Level IV evidence. No definitive conclusions regarding the natural history of lumbar stenosis can be drawn from this Level IV study.

As part of a prospective comparison to surgery, Mariconda et al[22] reported the outcomes of medical/interventional treatment of 22 patients with lumbar spinal stenosis. The clinical inclusion criterion was mild to moderate unilateral lower extremity pain. The radiographic inclusion

criterion was central spinal canal narrowing less than 130 mm^2. Patients with severe symptoms and lateral recess stenosis alone were excluded. Fourteen patients were randomized to the medical/interventional group. Eight patients who refused randomization chose medical/interventional care. Outcome was measured with the Beaujon Scoring System, which is a disease-specific outcomes instrument. Two patients were lost to follow-up. Two of the 22 patients underwent surgery before final follow-up. While 30% of patients reported that they were satisfied with medical/interventional treatment, there was no appreciable change in the Beaujon Scoring System values. In critique of this study, the medical/interventional group consisted of patients who refused surgical treatment during the randomization process and those who were randomized to medical/interventional treatment. Furthermore, the details of the medical/interventional treatment were not provided. With these limitations, the study provides Level IV prognostic evidence concerning the natural history of lumbar spinal stenosis.

During the performance of the literature review related to natural history of lumbar spinal stenosis, a series of important and often quoted articles were evaluated for possible inclusion in this guideline. Collectively, this series of articles reported results at various points in time of what has become commonly referred to as the *Maine Lumbar Spine Study*.[2,3,4,5,6,9] While these papers clearly document the natural history of a group of patients who did not receive surgical intervention for lumbar spinal stenosis, the patient samples contain patients with stenosis and patients with disc herniation. As a result, these reports do not allow subgroup analysis and could not be used as evidence regarding the natural history of patients with lumbar spinal stenosis. These papers are included in the evidentiary table (Appendix F).

An additional, often quoted article, the *Cochrane Review on Surgery for Lumbar Spondylosis,*[15] is noted in the Natural History Evidentiary Table for Degenerative Lumbar Spinal Stenosis but not included in the guideline. This Cochrane review addresses surgical outcomes and only references two articles containing evidence regarding the natural history of patients with lumbar spinal stenosis. Both of these references are included in the evidentiary table and discussed in this guideline, thus a discussion of the Cochrane review is not included in the guideline.

A secondary evidentiary table is presented that includes studies that were reviewed but cited separately from the primary table, because the comparison/control group in these studies underwent multiple medical/interventional therapies. These cointerventions were not adequately described and may have had some impact, thus limiting the ability to draw conclusions about the natural history of spinal stenosis. The outcomes of these treated comparison groups were similar and generally favorable, with the exception of those described by Zucherman et al,[33] whose medical/interventional treatment comparison group had a poorer outcome relative to other similarly treated groups in the literature. It should be noted that Zucherman et al used validated outcome measures not employed by the other authors. The lack of standardized outcome measures used in this set of papers and the diversity of medical/interventional therapies

make it difficult to draw conclusions regarding the natural history of patients with lumbar spinal stenosis.

It should also be noted that all the series reviewed above excluded patients with severe symptoms who were regarded as candidates for surgery. Therefore, the conclusions drawn from these reports regarding the natural history of patients with lumbar spinal stenosis are only applicable to patients with mild to moderate clinical symptoms. The natural history of medically/interventionally treated patients with clinically severe lumbar spinal stenosis is not described in the literature; therefore, no conclusions can be drawn about this patient population.

In patients with mild or moderate degenerative lumbar stenosis, rapid or catastrophic neurologic decline is rare.

Level of Evidence: II

The literature evaluated for the degenerative lumbar spinal stenosis guideline project included numerous reports describing the clinical course of patients with mild to moderate spinal stenosis. None of these reports described rapid or catastrophic neurologic decline in patients identified with mild or moderate lumbar spinal stenosis. While anecdotal experience may indicate the possibility of such a decline, evidence suggests that the occurrence of such a decline is exceedingly rare.[1-33]

Information in the literature is insufficient about the natural history of clinically or radiographically severe degenerative lumbar stenosis.

Level of Evidence: V (Consensus Statement)

It should be noted that all the series reviewed above excluded patients with severe symptoms who were regarded as candidates for surgery. Therefore, the conclusions drawn from these reports regarding the natural history of patients with lumbar spinal stenosis are only applicable to patients with mild or moderate clinical symptoms. The natural history of medically/interventionally treated patients with clinically severe lumbar spinal stenosis is not described in the literature; therefore, no conclusions can be drawn about this patient population.

Future Directions for Research

The work group identified the following potential studies, which could generate meaningful evidence to assist in further defining the natural history of degenerative lumbar spinal stenosis.

Recommendation #1:

A prospective study of untreated patients, all with lumbar stenosis of a moderate degree, would provide Level I evidence regarding the natural history of the disease. This study could include stratification as to type of stenosis (ie, central vs subarticular vs foraminal), and evaluate progression of radiographic severity and clinical severity over time.

Recommendation #2:

Any systematic study of patients with untreated severe stenosis would provide evidence regarding the natural history of the disease in this patient population. For example, defining and following a group of patients with severe lumbar stenosis that has not been treated would yield Level I evidence.

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IV. RECOMMENDATIONS FOR DIAGNOSIS AND TREATMENT OF DEGENERATIVE LUMBAR SPINAL STENOSIS

A. Diagnosis and Imaging

Assessing Evidence for Diagnostic Tests

Assessing the evidence for diagnostic tests poses some difficulties that are not seen in therapeutic studies. In the assessment of diagnostic tests, both accuracy and the effect of testing on outcome should be considered. The accuracy of a diagnostic test refers to the ability of the examination to detect and characterize pathologic processes. Accuracy is typically expressed in terms of sensitivity and specificity - sensitivity referring to the proportion of patients with the target disorder who will have a positive test, and specificity to the number of people without the disease who have a negative test.[4] With tests that have a high sensitivity, a negative test effectively rules out the disease. With tests that have a high specificity, a positive test effectively rules in the disease.

The performance of a test in a given population can also be stated in terms of positive and negative predictive value, which depends directly on the prevalence of disease in the tested population.[4] In populations with a high prevalence of disease, a test with a high accuracy will accurately predict the presence of disease. Conversely, the same test result will yield a large percentage of false positives in patient populations with a low incidence of disease (such as an asymptomatic population). One of the purposes of a history and physical examination is to increase the prevalence of disease in patients sent for advanced testing. For this reason, in our systematic review, we have attempted to identify those symptoms or findings which have a high likelihood ratio for lumbar spinal stenosis---those symptoms or findings expected in patients diagnosed with lumbar spinal stenosis, but not in those who do not have lumbar spinal stenosis. The use of these criteria should increase the prevalence of this disease in the population sent for cross-sectional imaging.[4] Positive CT or MRI findings in this population will have greater relevance relative to treatment and should lead to better outcomes.

Cross-sectional imaging exams have a low intrinsic specificity as evidenced by a significant incidence of stenosis and other pathologic findings in asymptomatic populations.[1,5] The results of any cross-sectional examination need to be closely correlated with the clinical examination. As a result, the accuracy of a spine MRI or CT should incorporate the ability of the test to directly visualize neurologic structures and the effect of pathologic processes on these structures. Direct

visualization of intrinsic neurologic processes and neural impingement is of obvious importance in determining the etiology of myelopathic and radicular symptoms.

The gold standard in the majority of the studies testing the accuracy of a cross-sectional imaging exam is surgery. The validity of surgery as a gold standard for the assessment of stenosis can be questioned, however, as findings at surgery can be subjective. The degree or severity of central stenosis can also be difficult to quantify at surgery as decompression often precedes direct examination of the central canal. For these reasons, a case can be made to use the best available cross-sectional imaging exam as a gold standard; however, this too can be problematic.

Outcome can also be used as a gold standard in the assessment of a diagnostic exam. The assessment of a diagnostic exam in this manner is obviously confounded by the type of treatment applied, the skill of the treating physician and patient psychosocial variables among other factors. Outcome studies can be very useful, however, in assessing the appropriate utilization of cross-sectional imaging. For example, two Level I studies have recently been published concerning the use of Rapid MRI.[2,3] In these studies, the value of obtaining an early MRI in the management of patients with low back pain was assessed using various outcome measures, including pain level, patient preference, patient satisfaction and cost or resource use. Each of these studies showed limited, if any, benefit in obtaining an MRI early in the course of a patient's treatment. Studies of this type were uncommon in our review, but are of obvious importance given rising health care costs.

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What are the most appropriate historical and physical findings consistent with the diagnosis of degenerative lumbar spinal stenosis?

Lumbar spinal stenosis should be considered in older patients presenting with a history of severe lower extremity pain which improves or resolves with sitting and postural abnormalities on physical examination such as a wide-based gait. Physical findings adding to this consideration include an abnormal Romberg test, thigh pain exacerbated with extension and neuromuscular deficits. Patients whose pain is not made worse with walking have a low likelihood of stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Katz et al[17] conducted a study assessing the value of historical and physical findings in the diagnosis of lumbar spinal stenosis. The study included 93 consecutive patients evaluated in a spine center. All patients underwent a standardized history and physical examination. Lumbar spinal stenosis was diagnosed in 46% (43 of 93) of patients by expert physician assessment with at least 80% confidence. The remaining patients had diagnoses including nonspecific musculoskeletal pain, scoliosis, spondylolisthesis and fibromyalgia. Imaging was available in 88% of patients with lumbar spinal stenosis and confirmed the diagnosis.

Historical findings most strongly associated with lumbar spinal stenosis, with a likelihood ratio (LR) greater than two, were greater age (LR 2.5), severe lower extremity pain (LR 2.0), absence of pain when seated (LR 6.6), and improvement of pain with sitting (LR 3.1). Symptoms worse with walking had a negative likelihood ratio of 0.96. Physical findings most strongly associated with lumbar spinal stenosis were wide-based gait (LR 14.3), abnormal Romberg test (LR 4.3), thigh pain after 30 seconds of lumbar extension (LR 2.5) and neuromuscular deficits (LR 2.1). Independent correlates of lumbar spinal stenosis were advanced age, wide-based gait and thigh pain with lumbar extension. The authors concluded that the history and physical examination were useful in the diagnosis of lumbar spinal stenosis.

In critique, this study relies on expert opinion as the "gold standard" for the diagnosis of lumbar spinal stenosis with radiographic confirmation in just 88% of patients. These patients were compared to patients with other clinical diagnoses without imaging. This comparative patient population is not well described. This study provides Level IV evidence that the diagnosis of lumbar spinal stenosis is suggested by greater age, severe lower extremity pain, absence of extremity pain when seated and/or improvement of pain when seated as well as lower extremity pain with spinal extension greater than 30°, an abnormal Romberg test and wide-based gait.

Additional Diagnostic and Imaging Considerations

Diagnostic Papers on Clinical Diagnostic Testing

The work group for this guideline identified several reports on the use of clinical diagnostic testing in the diagnosis of lumbar spinal stenosis. These techniques generally utilize measures of walking tolerance, time for onset of pain with exercise and recovery time. Several studies utilized treadmill or bicycle testing and attempted to measure the effect of posture on exercise tolerance. The utility of these tests can be limited, however, by the ability of sometimes frail elderly patients to complete testing. The results of several studies, such as the study by Fritz et al described below, are promising. Testing protocols are heterogeneous, however, and many have not been critically studied.

Fritz et al[9] reported on the initial experience with the two-stage exercise treadmill test (ETT) in the differential diagnosis of patients with low back pain, lower extremity pain and self-reported deficits in walking tolerance. The authors hypothesized that the findings on ETT would discriminate between stenotic and nonstenotic patients. Forty-five patients with low back pain, lower extremity pain and self-reported limitations in walking tolerance were studied with MRI or CT, Oswestry Disability Index (ODI), Visual Analog Scale (VAS), three self-reported postural variables and two-stage ETT. Based on imaging, all patients were classified as stenotic or nonstenotic (HNP, etc).

The authors reported that a linear discriminant analysis using time to onset of symptoms and recovery time resulted in a likelihood ratio of 14.5. Likelihood ratios on self-reported variables were much lower (<2.0). The authors concluded that a two-stage treadmill test may be useful in the differential diagnosis of lumbar stenosis. In critique, it was not clearly stated whether the patients were consecutively selected and there was no consistently applied and agreed upon gold standard. This study provides Level III diagnostic evidence that a two-stage treadmill test may be useful in the differential diagnosis of lumbar stenosis.

The work group concluded that while studies are limited, clinical diagnostic testing may be useful in selected patients to differentiate neurogenic from vascular causes of claudication.

Future Directions for Research

The work group identified the following potential studies that might generate meaningful evidence to assist in further defining the appropriate historical and physical findings consistent with the diagnosis of lumbar spinal stenosis.

Recommendation #1:

> A sufficiently powered observational study of the predictive value of historical and physical findings in patients with the diagnosis of lumbar spinal stenosis is proposed.

The study should utilize validated outcome instruments, such as the Zurich Claudication Questionnaire (ZCQ) and the VAS for back and leg pain, and CT myelography or MRI as the gold standard.

Recommendation #2.

A prognostic study with long-term follow-up of up to 10 years could be performed on the cohort of spinal stenosis patients defined in Study #1.

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Diagnosing Spinal Stenosis with Imaging

Limitations and Assumptions in MRI Studies

The results of this systematic review may not apply to all MRI systems. In general, the studies cited in this guideline utilized mid or high field strength MRI systems with dedicated surface coils. Their findings and the ensuing guideline's may not apply to low field strength systems. Only one study in our series, performed by Cihangiroglu et al, [12] evaluated both low and high field strength systems. This study showed that the interobserver variability was increased with use of the low field strength system and the authors recommended that a high field strength system should be used whenever anatomic detail is necessary for surgical planning. Additional research studies need to be performed to evaluate the performance of low field strength MRI relative to high field strength MRI, state-of the-art CT and CT myelography.

The results of our systematic review also assume adequate or state-of-the-art technique. MRI, and to a lesser extent CT, are user-dependent. The MRI studies cited in this guideline, in general, utilized thin (4-5 mm) sections and a combination of T1-, proton density and T2 pulse sequences in both the axial and sagittal planes. State-of-the-art protocols should utilize thin sections and provide excellent signal-to-noise ratios with high in-plane resolution. With routine indications, stacked axial sections should be obtained and should include at least the L5-S1, L4-5, L3-4 levels. Additional angled or stacked axial sections can be obtained through adjacent or more cephalad levels as indicated.

Evolution of Imaging Technology

Both CT and MRI technology have evolved and continue to evolve over time. In our review, early developmental studies were discarded because they did not use surface coils or because thick (10 mm) sections were used. The studies cited above, however, do not reflect more recent improvements in MRI and CT technologies. MRI coils, gradients and imaging sequences have continued to improve, and have resulted in further increases in signal-to-noise and further decreases in scan times. New sequences have been introduced, and most MRI centers now utilize multi-echo spin echo sequences for routine PD and T2-weighted imaging. STIR and T2 fat saturation images are also frequently used and may increase the sensitivity of MRI for inflammatory, neoplastic and traumatic pathologies.

CT technologies have also evolved. While one study (not included in the evidentiary tables) evaluated the application of helical scanning to spine imaging, no studies were identified which utilized more current 8 or 16 multidetector technologies. These technologies have resulted in a marked decrease in imaging times and many CT centers now routinely utilize 1 or 2 mm sections in the evaluation of the spine. The use of thin section technique has decreased partial voluming artifact, has improved the quality of sagittal reformations and has improved the abil-

ity of CT to evaluate the integrity of lumbar fusions. The impact of these technologies on overall accuracy needs to be studied.

While the accuracy of a state-of-the-art MRI system has not been compared to a state-of-the-art CT system in routine clinical imaging, the technical improvements in each modality have tended to parallel each other and the modalities remain complementary. MRI continues to provide superior soft tissue contrast with excellent visualization of soft tissue pathology, the dural sac interface and neural elements. CT continues to be more sensitive for calcified structures and provides better visualization of both structural integrity and bridging bone. MRI remains a nonionizing modality, while with CT, the dose of ionizing radiation may be increased with routine utilization of 1 or 2 mm sections. A masked, randomized, controlled study comparing the benefits of these two modalities would clarify the impact of these developments on their relative accuracy.

The evolution of MRI technologies has also resulted in the development of "open" MRI systems, small contained MRI systems for placement in a doctor's "back office" and upright MRI systems. Evolution is not always synonymous with improved quality, however, and both the accuracy and efficacy of these new systems also need to be evaluated.

What are the most appropriate diagnostic tests for degenerative lumbar spinal stenosis?

The most appropriate, noninvasive test for imaging degenerative lumbar spinal stenosis is MRI.

Grade of Recommendation: B

Bischoff et al[7] conducted a comparative study of the findings of MRI, myelography and CT myelography with intraoperative findings in 119 levels in 57 patients. They describe specificity and sensitivity values for these studies relative to operative findings. In making the diagnosis of lumbar spinal stenosis, CT myelography and MRI were equally accurate (85%), whereas myelography was the most specific (81%).

In critique of this study, the nonconsecutive patient population was limited to the 12% (59 of 475) of the available patients who had surgery and all three imaging studies preoperatively. This may present a selection bias toward patients with more difficult diagnoses. The interpretation of intraoperative findings was subjective. Also, Figure 1, as included in the article, demonstrates a very subtle degree of stenosis, interpreted as positive by the authors, raising a question about threshold. This study provides Level III evidence that the accuracy of CT myelography and MRI are comparable in the diagnosis of lumbar spinal stenosis.

Bolender et al[9] performed a study comparing the intraoperative findings, as the gold standard, with myelography (with extension) and CT. The study population included 24 patients with lumbar spinal stenosis confirmed by surgical exploration and 30 patients with abdominal CT scans performed for other reasons.

The anteroposterior (AP) diameter of the osseous canal on CT correlated with surgical findings in only 20% of cases. The AP diameter of the dural sac on myelography correlated with surgical findings in 83% of cases. The effectiveness of CT was improved by using the dural sac cross-sectional diameter. The authors proposed that a dural sac area (DSA) of 100 mm^2 was unequivocal evidence of stenosis, and concluded that myelography was more sensitive than CT and that CT assessment of the DSA was more accurate than measurement of bony diameter of the spinal canal.

In critique of the study, criteria for the intraoperative diagnosis of central stenosis were not detailed. Furthermore, CT technology has evolved significantly since this study was published. This study provides Level II evidence that the dimensions of the bony canal may significantly underestimate the severity of canal narrowing caused by soft tissue. The AP diameter of the dural sac on myelography and the dural sac area on CT represent better measures of central canal stenosis.

Jia et al[45] conducted a prospective comparison of MRI to myelography in 78 nonconsecutive patients who had surgery. Findings on MRI and myelography were compared with operative findings as the gold standard. MRI provided an accurate diagnosis in 85.2% of cases and myelography in 90% of cases. The authors found that MRI was as good as myelography for the diagnosis of herniated discs, and recommend MRI because it is noninvasive and nonionizing.

In critique of this early study, details of the raw data were not provided. This study provides Level III evidence that MRI is as good as myelography for the diagnosis of herniated discs or stenosis in the majority of patients.

Kent et al[49] performed a systematic review assessing the accuracy of CT, MRI and myelography in diagnosing patients with lumbar spinal stenosis. This meta-analysis identified 14/116 relevant studies with a reference standard other than another imaging test. All studies received a grade of C or D as a result of failure to assemble a representative cohort, small sample size or failure to maintain independent readings. The sensitivity of MRI in the diagnosis of adult spinal stenosis was 81-97%, sensitivity of CT was 70-100% and sensitivity of myelography was 67-78%.

In critique, although the results from the cited studies were difficult to pool, this was a thorough meta-analysis of literature from 1986 to 1991. This study provides Level II evidence sug-

gesting that each of these diagnostic studies is useful, and that none of the three is unequivocally superior in the diagnosis of adult lumbar spinal stenosis.

Modic et al[56] conducted a comparative study of surface coil MRI, CT and X-ray myelography in 60 consecutive patients with a clinical suspicion of a lumbar disc herniation or stenosis who were being evaluated for surgery. MRI was performed in every patient with surface coil technique. Myelography, CT or CT myelography (CTM) was performed in subsets of patients. Forty-eight patients were operated on at 62 levels with surgical findings as the gold standard. Masked interpretations of the imaging procedures were compared to each other and to the results of surgery. There was 86.8% agreement between MRI and CT/CTM at 151 levels. With respect to surgical findings, the accuracy for MRI was 82%, CT/CTM was 83% and myelography was 71%. In addition, myelography missed one metastatic lesion and CT missed an ependymoma. Findings on CT and MRI were complementary, however, as the diagnostic accuracy increased when studies were used in combination.

In critique, testing of patients was not uniform in that subset of patients who underwent CT and myelography, which introduces potential bias as the patients may have been referred for specific tests depending on the suspected pathology. Not every patient underwent surgery, and the criteria for a surgical diagnosis were not specified. This study provides Level III evidence that the accuracy of MRI and CT is comparable in the diagnosis of lumbar disc herniation and stenosis in patients who undergo surgery.

Postacchini et al[63] performed a study to evaluate the MRI findings and compare the diagnostic accuracy of this method of imaging with that of water soluble myelography and CT scanning in patients with stenosis of the spinal canal.

Twenty-two patients received myelography, CT and MRI. All patients had symptoms in lower limbs, and two had undergone previous surgery. Fifteen had MRI first; seven had myelography and/or CT first. Myelogram and CT were performed on separate occasions (ie, no postmyelographic CT done). MRI was performed with a 1.5T machine and CT was performed with 2-5 mm cuts. All studies were interpreted by a single-masked neuroradiologist. Patients were divided into two groups according to myelography findings. Group 1 consisted of 19 patients whose myelogram showed compression caused by stenosis; group 2 consisted of three patients with scoliosis with stenosis on MRI with negative myelogram. Stenosis was defined as a cross-sectional area of the dural tube less than 120 mm^2.

The authors reported that a complete block on myelogram always corresponded to a complete interruption of the dural sac on MRI, but that a partial block on myelogram was often interpreted as a complete block on MRI findings. MRI gave no false negatives. The noncontrast CT was then compared to MRI, but not to the myelogram. Of the 13 cases, five showed stenosis

on MRI, but not CT. The authors concluded that spinal canal stenosis surgery may be planned on the basis of MRI findings alone, except in scoliotic patients.

In critique, the study had a small sample size, with only three patients diagnosed with scoliosis. The CTs and myelograms were performed on separate occasions. This study provides Level III evidence that MRI is as sensitive but not as specific as myelography in the diagnosis of lumbar spinal stenosis. Furthermore, in this study MRI was shown to be more accurate than CT in diagnosis of stenosis.

Schnebel et al[76] conducted a retrospective comparison of imaging studies in patients with lumbar spinal stenosis. A single reader compared MRI and CT myelogram findings in 41 patients, of which eight had surgically confirmed stenosis and six had neurogenic claudication. The ability of CTM and MRI to detect disc degeneration, stenosis and spondylolisthesis was assessed and compared. MRI and CTM correlated in 96.6% of lumbar spinal stenosis cases. MRI was superior to CTM in demonstrating disc degeneration. The authors concluded that MRI is the imaging method of choice in patients with suspected lumbar spinal stenosis.

In critique, this is a retrospective comparison of CTM and MRI read by one individual in a small number of patients with lumbar spinal stenosis, demonstrating excellent correlation between the two methods. This study provides Level III evidence that MRI and CTM provide similar information in patients with lumbar spinal stenosis.

CT myelography is a useful study in patients who have a contraindication to MRI, for whom MRI findings are inconclusive or in patients for whom there is a poor correlation between symptoms and MRI findings.

Grade of Recommendation: B

Bischoff et al[7] performed a comparative study of the findings of MRI, myelography and CT myelography with intraoperative findings in 119 levels in 57 patients. They describe specificity and sensitivity values for these studies relative to operative findings. In making the diagnosis of lumbar spinal stenosis, CT myelography and MRI were equally accurate (85%), whereas myelography was the most specific (81%).

In critique of this study, the nonconsecutive patient population was limited to the 12% (59 of 475) of the available patients who had surgery and all three imaging studies preoperatively. This may present a selection bias toward patients with more difficult diagnoses. The interpretation of intra-operative findings was subjective. Also, Figure 1 within the article demonstrates a very subtle degree of stenosis, interpreted as positive by the authors, raising question about

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There was 86.8% agreement between MRI and CT/CTM at 151 levels. With respect to surgical findings, the accuracy for MRI was 82%, CT/CTM was 83% and myelography was 71%. Myelography missed one metastatic lesion and CT missed an ependymoma. Findings on CT and MRI were complementary, however, as the diagnostic accuracy increased when studies were used in combination.

In critique, testing of patients was not uniform in that subset of patients who underwent CT and myelography, which introduces potential bias as the patients may have been referred for specific tests depending on the suspected pathology. Not every patient underwent surgery, and the criteria for a surgical diagnosis were not specified. This study provides Level III evidence that the accuracy of MRI and CT is comparable in the diagnosis of lumbar disc herniation and stenosis in patients who undergo surgery.

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In critique, this is a retrospective comparison of CTM and MRI in a small number of patients with lumbar spinal stenosis demonstrating excellent correlation between the two methods. This study provides Level III evidence that MRI and CTM provide similar information in patients with lumbar spinal stenosis.

CT is a useful noninvasive study in patients who have a contraindication to MRI, for whom MRI findings are inconclusive or for whom there is a poor correlation between symptoms and MRI findings, and in whom CT myelogram is deemed inappropriate.

Grade of Recommendation: B

Bell et al[6] conducted a prospective comparison of metrizamide myelography and noncontrasted (not postmyelogram) CT to intraoperative findings. The authors developed a "correlation scale" to judge the degree of agreement between the imaging studies and surgical exploration among 122 patients with surgically-confirmed pathology. Masked readings of CT and myelographic images were compared with surgical findings. The strength of correlation was assessed. The details of the CT technique were not specified.

Based on their data, the authors concluded that myelography was 93% accurate and CT was 89% accurate in the diagnosis of lumbar spinal stenosis. The authors concluded that myelography is more accurate than CT in the diagnosis of stenosis.

In critique, site specific findings showed no significant difference between CT and myelography (67% and 68% accurate, respectively) in diagnosing spinal stenosis. This study provides Level II evidence that the accuracy of CT and myelography in the diagnosis of lumbar spinal stenosis is comparable.

Bolender et al[9] conducted a study comparing the intraoperative findings, as the gold standard, with myelography (with extension views) and CT. The study population included 24 patients with lumbar spinal stenosis confirmed by surgical exploration and 30 patients with abdominal CT scans performed for other reasons.

The AP diameter of the osseous canal on CT correlated with surgical findings in only 20% of cases. On the other hand, the AP diameter of the dural sac on myelography correlated with surgical findings in 83% of cases. The effectiveness of CT was improved by using the dural sac cross-sectional diameter. The authors proposed that a dural sac area (DSA) of 100 mm^2 was unequivocal evidence of stenosis, and concluded that myelography was more sensitive than CT and that CT assessment of the DSA was more accurate than measurement of bony diameter of the spinal canal.

In critique of the study, criteria for the intraoperative diagnosis of central stenosis were not detailed. CT technology has evolved significantly since this study was published. This study provides Level II evidence that the dimensions of the bony canal may significantly underestimate the severity of canal narrowing possibly caused by soft tissue. The AP diameter of the

dural sac on myelography and the dural sac area on CT represent better measures of central canal stenosis.

Herkowitz et al[33] described the use of CT in the evaluation of levels caudad to a complete, or near complete, myelographic block in 32 patients. They found that CT provided clinically useful information that was confirmed at the time of surgery. Sixty percent of the nonvisualized levels showed stenosis or a herniated disc that was confirmed at surgery.

In critique, this was an early study showing the value of CT in addition to myelogram in evaluating the spinal canal. This study provides Level II evidence that CT can provide useful information about levels below a myelographic block.

Johanson et al[47] performed a prospective study of X-ray myelography compared to noncontrast CT performed in 1986 on a nonconsecutive series of 30 patients who presented with clinical symptoms of a mononeuropathy, in which an isolated myelogram revealed a unilateral shortening of a nerve root sheath. After an average of six days, the same patients were imaged by CT. In 18 of these patients, the isolated myelogram was interpreted as evidence for lateral recess spinal stenosis; eight of these 18 had the diagnosis changed to "lateral disc herniation" when the CT images were reviewed.

In critique, this early report describes a nonconsecutive series of patients, and does not apply a clear gold standard. This early study presents Level III evidence that X-ray myelography may allow some isolated root compression, actually caused by a disc herniation, to be misinterpreted as lateral recess stenosis. Noncontrast CT imaging may be more useful than X-ray myelography in the assessment of the etiology of nerve root compression in the lateral recess.

Kent et al[49] conducted a systematic review assessing the accuracy of CT, MRI and myelography in diagnosing patients with lumbar spinal stenosis. This meta-analysis identified 14/116 relevant studies with a reference standard other than another imaging test. All studies received a grade of C or D because of a failure to assemble a representative cohort, small sample size or failure to maintain independent readings. The sensitivity of MRI in the diagnosis of adult spinal stenosis was 81-97%, sensitivity of CT was 70-100% and sensitivity of myelography was 67-78%.

In critique, although the results from the cited studies were difficult to pool, this was a thorough meta-analysis of literature from 1986 to 1991. This study provides Level II evidence (based on the levels of evidence of the studies reviewed) suggesting that each of these diagnostic studies are useful, and that none of the three is unequivocally superior in the diagnosis of adult lumbar spinal stenosis.

Risius et al[72] reported the findings in 25 patients with negative myelography and abnormalities within the neural foramina on CT. The authors utilized a grading system assessing a decrease in the size of the neural foramen and the effacement of perineural fat in the neural foramina and compared these findings to the results at surgery in a subset of patients. In 24 of the 25 patients, the CT abnormality corresponded to the side of the patient's symptoms. Fourteen patients underwent surgery and 11 experienced excellent results. The authors concluded that abnormalities within the neural foramen on CT should be operated on if they correlate with the patient's symptoms.

In critique, this study had a small number of patients that were selected because of a discrepancy in the findings, and offers no mention of sensitivity or specificity. This study provides Level IV evidence that CT can detect abnormalities in the neural foramen not seen on myelography.

Additional Diagnostic and Imaging Considerations

Diagnostic Papers on Postural Adjustment During Diagnostic Imaging

The work group for this guideline identified several techniques utilized to increase sensitivity to the presence of spinal stenosis. These techniques are collectively referred to as postural adjustment techniques and have been applied in different manners to myelography, CT scanning and MRI scanning. Papers on these techniques are heterogeneous and the techniques themselves have not been critically studied. However, postural adjustment techniques appear to have diagnostic value potentially. These papers are commented upon below.

Sortland et al[82] reported the results of static and dynamic (flexion and extension) water-based myelography in patients with a clinical diagnosis of spinal stenosis. The results were compared to those of a control group of patients with complaints of back pain or sciatica, without a diagnosis of spinal stenosis. This Level IV study noted that patients with a clinical presentation of spinal stenosis frequently demonstrated narrowing of the canal that worsened significantly in extension. In eight of the 36 stenosis patients, a complete myelographic block was seen on the images obtained in extension but not on myelographic images with the patient in the neutral position. In contrast, only small differences in canal dimensions with flexion and extension were noted in the control group.

Similar findings were reported in other Level IV reports.[52,60,92,95,96] All of these authors reported that in some patients, imaging obtained in the flexed or extended position might reveal spinal canal narrowing not documented by static imaging. Unfortunately, there are no evidence-based conclusions available to specifically correlate these observations with clinical symptoms or patient outcomes.

Several authors have also reported significant changes in the dural sac cross-sectional area with axial loading on CT and MRI.[18,55,93,94] Willen et al, [93] in a study of 172 patients, reported significant changes on axial CT in 69% of patients with neurogenic intermittent claudication, 14% of patients with sciatica and 0% of patients with isolated back pain. Again, the significance of these findings relative to patient prognosis or outcome has not been determined.

Electrodiagnostic Studies

Little evidence is dedicated to evaluating the utility of standard electrodiagnostic studies in lumbar spinal stenosis. In 2006, Haig et al[30] performed a prospective, masked, double-controlled trial of 150 patients to determine if electrodiagnostic studies relate to the clinical or radiographic diagnosis of lumbar spinal stenosis. This study utilized a paraspinal mapping technique described by Haig in 1997[29] and showed that electrodiagnostic findings were not significantly predictive of the clinical diagnosis. In addition, Molitor et al[58] determined that somatosensory evoked potentials were not helpful in the diagnosis of lumbar stenosis.

It is the consensus of this work group that, in isolated lumbar stenosis, electrodiagnostic studies do little to enhance the diagnosis or treatment of lumbar stenosis compared with history, physical examination and imaging studies. Electrodiagnostic studies are best utilized when there is concern about additional neurologic compromise, such as peripheral polyneuropathy. In addition, Molitor et al[58] determined that somatosensory evoked potentials were not helpful in the diagnosis of lumbar stenosis.

Observer Reliability

While not a focus of the imaging section of the lumbar spinal stenosis guideline, the issue of observer reliability in imaging is pertinent and is addressed by several articles derived from the primary literature search. Thus a separate, secondary evidentiary table on observer reliability was created to investigate these papers further.

Each study is well-designed with appropriate techniques of masking and the use of kappa statistics to evaluate the levels of inter-rater and intra-rater reliability. These studies, however, do not fit well into the Levels of Evidence Table as diagnostic studies. Rather the decision was made to consider these studies to be prognostic studies as defined in the Levels of Evidence Table.

The paper by Coste et al[13] is the oldest of these papers reviewed. The technology evaluated was CT scanning which, while improved since the publication date, was a mature technology in 1994. In this case control study, 20 patients with sciatica were compared to 20 gender and age-matched asymptomatic volunteers. All subjects were scanned at the lower two lumbar disc levels with 4 mm cuts and 1 mm overlap. The 40 scans were independently interpreted by two ra-

diologists and two rheumatologists, all of whom were masked. All the scans were re-read four months later in a masked fashion by the same individuals. Inter- and intra-rater reliabilities were assessed by kappa statistics.

Four diagnoses were considered: herniated nucleus pulposus (HNP), disc bulge, spinal stenosis and facet arthrosis. Only for a diagnosis of HNP was inter- and intra-rater reliability determined to be high by the Landis and Koch criteria employed with an inter-rater reliability of kappa=.7 and intra-rater reliability of kappa=.9. Both inter- and intra-rater reliability for disc bulge, spinal stenosis and facet arthrosis were poor. Reliability was the poorest for the diagnosis of spinal stenosis (inter-rater kappa=.20 at L5-S1 and intra-rater kappa=.38 at L-S1).

This study is considered to present Level I prognostic evidence that unenhanced CT scanning of the lumbar spine is useful only for the diagnosis of HNP and should not be used as the sole study to diagnose lumbar spinal stenosis.

A second study utilizing CT scans was published in 2000 by Drew et al[21] in which inter- and intra-rater reliability was tested in specifically diagnosing lumbar spinal stenosis. In this study, thirty CT scans were selected from a database by two neuroradiologists to represent normal to severally stenosed lumbar spines in patients not previously operated on. The scans contained both bony and soft-tissue windows, 3 mm cuts and sagittal reconstructions. These 30 scans were each reviewed in a masked fashion by four spinal surgeons and their findings recorded. All scans were re-read in a masked fashion by the same surgeons four weeks later.

Analysis of inter-and intra-rater reliability was represented by kappa statistics. There was moderate inter-rater agreement by the Landis and Koch criteria (kappa=.58 +/- 0.06) and intra-rater agreement (kappa=.59 +/- 0.04) on the overall presence or absence stenosis. However, when asked to assess the degree of stenosis on a 7-point scale, inter-rater agreement was poor (kappa=.26 +/- .04). Furthermore, inter-rater reliability worsened when stenosis was assessed from the central canal to the foramen (central stenosis: kappa=.46 +/- .04; lateral recess stenosis: kappa=.32 +/-.04 and foraminal stenosis: kappa=0.18 +/- .04). The authors concluded that the poor reliability of CT scans in diagnosing varying degrees of spinal stenosis brings into question the results of studies using this diagnostic test for this diagnosis.

The study is considered to present Level I prognostic evidence that CT scans are useful in the general diagnosis of lumbar spinal stenosis but not reliable in specifically identifying the level and type of stenosis present. These findings are consistent with the findings of Coste et al.[13]

Speciale et al[83] published an MRI study in 2002 asking questions similar to those in the two CT based studies cited above. In this study, fifteen MRI scans of the lumbar spine from patients diagnosed clinically with spinal stenosis were evaluated. All of the patients reported radiculopathy or claudication and 60% reported back pain. These MRIs were read in a masked fashion by

seven observers: two orthopedic spinal surgeons, two neurosurgeons and three neuroradiologists. The scans were re-read between two and three months after the initial reading, again in a masked fashion. Inter- and intra-rater reliable was estimated with kappa statistics.

Inter-rater reliability was fair by the Landis and Koch Scale (kappa=.26 +/-.26). Intra-rater reliability was poor overall (kappa=.11). These poor results were interpreted by the authors as stemming from the lack of clearly articulated MRI criteria to support diagnostic categories.

This study provides Level I prognostic evidence that observer reliability in diagnosing lumbar spinal stenosis by MRI is poor.

A second MRI study addressing observer reliability in diagnosing lumbar spinal stenosis was published in 2004 by Cihangiroglu et al.[12] In this study, 95 patients with acute low back pain or radiculopathy were prospectively studied by MRI on either 0.3 Tesla (57 patients) or 1.5 Tesla (38 patients) scanners. The lower three lumbar disc levels only were evaluated. Two independent and masked neuroradiologists read each study and then re-read each study, masked, 15 days later. Final diagnosis was by a consensus reading a third time by the same radiologists. Inter- and intra-rater reliability was assessed by kappa coefficients.

Inter- and intra-rater reliability was rated as "almost perfect" (kappa=.81-1.00) for detecting disc pathology; "substantial" (kappa=.61-.80) for defining the disc pathology; but only "moderate" (kappa= .41-.60) for diagnosing root compression and stenosis. For the more difficult root compression and stenosis diagnoses, the higher Tesla MRIs yielded slightly higher scores. The authors concluded that higher field machines should be used for surgical decision making and that MRI findings alone should not be used to make surgical decisions when stenosis is the diagnosis. This study provides Level I prognostic data showing large inter- and intra-rater variability in diagnosing root compression and spinal stenosis by MRI and supports the findings of Speciale et al.[83]

These four studies evaluating rater reliability in spinal imaging raise serious questions both about the clinical reliability of the diagnosis of lumbar spinal stenosis by CT and MRI scans in the practice of medicine as well as questions about the conclusions reached in research studies using these scans to assess spinal stenosis and its treatment. Although these four studies are not included in the primary evidentiary table, it is important to keep these studies in mind when evaluating the data and conclusions of the studies reviewed elsewhere in this guideline. The primary issue appears to be a lack of consensus on diagnostic criteria for stenosis on cross-sectional imaging modalities, leading to marked variability in interpretations.

No studies were found in the systematic literature review that attempted to develop more reproducible criteria for diagnosis of lateral recess or foraminal stenosis on CT or MRI. Two studies did suggest quantitative criteria for the diagnosis of central canal stenosis. The incorpo-

ration of quantitative criteria for this diagnosis could improve inter-observer reliability on cross-sectional examinations. Hamanishi et al[31] reported that a decrease in the dural sac diameter to below 100 mm^2 at more than two of three levels was highly associated with the presence of intermittent claudication. Bolender et al[9] demonstrated that the effectiveness of CT was improved by using the dural sac cross-sectional diameter and proposed that a dural sac area (DSA) of 100 mm was unequivocal evidence of central canal stenosis. Because of the large variability in the size of the lateral recesses and foramina and in the position of the ganglia and nerve root sleeve, any grading system for lateral recess and foraminal stenosis will have to incorporate some measure of perineural effacement, nerve root or ganglionic displacement and neural compression.

Future Directions for Research

The work group identified the following potential studies that would generate meaningful evidence to assist in further defining the appropriate diagnostic tests for lumbar spinal stenosis.

Recommendation #1:

Develop reliable and reproducible criteria for the diagnosis by cross-sectional imaging of central, subarticular recess and foraminal stenosis.

Recommendation #2:

Repeat interobserver and intraobserver variability studies with MRI and CT myelography using dural sac area as a measure of central canal stenosis.

Recommendation #3:

Evaluate the significance of lateral recess and neuroforaminal size, effacement of perineural fat, nerve root sleeve anatomy and nerve root or ganglion displacement and compression with respect to symptomatic radiculopathy and the outcome with surgical decompression.

Recommendation #4:

A prospective study is proposed evaluating the significance of additional findings on axial loaded cross-sectional imaging on patient prognosis and surgical decompression in patients with neurogenic intermittent claudication and radiculopathy.

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B. Outcome Measures for Medical/Interventional and Surgical Treatment

What are the appropriate outcome measures for the treatment of spinal stenosis?

The Oswestry Disability Index (ODI) and Swiss Spinal Stenosis Questionnaire (SSS)/ Zurich Claudication Questionnaire (ZCQ) outcome tools are appropriate measures for treatment of lumbar spinal stenosis.

Grade of Recommendation: B

Stucki et al[35] conducted a case series for outcome assessment. The purpose of this study was to develop a short self-administered questionnaire on symptom severity, physical functional status and patient satisfaction. The study design was a prospective multicenter case series with 193 consecutive patients with spinal stenosis. Follow-up at six months was selected as the point of maximum benefit.

Scale characteristics and validity were assessed on data from 193 patients. Responsiveness was assessed on 130 of the 193 patients. Of the 193 patients, 29 did not return the questionnaire, eight submitted incomplete questionnaires at six months, and at the time of analysis, 25 study patients had not reached the six-month follow-up. The test/retest reliability was assessed on a random sample of 23 patients and ranged from 0.82 to 0.96. The internal consistency ranged from 0.64-0.92 and the responsiveness from 0.96-1.07.

The questionnaire was compared to the following standardized outcome measures: visual analog scale (VAS), sickness impact profile (SIP), cumulative illness rating scale and neuromuscular impairment index.

In critique, the reproducibility, internal consistency, validity and responsiveness of this test were determined by comparison with known validated outcome measurement instruments, though these instruments are not necessarily specific to lumbar spinal stenosis. This study gives Level II evidence that the devised questionnaire scales of symptom severity, physical function and satisfaction are reproducible, internally consistent, valid and responsive measures of outcome in patients with lumbar spinal stenosis. This instrument is currently referred to as the Zurich Claudication Questionnaire (ZCQ) or Swiss Spinal Stenosis Questionnaire (SSS).

Tuli et al[41] applied the Swiss Spinal Stenosis Questionnaire (SSS) to a group of patients surgically treated for spinal stenosis. The questionnaire has three domains: physical functioning, symptom and severity. The threshold values for improvement had been validated

for individual domains in a prior study. Patient satisfaction was utilized to determine appropriate responsiveness of the instrument. The study evaluated sensitivity and specificity of success based on achievement of one, two or all three domains. The authors concluded that achieving two domains provided the best balance of satisfactory sensitivity and specificity for minimally clinically important difference.

In critique of this study, although there is no consensus on how to determine a minimally clinically important difference, the authors were able to evaluate a large number of patients using domains with prior validated threshold measures. These data offer Level II evidence that the SSS can be used as a validated questionnaire in assessing the success of surgery for spinal stenosis. Exceeding threshold values for two of three domains gave satisfactory balance of sensitivity and specificity.

The Maine-Seattle Back Questionnaire (MSBQ), Oxford Claudication Score (OCS), Shuttle Walking Test (SWT) and Exercise Treadmill Test (ETT) outcome tools are appropriate measures for treatment of lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Atlas et al[2] performed a prospective, diagnostic case series looking at the use of the Maine-Seattle Back Questionnaire (MSBQ) as compared to the gold standard 23-item Roland Morris Disability Questionnaire (RMDQ). The study included 507 HNP patients with sciatica and 148 lumbar spinal stenosis patients. To validate the MSBQ, this study looked at internal consistency, construct validity, reproducibility and responsiveness in detecting change over a three-month period. The comparative analysis demonstrated internal consistency was lower for the 12-item MSBQ than for the RMDQ. Reproducibility with the MSBQ was good over three months. There was a high degree of construct validity and responsiveness in comparison to the RMDQ.

In critique, this study documents a high level of internal consistency, construct validity and responsiveness for this questionnaire. This study provides Level II evidence that the MSBQ is a potentially valid measurement of disability in a population of patients with lumbar spinal stenosis. Until this is used in additional research settings, it should be considered a "potentially" valid measurement.

Pratt et al[31] evaluated the reliability of four different outcome assessments for spinal stenosis, including shuttle walking test (SWT), ODI, Swiss Spinal Stenosis Questionnaire (SSS) and the Oxford Claudication Score (OCS) used to study 32 clinic patients with the diagnosis of spinal stenosis one week apart to test reliability. The outcome assessments were then applied to 17 pa-

tients who had undergone surgery for spinal stenosis and had preoperative evaluation scores as well as 18-month follow-up. All tests appeared to be appropriately responsive and reliable. Significant improvements in SWT were noted in 11 of 17 patients. ODI correlated most closely with patient satisfaction. SSS was most reproducible. Authors concluded that they successfully validated the reliability of the four assessment tools.

In critique, this study had a small sample size and large subgroup variance. An external reference standard of patient satisfaction was used for comparison purposes. These findings offer Level III evidence that three outcome questionnaires, one general (ODI) and two specific (SSS and OCS) are reliable and responsive measures of spinal stenosis, as is a functional exam (SWT). The ODI may allow comparison of outcomes across multiple "disabilities."

Tenhula et al[38] conducted a prospective study of 32 patients undergoing surgery for spinal stenosis, assessing the functional evaluation of surgical treatment by comparing functional tests to known validated outcome measures. Of these 32 patients, 26 underwent fusions: 11 at one level, 21 at multiple levels. Results were assessed by treadmill and bicycle tests as well as ODI and VAS scores. There were significant improvements in ODI and VAS at one and two years. Performance on the treadmill test correlated well with these scores; however, the bicycle test was less responsive.

In critique of this study, there were a small number of patients. These data provided Level II evidence that treadmill testing for walking ability provides a satisfactory functional measure of outcomes for surgery for spinal stenosis.

Yamashita et al[45] performed a prospective evaluation of 77 patients undergoing surgical decompression for spinal stenosis, comparing patient satisfaction to measures of pain as well as self-reported walking ability (five-tiered scale, arbitrarily based on time). Follow-up was from one to seven years. There were significant correlations, although functional ability (walking) was least correlated with satisfaction.

In critique of this study, nonvalidated outcome measures were used. This study provided Level IV evidence that patient satisfaction was more dependent on degree of pain than loss of function. *Care must be taken when deciding on the type of outcome measures to use. In particular, the degree of satisfaction may not reflect improvements in walking ability.*

Valid health state measurements that are selected to assess the effectiveness of treatment of lumbar spinal stenosis must be used carefully.

Grade of Recommendation: B

McDonough et al[27] conducted a prospective, multicenter trial that evaluated 2097 patients with diagnoses of HNP, spinal stenosis or degenerative spondylolisthesis. One of the objectives was to conduct a cost-effective analysis of surgical versus medical/interventional treatment using quality of life years (QALY). This required the use of preference-weighted, health state classification systems. Four such validated instruments were evaluated in this study including the EQ-5D, HUI, SF-6D and SF-36 derived EQWB.

They tested each instrument's ability to discriminate between health categories and level of system satisfaction. Responsiveness was compared to each other as well as the ODI, the VAS and a patient satisfaction questionnaire. All instruments responded appropriately, although there was variation in the magnitude and the sensitivity of response. This study is still in progress.

In critique, this study is well designed, but final conclusions regarding responsiveness of these tools are still pending completion of the study. This study provides Level II evidence that valid health state measurement instruments to evaluate QALY can be used to reliably assess the effectiveness of treatment in lumbar spinal stenosis. However, there is variation in measurement across instruments. Thus, these are not interchangeable and ultimate conclusions can be affected by choice of instrument. For now, caution should be used when comparing cost-effectiveness ratios across studies, and until a superior tool is better defined, researchers should use a measurement tool that best fits the condition under investigation. Beyond this, it was a common theme in studies of all levels of evidence that selection and validation of outcomes instruments were crucial to accurate assessment of results. Great care should be taken in assigning the appropriate instruments when conducting investigative studies. In addition, a thorough understanding of the validity and limits of each instrument is necessary to properly interpret the literature.

Future Directions for Research

Further studies are needed to validate additional outcome measures for the treatment of lumbar spinal stenosis. Currently, the best and most specific outcome measure for spinal stenosis appears to be the Zurich Claudication Questionnaire (Swiss Spinal Stenosis Questionnaire). In future studies of specific outcome measures for the treatment of lumbar spinal stenosis, this questionnaire could be considered to be a potential gold standard.

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C. Medical and Interventional Treatment

Do medical/interventional treatments improve outcomes in the treatment of spinal stenosis compared to the natural history of the disease?

A systematic review of the literature yielded no studies to answer this question.
An extensive review of all articles cited in the reference section found no direct comparison of active treatment (medical/interventional) to an untreated control group (natural history).

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of medical treatment for lumbar spinal stenosis.

Recommendation #1:

Future studies of the effects of medical, noninvasive interventions for lumbar spinal stenosis should include an untreated control group when ethically possible.

Recommendation #2:

Future outcome studies of lumbar spinal stenosis should include results specific to each of the medical/interventional treatment methods.

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What is the role of pharmacological treatment in the management of spinal stenosis?

There is little evidence that pharmacological treatment, including intranasal calcitonin, intramuscular calcitonin, methylcobalamin or intravenous lipoprostaglandin E(1), provides long-term benefit in patients with lumbar spinal stenosis.

Grade of Recommendation: B

Eskola et al[3] performed an "open follow-up study" to test the efficacy of intramuscular calcitonin for the treatment of lumbar spinal stenosis. The methodology was not clearly stated as retrospective or prospective. The study followed fifteen patients with neurogenic claudication with lumbar spinal stenosis over a period of six months. Clinical inclusion criteria were bilateral leg pain and maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, symptom intensity (scored using a numerical system) and a performance test of power and swiftness of the lower extremities.

At three-month follow-up, there was a statistically significant improvement in symptom intensity score. At six-month follow-up, there were statistically significant improvements in lower extremity performance tests. There was an average improvement of 491 meters walking distance. In critique of this study, the authors did not use a validated outcomes instrument, the study population was small, there was no control group, follow-up was short and the methodology unclear. With these limitations, this study provides Level IV therapeutic evidence for the effectiveness of intramuscular calcitonin treatment for neurogenic claudication associated with lumbar spinal stenosis.

Eskola et al[4] conducted a double-masked, randomized controlled, crossover trial of 39 patients with neurogenic claudication from lumbar spinal stenosis. With this design, every patient was treated with intramuscular calcitonin for a portion of the study period so that each patient could serve as their own control. Clinical inclusion criteria were bilateral leg pain and maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, pain (Visual Analog Scale) and a performance test of power and swiftness of the lower extremities.

At three- to six-month follow-up, walking distance and pain were improved during calcitonin treatment. After crossover, pain relief was better than walking distance improvement. Patients with mild pain or severe neurogenic claudication showed no improvement. In critique of the study, the radiographic inclusion criteria were somewhat contradictory. While the authors stated that all patients had less than 10 mm sagittal canal diameter, they subsequently stated that only 19 of 39 patients had central stenosis. The two groups were not matched for severity of

initial symptoms nor were their baseline characteristics statistically compared. The results are not stratified between patients with central or lateral recess stenosis. Notwithstanding the VAS pain score, the other outcome measures were not validated or disease-specific instruments. These data represent Level II therapeutic evidence of the effectiveness of calcitonin in the treatment of lumbar spinal stenosis.

Iwamoto et al[7] performed a prospective evaluation of 20 elderly men (average age 67 years old) treated with intravenous lipoprostaglandin E(1) with neurogenic claudication from lumbar spinal stenosis. The study population included patients with burning sensation in the legs and perineal region while walking, with or without urinary disturbance (12 patients). In an additional 18 patients, symptoms also included radiculopathy. There were no stated radiographic inclusion criteria. Outcome was measured using the Japanese Orthopaedic Association score.

Total score was statistically improved from 14.3 to 16.8. The authors concluded that intravenous treatment with lipoprostaglandin E(1) can improve subjective symptoms in elderly male patients with lumbar stenosis. In critique of this study, the patient population was small and there were no stated radiographic inclusion criteria. Follow-up was short at six months. As this was a noncomparative, nonrandomized study, this study provides Level IV therapeutic evidence for the efficacy of lipoprostaglandin E(1) for the treatment of lumbar spinal stenosis.

Murakami et al[9] reported the results of a series of 37 patients with neurogenic claudication with lumbar spinal stenosis treated with intravenous lipoprostaglandin E(1). The study population included patients with burning sensation in the legs and perineal region while walking, with or without urinary disturbance (cauda equina group, eight patients), those with radicular symptoms only (11 patients) and those with mixed symptoms (21 patients). There were no stated radiographic criteria for inclusion in the study. Outcome was measured using the Japanese Orthopaedic Association (JOA) score.

In short-term follow-up (10 days), overall scores improved from 15.8 to 19.2. There were statistically significant improvements in all subcategories of the JOA score except for clinical signs. In subgroup analysis, the cauda equina and mixed group showed statistically significant improvements in overall JOA scores; however, the radicular group did not. According to the authors' categorization of JOA score changes, 22 were considered to have good to excellent results. At long-term follow-up (defined by the authors as two to 23 months) of 31 patients with fair, good or excellent initial results, only 10 showed sustained improvement while 21 returned to their baseline level. In critique of this study, the patient numbers were small, and the follow-up was variable and incompletely documented. These date provide Level IV therapeutic evidence that intravenous lipoprostaglandin E(1) may provide short-term (10 days) benefit in patients with lumbar spinal stenosis but little long-term relief.

Podichetty et al[10] reported the results of a randomized, double-masked, controlled trial studying the effectiveness of intranasal salmon calcitonin for the treatment of lumbar spinal stenosis. Fifty-five patients were randomized--- 36 to the treatment group and 19 to the control group. After an initial six-week period, the placebo group was given calcitonin as a crossover group; however, the treatment group continued receiving calcitonin. Inclusion criteria were pseudoclaudication, defined as discomfort, pain, numbness, weakness, heaviness or vague discomfort in one or both lower extremities made worse by standing, walking or extension and relieved by sitting, squatting or forward flexion. The investigators stated that stenosis was radiographically confirmed, however, criteria were not listed. Outcome measures included the Modified Oswestry Low Back Pain questionnaire, walking time and distance, Lumbar Canal Stenosis (LCS) specific questionnaire, SF-36 and Visual Analog Scale for pain.

At final follow-up, eight patients withdrew from the calcitonin group and four from the placebo group. Baseline characteristics for the two groups were statistically comparable. There were no significant differences between the treatment and control groups in VAS pain, SF-36 or total walking time or distance. In critique of this study, the patient numbers were low, the follow-up period was relatively short, and there was a fairly high attrition rate (22%). While this study was potentially a Level I investigation, these shortcomings limit the data to Level II therapeutic evidence that intranasal salmon calcitonin is not effective for the treatment of lumbar spinal stenosis.

Waikakul and Waikakul[13] performed a randomized controlled trial to evaluate the effect of methylcobalamin as an adjunct to medical/interventional treatment in 152 patients with lumbar spinal stenosis. Treatment with methylcobalamin was continued for six months; follow-up was two years. Patients reported moderate symptoms. Plain radiographs were obtained for all patients; MRI or CT was obtained in some cases. There were no reported radiographic inclusion criteria. Conservative care was administered to both groups, which included patient education, activity modification, exercises/physical therapy, oral analgesics, muscle relaxants and epidural steroid injections. There were no standard or systematic outcome measurements. Outcomes were limited to physical examination findings and walking distance.

Both groups showed improvement in physical examination findings but there were no significant differences between them. There was a trend for a greater number of patients who could walk more than 1000 m after treatment; however, this could not be statistically confirmed. In critique of the study, the randomization process was not masked as it relied on medical record numbers. Furthermore, no validated or standardized outcome measures were used. Numerous cointerventions were applied. Lastly, this randomized study demonstrated no significant differences in outcomes but did not calculate or report confidence intervals. A potential Level I study, this report had serious design flaws resulting in Level II therapeutic evidence that methylcobalamin is not effective for the treatment of lumbar spinal stenosis.

There is weak evidence that intramuscular calcitonin provides some short-term benefit in patients with moderate lumbar spinal stenosis.

Grade of Recommendation: C

Eskola et al[3] performed an "open follow-up study" to test the efficacy of intramuscular calcitonin for the treatment of lumbar spinal stenosis. The methodology was not clearly stated as retrospective or prospective. The study followed 15 patients with neurogenic claudication with lumbar spinal stenosis over a period of six months. Clinical inclusion criteria were bilateral leg pain and maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, symptom intensity (scored using a numerical system) and a performance test of power and swiftness of the lower extremities.

At three-month follow-up, there was a statistically significant improvement in symptom intensity score. At six-month follow-up, there were statistically significant improvements in lower extremity performance tests. There was an average improvement of 491 meters walking distance. In critique of this study, the authors did not use a validated outcomes instrument, the study population was small, there was no control group, follow-up was short and the methodology unclear. With these limitations, this study provides Level IV therapeutic evidence for the effectiveness of intramuscular calcitonin treatment for neurogenic claudication associated with lumbar spinal stenosis.

Eskola et al[4] conducted a double-masked, randomized controlled, crossover trial of thirty-nine patients with neurogenic claudication from lumbar spinal stenosis. With this design, every patient was treated with intramuscular calcitonin for a portion of the study period so that each patient could serve as their own control. Clinical inclusion criteria were bilateral leg pain and maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, pain (Visual Analog Scale) and a performance test of power and swiftness of the lower extremities.

At three- to six-month follow-up, walking distance and pain were improved during calcitonin treatment. After cross over, pain relief was better than walking distance improvement. Patients with mild pain or severe neurogenic claudication showed no improvement. In critique of the study, the radiographic inclusion criteria were somewhat contradictory. While they stated that all patients had less than 10 mm sagittal canal diameter, the authors subsequently stated that only 19 of 39 patients had central stenosis. The two groups were not matched for severity of initial symptoms nor were their baseline characteristics statistically compared. The results are not stratified between patients with central or lateral recess stenosis. Notwithstanding the VAS

pain score, the other outcome measures were not validated and none of the outcome measures were disease-specific. These data represent Level II therapeutic evidence of the effectiveness of calcitonin in the treatment of lumbar spinal stenosis.

Future Directions for Research

General Recommendation:

> The role of routine pharmacological treatment including NSAIDS, muscle relaxants and analgesics, used extensively in the treatment of spinal stenosis as well as other back conditions, needs to be to investigated in patients with spinal stenosis using untreated control groups with spinal stenosis.

The work group identified the following potential study, which would generate meaningful evidence to assist in further defining the role of pharmacological treatment for lumbar spinal stenosis.

Recommendation:

> A large, double-masked, randomized controlled trial with a long-term observation period to examine the potential benefits of intramuscular calcitonin for the treatment of lumbar stenosis.

Pharmacological Treatment References

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What is the role of physical therapy/exercise in the treatment of spinal stenosis?

A systematic review of the literature yielded insufficient evidence to draw conclusions regarding the effectiveness of physical therapy or exercises as stand-alone treatments for lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

Onel et al[10]conducted a prospective case series of 145 patients with neurogenic claudication diagnosed with CT with or without myelography as having lateral and/or central canal stenosis were prospectively evaluated. Treatment was one month of inpatient therapy that included ultrasound, infrared heating, active therapy (William's flexion and McKenzie extension) and treatment with subcutaneous salmon calcitonin. Tested parameters were pain on motion, lumbar range of motion, straight leg raise (SLR), neurologic exam and walking distance. Results demonstrated that 91% became pain-free with range of motion (100% were painful prior to treatment). Fifty-five percent (67 of 112) of patients with limited lumbar extension improved to "normal" range of motion. Flexion was limited in 30% (43 of 112) of patients prior to treatment. After treatment, 70% (20 of 43) gained normal movement with flexion. SLR was limited in 29% (33 of 112) of patients prior to treatment; of these, 70% (23 of 33) regained a "normal" SLR after treatment. All 145 patients experienced neurogenic claudication prior to treatment; after treatment 89% improved and 29% had unlimited walking capacity. Before treatment, 29% experienced motor impairment; after treatment 53% (23 of 43) had normal motor function.

In critique, this study was conducted during a one-month hospitalization and there was no subsequent follow-up. This was an uncontrolled study with multiple treatment modalities. No validated outcome measures were employed. This study provides Level IV therapeutic evidence that multiple modalities of physical therapy in combination with subcutaneous salmon calcitonin can relieve symptoms of lumbar spinal stenosis for the duration of therapy. No conclusions regarding the management of lumbar spinal stenosis by physical therapy can be drawn based on the results of this study.

Use of physical therapy and exercise may be beneficial in controlling symptoms of lumbar spinal stenosis with neurogenic claudication in certain subgroups of patients.

Level of Evidence: V (Expert Consensus)

Whereas a systematic search of the literature revealed no evidence regarding the usefulness of physical therapy and exercise as stand-alone treatments in patients with lumbar spinal stenosis and neurogenic claudication, clinical experience suggests that physical therapy and exercise may be effective in controlling symptoms as part of a comprehensive treatment strategy. This conclusion is inferred from the literature noted throughout the degenerative lumbar spinal stenosis guideline. Therefore, it is the consensus of the work group that a limited course of physical therapy is reasonable in patients with lumbar spinal stenosis.

Future Directions for Research

The work group suggests the need for an appropriately powered, randomized controlled trial comparing physical therapy to the natural history of lumbar spinal stenosis using standardized techniques and validated outcome measures.

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What is the role of manipulation in the treatment of spinal stenosis?

The evidence that spinal manipulation offers benefit in the treatment of lumbar spinal stenosis is insufficient.

Grade of Recommendation: I (Insufficient Evidence)

Murphy and Hurwitz[2] performed a prospective observational case series of 57 consecutive patients with clinically and radiographically defined lumbar spinal stenosis. The mean age of patients was 65 years and two thirds of patients were female. Patients were treated with distraction manipulation (DM) by the standard technique of Cox, neural mobilization (NM) and designated exercises. In some patients, physical therapy with spinal mobilization and stabilization was added. Patients were treated two or three times weekly for a mean number of 13 treatments (range 2-50). Mean follow-up was 16 months (range 3-48). There were 44 patients available for long-term follow-up. Outcome measures included the Roland Morris Disability Questionnaire (RMDQ) score, a patient self assessment of improvement and the average pain intensity rating by VAS.

The authors reported mean improvement in the RMDQ score at long-term follow-up was 5.2. Clinically significant improvement of greater than three points in the RMDQ score was achieved by 66.7% of patients. At long-term follow-up current pain decreased by a mean of 38.4%, average pain by 51.7% and worst pain by 44.7%. Self-rated improvement was 75.6% overall.

In critique, the results of this case series are compromised by the inclusion of additional physical therapies and treatments. The wide range in ages of the study population (32-80 years), number of treatments (2-50), the variable duration of follow-up averaging less than two years (3-48 months) and the 23% study dropout rate decrease the value of this study.

This study provides Level IV therapeutic data suggesting that distraction manipulation and neural mobilization may be beneficial in the treatment of lumbar spinal stenosis.

Future Directions for Research
The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of manipulation in the treatment of lumbar spinal stenosis.

Recommendation #1:

Future studies should include a controlled trial comparing manipulation to natural history of lumbar spinal stenosis using standardized techniques and validated outcome measures.

Recommendation #2:

Future studies should utilize validated outcome measures to compare manipulation to other medical/interventional treatments for spinal stenosis, and should assess long-term effectiveness and cost effectiveness.

Manipulation References

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What is the role of contrast-enhanced, fluoroscopic guidance in the routine performance of epidural steroid injections for the treatment of lumbar spinal stenosis?

Using contrast-enhanced fluoroscopy to guide epidural steroid injections improves the accuracy of medication delivery.

Grade of Recommendation: A

Nonfluoroscopically-guided caudal epidural injections have a rate of inaccurate placement ranging from 25-53%.[45,57,64] Nonfluoroscopically-guided lumbar interlaminar epidural injections have a rate of inaccurate placement ranging from 17-30%.[34,64]

Mehta et al[34] assessed the ability to accurately access the spinal canal using a nonfluoroscopically-guided interlaminar epidural injection technique in 100 patients with a variety of lumbar spinal conditions. In 17% of cases, the injection was completely or partially outside of the spinal canal. In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind interlaminar injection is correct in 83% of cases.

Renfrew et al[45] examined the accuracy of needle placement during nonfluoroscopically-guided caudal epidural steroid injection in 328 patients, some of whom had lumbar spinal stenosis. Results were categorized according to technician experience. Injections by physicians who had performed less than 10 procedures were in the epidural space in 47% of cases. Injections by those who had performed 10 to 50 procedures were in the epidural space in 53% of cases. Injections by those who had performed more than fifty procedures were correctly placed in 62% of cases. In critique, the population had a variety of lumbar diagnoses not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal injection is correct in 47-62% of cases.

Stitz et al[57] assessed the accuracy of nonfluoroscopically-guided caudal epidural injections in the lumbar spine of 54 patients. Needles were first placed in a masked manner by palpation of landmarks only. Fluoroscopic evaluation with contrast demonstrated that the needle was in the epidural space in 74.1% of cases. In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 74% of cases.

White et al[64] found that in 300 consecutive cases, caudal injection using palpable landmarks alone was incorrectly placed 25% of the time, as confirmed by contrast-enhanced fluoroscopy. Needle placement was incorrect in 30% of cases during interlaminar injection by landmark pal-

pation alone. In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 75% of cases and that blind interlaminar epidural injection is accurately placed in 70% of cases.

What is the role of epidural steroid injections in the treatment of lumbar spinal stenosis?

Nonfluoroscopically-guided interlaminar epidural steroid injections can result in short term (two to three weeks) symptom relief in patients with neurogenic claudication or radiculopathy. There is, however, conflicting evidence concerning long-term efficacy.

Grade of Recommendation: B

Cuckler et al[12] performed a prospective, randomized, double-masked trial comparing nonfluoroscopically-guided single injections of epidural steroid to placebo injections in 73 patients with radicular pain, 37 of whom experienced neurogenic claudication from lumbar spinal stenosis. The steroid group included 20 stenotic patients and the placebo group included 17 patients. The outcome measure was physician assessment of pain improvement. Investigators defined a successful outcome as greater than 75% pain decrease.

At an average follow-up of 21.5 months, there was no significant difference in the number of successes in the treatment and control groups. In critique of this study, the number of stenotic patients included was small and the definition of success was subjective and not based on a standardized outcome measure. Furthermore, a group of 15 patients who underwent a second injection with steroid in a nonmasked fashion were not analyzed separately. The attrition rate was not reported. While potentially a Level I randomized controlled trial, the lack of masking in the treatment of some of the patients would lower the level of evidence from this study to Level II. Furthermore, because of the 41% (15 of 37) crossover rate to nonmasked injections, the lack of reporting of the attrition rate and the lack of validated outcome measures, the work group felt this study should be considered Level III treatment evidence that a single, nonfluoroscopically-guided caudal injection does not produce long-term (average 21.5 months) relief.

Fukusaki et al[17] conducted a prospective, randomized, double-masked trial evaluating the efficacy of a single interlaminar nonfluoroscopically-guided epidural steroid injection in 53 patients with lumbar spinal stenosis. Patients were randomized to three groups: epidural saline injection (16 patients), epidural local anesthetic (18 patients) and epidural anesthetic plus steroid (19 patients). The clinical inclusion criteria were neurogenic claudication with leg pain and a walking tolerance less than 20 m. Radiographic inclusion criteria were central stenosis with less than 15 mm sagittal canal diameter on CT and/or MRI, lateral recess stenosis or mixed central

and lateral recess stenosis. The only outcome measure was walking distance rated as excellent (greater than 100 m), good (20 to 100 m) and poor (less than 20 m).

At one month, 6.3% of the saline patients experienced good or excellent results while 16.7% and 15.8% of the anesthetic and anesthetic-steroid group, respectively, experienced good or excellent results. This difference was significant. However, at three months, there were no significant differences among the groups.

In critique of this study, the only measured outcome was walking distance. In favor of the study, there were no study drop-outs and the three groups were homogenous in baseline characteristics. These data provide Level II treatment evidence that a single nonfluoroscopically-guided interlaminar ESI for spinal stenosis can improve walking distance at one month, but not at three months.

Papagelopoulos et al[42] presented a prospective case series of 50 patients, 13 of which experienced radicular pain from spinal stenosis, who underwent a single nonfluoroscopically-guided interlaminar injection with anesthetic and steroid. Four patients had central stenosis; nine patients had lateral recess stenosis. CT or MRI were performed on all patients, however, the authors did not list specific radiographic inclusion criteria. Follow-up was at a mean of 24 months. The outcome measure was unclear but was presented as excellent, good, fair or poor.

Four patients with central stenosis completely improved, two experienced some improvement and one patient underwent surgery after six months. In the lateral recess group, seven completely improved and two experienced some improvement. In critique of this study, the outcome measure was not described and therefore its clinical relevance is unclear. Patient numbers were low. This study provides Level IV therapeutic evidence that a single nonfluoroscopically-guided interlaminar injection can provide some long-term improvement in patients with radicular pain from spinal stenosis.

A single radiographically-guided transforaminal epidural steroid injection can produce short term relief in patients with radiculopathy from lumbar spinal stenosis. There is, however, conflicting evidence concerning the long-term efficacy of a single injection.

Grade of Recommendation: B

Ng et al[40] conducted a prospective, randomized controlled trial evaluating the efficacy of a single transforaminal fluoroscopically-guided contrast-enhanced injection. Thirty-two of the patients had spinal stenosis. The inclusion criterion was unilateral leg pain from foraminal stenosis confirmed by MRI. All patients had failed six weeks of medical/interventional treatment that included physical therapy and NSAIDs. Fifteen patients received an injection with local

anesthetic alone and seventeen received anesthetic and steroid. Outcome measures were ODI, VAS and walking distance.

At all time periods during a maximum follow-up of 12 weeks, there were no significant differences between the two groups. In critique of the study, the absolute values of the stenotic group were not presented. More importantly, the control group received an anesthetic injection, which may have had a therapeutic effect on its own. There were no confidence intervals reported for this study that showed no significant differences. Because of these deficiencies, this potentially Level I randomized controlled trial was downclassified to a Level II study. This study provides Level II treatment evidence that the addition of steroid to a transforaminal anesthetic injection offers little clinical benefit.

Ng et al[39] reported results of a prospective case series evaluating the effect of a single transforaminal injection with steroid in 117 patients with chronic radicular pain from herniated disc or spinal stenosis. Sixty-two patients had spinal stenosis diagnosed by MRI. Outcome measures were ODI, VAS, modified Zung depression score and the Low Back Outcome Score (LBOS). Follow-up was a maximum of three months. The ODI improved by six points, the VAS improved by 12 points and the LBOS improved by 26 points. Sixteen percent (10 of 62) of patients dropped out to undergo surgery.

In critique of this study, there was no statistical comparison of the treatment effect in the spinal stenosis group alone. With this, the clinical effect is difficult to discern. This case series provides Level IV diagnostic evidence that a single transforaminal ESI can provide a small, three month effect on chronic, unilateral radicular pain from spinal stenosis.

Zennaro et al[67] published a case series of 41 patients, 21 of whom were diagnosed with foraminal stenosis and underwent a single CT-guided transforaminal epidural steroid injection. Clinical inclusion criterion was radicular pain. Imaging studies included CT; some also had an MRI. The average follow-up was nine months. The outcome measure was a pain questionnaire, the details of which were not described. Ninety-five percent of patients with lumbar stenosis experienced pain relief at final follow-up. Three patients experienced recurrence of pain during the follow-up period.

In critique of this study, the pain score was not detailed and no validated outcome measure was used. The absolute reduction of pain scores was not reported, limiting evaluation of the magnitude of clinical effect. This case series provides Level IV evidence that CT-directed transforaminal ESI can have a high success rate for radicular pain from foraminal stenosis.

A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injections can produce long-term relief of pain in patients with radiculopathy or neurogenic intermittent claudication (NIC) from lumbar spinal stenosis.

Grade of Recommendation: C

The "multiple injection" regimen referred to in this recommendation, and utilized in the studies cited below, should be distinguish from a "series" of injections which has been utilized in several older studies. In a multiple injection protocol, a patient is a candidate for additional injections when their pain recurs or becomes severe again. In these studies, additional injections were performed either on patient demand, or when the patient's pain exceeded a preset level. The purpose of the multiple injection protocol is to control pain over a longer period of time in order to maximize the chance that a patient will respond to medical/interventional therapy. A "series" of injections, typically three, is performed at 24-hour or one week intervals regardless of the patient's symptoms. The patient is not allowed repeat injections if their pain recurs during the course of medical/interventional therapy.

Botwin et al[9] reported results of a prospective, case series of 34 patients with unilateral radicular leg pain from spinal stenosis who had failed six weeks of noninvasive medical/interventional treatment that included NSAIDs and/or physical therapy. All patients underwent a multiple-injection protocol of transforaminal fluoroscopically-guided contrast-enhanced epidural steroid injections. MRI was obtained in all patients. Radiographic inclusion criteria were mild, moderate or severe central stenosis with lateral recess or foraminal stenosis. Outcome measures were Visual Analog Scale for pain, Roland five-point pain scale, a five-tiered standing and walking tolerance measure and a five-tiered patient satisfaction scale. Follow-up at 12 months was assessed by mailed-questionnaire.

Sixty-four percent of patients experienced improved walking tolerance, 75% reported greater than 50% reduction in pain and 57% experienced improved standing tolerance. Patients had an average of 1.9 injections.

In critique of this study, the patient numbers were small. Notwithstanding the VAS pain score, the other outcome measures were not validated instruments. This study represents Level IV treatment evidence that transforaminal fluoroscopically-guided contrast-enhanced epidural steroid injections can provide long-term (12 months) relief in about two thirds of patients with unilateral radiculopathy from lumbar spinal stenosis.

Ciocon et al[11] conducted a prospective case series of thirty patients with lumbar spinal stenosis who underwent a series of three caudal epidural steroid injections without fluoroscopic guidance. The agents used were depomedrol and xylocaine. Patients' complaints included leg pain with or without back pain. All had confirmation of stenosis by MRI that was graded as mild in

seven patients (23%), moderate in 20 patients (67%) and severe in three patients (10%). Outcome measure included a Roland five-point pain scale and patients were followed for four to 10 months. Pain scores decreased from an average 3.4 to 1.5 after treatment. Notably, the investigators found that the degree of pretreatment pain correlated with the degree of radiographic central stenosis. The response to injection was not correlated with the degree of radiographic stenosis.

In critique of this study, patient numbers in this case series were low. These data offer Level IV treatment evidence that a series of three nonfluoroscopically-guided caudal epidural blocks can decrease pain from lumbar spinal stenosis at four to 10 months follow-up.

Delport et al[13] published the outcomes of a retrospective case series of 140 patients with lumbar spinal stenosis treated with a multiple injection protocol of fluoroscopically-guided transforaminal or caudal epidural steroid injections. Radiographic inclusion criterion was MRI-confirmed central, lateral recess or foraminal stenosis at one or more levels. Clinical inclusion criteria included leg pain or neurogenic claudication with or without back pain. The investigators stated they directed injections to the site of neural compression noted on imaging. They employed caudal blocks for multilevel central canal stenosis and presumably transforaminal injection for single-level disease. Follow-up was conducted by telephone interview between six to 36 months. Outcome measures were pain rated by a three-tiered system, duration of pain relief and the impact on daily activities.

Thirty-two percent reported more than two months of pain relief, 38% reported less than two months, 29% reported no pain relief, 21% reported improvement in daily activities and 20% eventually underwent surgery after an average of 2.23 injections were administered.

In critique, the results were not stratified for the caudal injection versus the transforaminal injections, limiting conclusions of the results of these two techniques. As the investigators stated that they employed caudal injections for multilevel disease, a stratification of results according to extent of disease would also have been useful. This case series provides Level IV diagnostic evidence that multiple fluoroscopically-guided transforaminal or caudal epidural injections can reduce pain and improve daily function for at least two months in about one third of patients with leg pain or neurogenic claudication from spinal stenosis.

Hoogmarten et al[23] reported the results of a retrospective case series of 49 patients with lumbar spinal stenosis with neurogenic claudication undergoing a multiple injection protocol of caudal epidural steroid blocks with radiographic guidance. The clinical inclusion criterion was walking distance of 100 m or less. Injections were a combination of local anesthetic and steroid. Imaging was not standardized and not obtained in all patients. There was a 22% dropout rate from the study. The outcome measure was a mailed-questionnaire that judged outcome as excellent, good, fair and poor.

At an average 23-month follow-up, 32% reported good or excellent results, 16% reported fair results and 52% reported poor results. In critique of this study, the details of the outcome questionnaire were not provided, limiting the generalizability of the data. This study offers Level IV diagnostic evidence that a multiple caudal injection protocol produces good or excellent results in about one third of patients at 23-month follow-up.

Riew et al[46] performed a prospective, randomized, double-masked trial of 55 patients with radicular pain from herniated disc or spinal stenosis who underwent a multiple injection transforaminal fluoroscopically-guided protocol. The clinical inclusion criterion was radicular leg pain. The radiographic inclusion criterion was nerve root compression diagnosed by MRI or CT. While the authors stated that there were no significant differences in the number of patients with herniated disc or spinal stenosis in the two groups, the actual patient numbers were not reported. Follow-up was 13 to 28 months. Outcome measures included the North American Spine Society Outcome Instrument and the avoidance of undergoing a subsequent surgery.

In the stenosis patients who did not undergo surgery, there was a significant decrease in neurologic symptoms and low back pain. Stenotic patients who received steroid and anesthetic reported a significant decrease in low back pain and significant improvement in treatment expectation scores. In total, 47% (26 of 55) of patients eventually underwent surgery. The use of steroid and local anesthetic resulted in a significant decrease in the rate of surgery, but it is not clear how many were stenosis versus herniated disc patients.

In critique of this study, the number of patients with stenosis is not reported. Thus, it is not possible to determine the power of the study. In addition, the absolute improvements of the primary outcome score (NASS Outcome Instrument) were not reported, although the authors stated that these values improved in the stenotic patients who received steroid and anesthetic. The authors do not separately report the results of anesthetic injection alone in the stenotic patients. Because of the methodological limitation, the potentially Level I randomized controlled trial was downgraded to a Level II study. This study provides Level II treatment evidence that transforaminal ESI can decrease the likelihood that a patient with radicular leg pain and spinal stenosis will undergo an operation.

Future Directions for Research

The work group identified the following potential studies that would generate meaningful evidence to assist in further defining the role of epidural steroid injection in the treatment of lumbar spinal stenosis.

Recommendation #1:

A large double-masked, randomized, controlled clinical trial with at least one-year follow-up in patients with unilateral leg pain from lumbar spinal stenosis treated by

fluoroscopically-guided contrast-enhanced transforaminal epidural steroid injections in which the control group receives saline placebo injections.

Recommendation #2:

A large double-masked, randomized, controlled clinical trial with at least two-year follow-up in patients with neurogenic claudication from lumbar spinal stenosis treated by fluoroscopically-guided interlaminar or caudal epidural steroid injections in which the control group receives saline placebo injections.

Injections References

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What is the role of ancillary treatments such as bracing, traction, electrical stimulation and transcutaneous electrical stimulation (TENS) in the treatment of lumbar spinal stenosis?

The use of a lumbosacral corset can increase walking distance and decrease pain in patients with lumbar spinal stenosis. There is no evidence that results are sustained once the brace is removed.

Grade of Recommendation: C

Prateepavanich et al[13] performed a self-controlled comparative study of 21 patients with a mean age of 62.5 using a lumbosacral corset for the treatment of symptomatic degenerative lumbar spinal stenosis with neurogenic claudication. Patients with an age over 50, reproducible neurogenic claudication, degenerative changes on radiographs and no contraindications to using a treadmill or corset were included in the study. The outcome measures were VAS in daily activities and walking distance.

Patients served as their own control. Each patient was walked on a treadmill with and without the use of a corset, one week apart, and claudication distances were recorded. This process was repeated three times. Patients also reported VAS during daily activities.

There was a statistically significant increase in walking distance (from 314 to 393 feet) and a decrease in pain (VAS from 5.9 to 4.7) with the use of the corset. In critique, the sample size of patients was small. The study is otherwise well designed for the authors' goal. This study provides Level III therapeutic evidence that the use of a lumbosacral corset can increase walking distance before claudication and reduce pain in patients with lumbar spinal stenosis. There is no evidence that use of a brace has any lasting results once discontinued.

Willner[16] conducted a prospective case series of 48 patients with a mean age of 45 years. Of these patients 15 had spondylolisthesis, 26 had long-term low back pain of unknown etiology, and the remaining seven had lumbar spinal stenosis confirmed by myelography with symptoms of claudication. All patients were placed in a Flexaform (rigid lumbosacral orthosis) brace for an average of one year. Outcome measures were not defined.

In the group with spinal stenosis, two cases were totally free from pain, four patients reported an obvious improvement with increased walking capacity and in one case the pain was unchanged. In critique, the sample size of patients in this study with spinal stenosis was extremely small and no validated outcome measures were used. There is no documentation of compliance with brace use or pain reduction when out of the brace. This study provides Level IV therapeutic evidence that bracing can reduce pain in spinal stenosis.

A systematic review of the literature yielded insufficient evidence to address the role of traction, electrical stimulation or TENS in the treatment of lumbar spinal stenosis.

Grade of Recommendation: I (Insufficient Evidence)

An extensive review of all articles cited in the reference section found no direct comparison of ancillary treatments (traction, electrical stimulation or TENS) to an untreated control group (natural history).

Future Directions for Research
The work group suggests a randomized, controlled trial comparing the use of individual ancillary treatments to a control, preferably masked, in patients with lumbar spinal stenosis.

Recommendation #1:

> An appropriately powered study is proposed containing three groups with symptomatic lumbar spinal stenosis comparing soft bracing, rigid bracing and untreated controls (no bracing). Outcome measures could include the ZCQ, VAS, walking distance and a validated, health-related quality of life measure such as the SF-36 or ODI.

Bracing, Traction, Electrical Stimulation and TENS References

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What is the long-term result of medical/interventional management of spinal stenosis?

Of patients with mild to moderate lumbar spinal stenosis initially receiving medical/interventional treatment and followed for two to 10 years, approximately 20-40% will ultimately require surgical intervention. Of the patients who do not require surgical intervention, 50-70% will have improvement in their pain.

Grade of Recommendation: C

Because of the limited availability of evidence, the work group defined long-term results as any study that included two or more years of follow-up.

Amundsen et al[2] performed a case control, comparative study of 100 patients with symptomatic spinal stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 patients were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months and participated in back school and physical therapy when out of the brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

To review long-term outcomes, we reviewed 50 patients who were selected for medical/interventional treatment because of moderate symptoms and the 18 medical/interventional patients who were randomly assigned, for a total of 68 patients treated medically/interventionally in this study.

At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain. For evaluation of this article, the reviewers chose to include only the patients in the medical/interventional treatment groups, limiting this study to a case series, or Level IV evidence. In critique of this study, no standardized outcome measures were used, and substantial numbers of patients died or crossed over to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay in an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment, but this program appears reasonably effective. It is unclear if the results of initial treatment rendered differ from the natural history of spinal stenosis.

Simotas et al[38] studied a case series of 49 people, with a mean age of 69, meeting radiologic and clinical criteria of spinal stenosis. Patients were treated medically/interventionally with exercises, analgesics and epidural steroid injections. Patients were followed an average of 33 months.

Outcome measures were VAS, Roland Morris Disability Questionnaire score, an overall rating of depression and anxiety levels, an outcome measure of lumbar stenosis by Stucki et al[42] and a motor examination.

At three years, nine of these patients underwent surgical decompression. Of the remaining 40 patients, 12 reported no or only mild pain, 11 reported mild improvement, 12 reported no change, the remaining five were probably or definitely worse. Two of these patients experienced significant motor deterioration. In critique, this study used validated outcome measures and a defined medical/interventional treatment method. This study provides Level IV evidence that 71% (35 of 49) of patients with lumbar spinal stenosis will remain the same or improve with medical/interventional treatment over three years. The remainder will worsen, 18% (9 of 49) to the point that they require surgery.

Waikakul and Waikakul[47] performed a prospective cohort study on the treatment of lumbar spinal stenosis using methylcobalamin as an adjunct to medical/interventional care. Conservative care consisted of patient education, activity modification, exercises to strengthen the trunk and abdominal muscles, physical therapy, NSAIDS, analgesics, muscle relaxants and epidural steroid injections. The patients were followed for two years.

Outcome measures were physical examination and distance walked without neurogenic claudication (1000 m). In the group that received medical/interventional care only, 59 out of 82 patients were unable to walk 1000 m without claudication upon entry into the study. At two years, only 12 out of 80 were unable to walk 1000 m without claudication. Two patients underwent surgery.

In the group that was treated with methylcobalamin and medical/interventional care, 50 out of 70 could not initially walk 1000 m without claudication. At two years, 69 of the 70 patients could walk greater than 1000 m without claudication. One single patient required surgical intervention.

In critique, we have opted to judge this study as two case series of medical/interventional care when evaluating long-term outcomes. This study is limited by lack of standardized medical/interventional treatment or standardized outcome measures. This study provides Level IV treatment evidence that medical/interventional care can improve walking ability in spinal stenosis patients. Adding methylcobalamin to the medical/interventional regimen improves walking distance in an added percentage.

In 2005, Zucherman et al[51] released two-year data on patients treated with X STOP for lumbar spinal stenosis. Patients were randomized into two groups, one treated with X STOP and one treated medically/interventionally. Nonsurgical treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years.

The primary outcome measure was the Zurich Claudication Questionnaire. Secondary outcomes included the SF-36 and range of motion.

At follow-up, 81 of the 91 medical/interventional patients were available for assessment. Of the patients who were in the medical/interventional group, 44% experienced at least some improvement in their pain and 43% of patients experienced at least some improvement in their physical function. In critique, medical/interventional treatment was not controlled and secondary outcome measure results were not available. Data of two-year outcomes for the medical/interventional group show poorer results than other medical/interventional studies. This study provides Level IV evidence that approximately 40% of patients treated medically/interventionally will show improvements in pain and physical function.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of medical treatment for lumbar spinal stenosis.

Recommendation #1:

> Future long-term studies of the effects of medical, noninvasive interventions for lumbar spinal stenosis should include an untreated control group.

Recommendation #2:

> Future long-term outcome studies of lumbar spinal stenosis should include results specific to each of the medical/interventional treatment methods.

Long Term Outcomes (Medical/Interventional) References

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D. Surgical Treatment

Do surgical treatments improve outcomes in the treatment of lumbar spinal stenosis compared to the natural history of the disease?

In patients with severe symptoms of lumbar spinal stenosis, decompressive surgery alone is effective approximately 80% of the time.

Grade of Recommendation: C

In patients with moderate to severe symptoms of lumbar spinal stenosis, surgery is more effective than medical/interventional treatment.

Grade of Recommendation: C

In patients with mild to moderate symptoms of lumbar spinal stenosis, medical/interventional treatment is effective approximately 70% of the time.

Grade of Recommendation: C

Amundsen et al[1] performed a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 with moderate to severe symptoms were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months and participated in back school and physical therapy when out of the brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

With medical/interventional treatment, a good result was reported by 70% (35 of 50) of patients at six months, 64% (32 of 50) at one year and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year and 84% (16 of 19) at four years.

Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (seven of 18) at six months, 33% (6 of 18) at one year and 47% (8 of 17) at four years. Of these patients, 56% (10 of 18) reported being worse at six months. Of the patients randomly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (9 of 13) at one year and 92% (11 of 12) at four years. At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.

In critique, no standardized outcome measures were utilized, and there were substantial numbers of patient deaths and patients crossing over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment rendered differed from the natural history of spinal stenosis. Also, the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc).

The surgically treated group improved more than the medically/interventionally treated group, though of the group with medical/interventional treatment, a large number of patients did quite well. When analyzing the small subset of randomized patients, this study provides Level II therapeutic evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result only about 40% of the time. Analysis of the surgically treated cohort of severely symptomatic patients provides Level IV evidence that a good outcome with decompression can be expected 80-90% of the time . Analysis of the cohort of patients with moderate symptoms suggested a good outcome with medical/interventional treatment about 70% of the time.

Herno et al[20] performed a retrospective, cohort study using a matched pair design of operated and nonoperated patients with spinal stenosis. Operative indications included disabling leg pain, progressively limited walking distance and presence of major or progressive neural deficits. Of the 57 patients treated medically/interventionally, 54 were matched with 54 of the 496 treated surgically. Twenty-five percent of the patients had previous back surgery and were excluded. ODI and functional status were evaluated only at follow-up. The average follow-up was 4.3 years. Men fared slightly better with operative intervention than without it ($p<0.05$). There was no difference in outcome between the matched pair groups. They concluded that medical/interventional treatment is a reasonable option in patients with moderate spinal stenosis.

In critique, the study suffered from diagnostic variability in the patient population and a wide variation of surgical techniques. Of the 54 medically/interventionally treated patients, 10 had been offered and refused surgical treatment. The medical/interventional group experienced less severe symptoms than the operative group (37/57). Of the 54 surgically treated patients, 10 had unclear reasons for surgery. The initial clinical status of these patients at the time of the index myelogram was unknown. Because of these deficiencies, this potentially Level III study was downclassified to a Level IV study.

This study provides Level IV therapeutic evidence that patients with mild or moderate stenosis and severe comorbidities may be managed medically/interventionally. For stenosis with complete myelographic block and severe symptoms, surgical decompression is the method of choice. No definitive conclusions regarding surgical management versus natural history of lumbar stenosis can be drawn from this study.

Hurri et al[22] studied a retrospective series of 75 patients with lumbar stenosis diagnosed by myelography and CT. The patients were treated and followed for 12 years. Baseline symptoms included: 98% low back pain (LBP), 80% leg pain, 21% leg fatigue and 41% leg numbness. Fifty-seven patients were treated operatively by various techniques and 18 patients were treated medically/interventionally. The authors did not detail the medical/interventional treatment. The authors showed at least slight improvement in 63% of surgically treated and 44% (eight of 18) of medically/interventionally treated patients. They reported worsening in 18% of operatively treated and 11% (two of 18) of medically/interventionally treated patients over time. Outcomes on the Oswestry Disability Index (ODI) demonstrated no differences between these groups.

In critique, this paper is limited by the nonstandardized, medical/interventional treatment and failure to stratify outcomes such as claudication, neurologic function and pain. The only reported outcome that allowed subgroup analysis of the medical/interventional group was ODI. The strengths of this study include its long follow-up and use of the ODI as an outcome measure. This study provides Level IV therapeutic evidence that a poorly defined surgical treatment group has the same ODI as this group of medically/interventionally treated patients. Radiographic severity of stenosis effects clinical trials and outcomes of lumbar spinal stenosis.

Johnsson et al[25] reported a case series of 63 patients with moderate of severe lumbar stenosis as diagnosed by myelography (partial block was diagnostic of moderate stenosis, a total block of severe stenosis) and symptoms of neurogenic claudication, radiculopathy or mixed symptoms. All patients were offered surgery. Patients who were too ill to have surgery as determined by anesthesia or declined surgery were placed in the no care group (19 patients), the remaining 44 patients had decompressive surgery without fusion. Outcomes included a four-level pain scale, a 100 mm VAS for degree of improvement or deterioration, a measure for walking capacity and electrodiagnostic studies.

At follow-up, 42% (eight of 19) of the nonoperated patients, 33% (10 of 30) of the surgical patients with moderate stenosis and 57% (8 of 14) of the surgical patients with severe stenosis were symptom free. With regard to patient pain rating at follow-up, in the nontreatment group, 32% (6 of 19) noted improvement in pain, compared with 57% (17 of 30) in the surgical group with moderate stenosis and 64% (nine of 14) in the surgical group with severe stenosis. Patients who felt their pain was worse at follow-up included 10% (two of 19) in the nontreated group compared with 20% (6 of 30) in the surgical group with moderate stenosis and 36% (five of 14) in the surgical group with severe stenosis. Severe deterioration was not found in untreated patients. Electrophysiologic parameters seemed to worsen equally in both groups.

In critique, the authors used nonvalidated outcome measures as their VAS for pain was divided into only four strata. Length of follow-up is not clearly listed and some data are ambiguous. In this study, "no surgery" apparently was the same as no treatment other than pain medication, though treatment for this group is not clearly defined. This study demonstrates Level IV therapeutic evidence that decompression provides improvement in pain 50-60% of the time, however 20-36% of patients are likely to worsen. This study also demonstrates Level IV evidence that medical/interventional management will provide pain relief about 33% of the time, while about 10% of the time pain is likely to worsen.

Four additional studies were evaluated and included in a secondary evidentiary table. These studies were not included in recommendations in this section of the guideline for the following reasons: (1) Atlas et al[5] included a mixed diagnostic group of patients with degenerative stenosis and herniated discs; (2) Chang et al[12] presented a reiteration of the Maine (Atlas, et al[5]) studies; (3) Gibson et al,[18] a Cochrane review, discussed the broader topic of lumbar spondylosis, which includes a wider variety of diagnoses than this work group is addressing, and we have evaluated the appropriate articles included in his review separately here; and (4) the analysis by Turner et al[34] included only low quality studies published before 1992 which we individually discarded from our evidentiary table.

In patients with mild to moderate symptoms of lumbar spinal stenosis placement of the X-STOP is more effective than medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Although the study cited in support of this recommendation is a Level I study, it is a single study. Therefore, until further evidence is published there remains insufficient evidence to make a recommendation.

Zucherman et al[38] performed a prospective, randomized, controlled trial of 191 patients with mild to moderate symptoms of lumbar stenosis. Diagnostic criteria were an age of at least 50 years, the presence of leg, buttock or groin pain with or without back pain that was relieved during flexion, the ability to sit for 50 minutes without pain, the ability to walk at least 50 feet and stenosis at one or two levels as seen on CT or MRI. The surgery group included 100 patients who had placement of the X STOP. The control group consisted of 91 patients who were medically/interventionally managed. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years. The primary outcome measure was the Zurich Claudication Questionnaire, a validated outcome measure for lumbar spinal stenosis. Secondary outcomes included the SF-36 and range of motion.

At two years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X STOP group and by 7.4% in the control group. At the same point, the mean Physical Function scores improved by 44.3% in the X STOP group and by -0.4% in the control group. At the two-year evaluation, 60% (56 of 93) of surgical patients reported a clinically significant improvement in the Symptom Severity domain compared with 19% (15 of 81) of patients in the control group, 57% (53 of 93) of patients reported clinically significant improvement in the Physical Function compared with 15% (12 of 81) of patients in the control group and 73% (68 of 93) of patients were at least somewhat satisfied compared with 36% (28 of 78) of patients in the control group.

In critique, medical/interventional treatment was not controlled and secondary outcome measures were not available. Data on two-year outcomes of the medical/interventional group showed poorer results than other medical/interventional studies. This study provided Level I evidence, in the early evaluation of that placement of the X STOP in patients with mild to moderate symptoms of stenosis was more effective than the medical/interventional treatment regimen described in this study.

Future Directions for Research

Recommendation #1:

A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with moderate stenosis, comparing lumbar decompression to a well-defined medical/interventional treatment program and a natural history group of untreated patients.

Recommendation #2:

A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with moderate stenosis, comparing the use of X STOP to a mi-

crolaminotomy decompression and a well-defined medical/interventional treatment program.

Surgical Treatment Versus Natural History References

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What is the role of decompression in the treatment of spinal stenosis?

At long-term follow-up (8-10 years), surgical decompression in the treatment of lumbar spinal stenosis is consistently supported when compared to medical/interventional treatments.

Grade of Recommendation: B

Amundsen et al[2] conducted a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 with moderate to severe symptoms were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

With medical/interventional treatment, a good result was reported by 70% (35 of 50) of patients at six months, 64% (32 of 50) at one year and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year and 84% (16 of 19) at four years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (seven of 18) at six months, 33% (six of 18) at one year and 47% (8 of 17) at four years. Of these patients, 56 % (10 of 18) reported being worse at six months. Of the patients randomly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (nine of 13) at one year and 92% (11 of 12) at four years.

At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.

In critique, no standardized outcome measures were utilized, and there were substantial numbers of patient deaths and patients crossing over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay on an

inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment rendered differed from the natural history of spinal stenosis. Also, the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc).

The surgically treated group improved more than the medically/interventionally treated group, although of the group with medical/interventional treatment, a large number of patients did quite well. This study provides Level II therapeutic evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result only about 40% of the time. This study also provides Level IV evidence that a cohort of patients with severe symptoms at presentation will have a good outcome with decompression 80-90% of the time and a cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.

Atlas et al[7] conducted a prospective, cohort study involving 148 patients, of which 81 underwent surgery and 67 received medical/interventional management. Outcome was assessed using the modified RMDQand the SF-36. On average, patients in the surgical group had more severe imaging findings and symptoms and worse functional status than patients in the medical/interventional group at entry. Few patients with mild symptoms were treated surgically, and few patients with severe symptoms were treated medically/interventionally. However, of the patients with moderate symptoms, a similar percentage of patients were treated surgically or medically/interventionally.

One year after study entry, 28% of medically/interventionally and 55% of surgically treated patients reported definite improvement in their predominant symptoms ($p < 0.003$). For patients with moderate symptoms, outcomes for surgically treated patients were also improved compared with those of medically/interventionally treated patients. Surgical treatment remained a significant determinant of one-year outcome, even after adjustment for differences between treatment groups at entry ($p < 0.05$). The maximal benefit of surgery was observed by the time of the first follow-up evaluation, which was at three months. Although few medically/interventionally treated patients experienced a worsening of their condition, there was little improvement in symptoms and functional status compared with study entry.

The authors concluded that when evaluating one-year, patient-reported outcomes, patients with severe lumbar spinal stenosis who were treated surgically experienced greater improvement than patients treated medically/interventionally.

In critique, the study was nonrandomized. On average, patients in the surgical group had more severe imaging findings and symptoms and worse functional status than patients in the medi-

cal/interventional group at entry. Few patients with mild symptoms were treated surgically and few patients with severe symptoms were treated medically/interventionally. There was short follow-up of only one year. There were two groups of patients included in this study. One group presented with neurogenic claudication and radiographic findings of lumbar spinal stenosis. The second group presented with radiculopathy (sciatica) and radiographic findings of lumbar spinal stenosis and concomitant HNP. No attempt was made to separate these two groups for data analysis. This paper provides Level II therapeutic evidence that surgical treatment provides greater improvement in patients with spinal stenosis compared with medical/interventional treatment at one-year follow-up. Of the surgical group, 80% reported improvement at one year.

Atlas et al[8] reported a prospective comparative study involving the same 148 patients described in the aforementioned study, of which 81 underwent surgery and 67 received medical/interventional management. Eighty-three percent of patients treated surgically and 78% of patients in the medical/interventional group were available for four-year follow-up, respectively. Outcome was assessed using the modified Roland Morris Disability Questionnaire and the SF-36.

After four years, there was a 22.1% crossover rate to surgery from the medical/interventional group. Seventy percent of the surgically treated and 52% of the medically/interventionally treated patients reported that their predominant symptom, either leg or back pain, was better ($p < 0.05$). Satisfaction of patients with their current state at four years was reported by 63% of the surgically treated and 42% of the medically/interventionally treated patients ($p < 0.04$). Surgical treatment remained a significant determinant of four-year satisfaction, even after adjustment for other independent predictors ($p < 0.001$). For the medically/interventionally treated patients, there was no significant change in outcomes over four years, whereas the initial improvement seen in the surgically treated patients modestly decreased over the subsequent four years. Relative benefit of surgery declined with time whereas medical/interventional group remained stable with time.

The critique of this study is the same as that for Atlas et al[7]. In addition, follow-up was moderate at four years and longer follow-up could show further deterioration of results.

This paper provides Level II therapeutic evidence that surgical treatment provides greater improvement in patients with spinal stenosis compared with medical/interventional treatment at four-year follow-up. Of the surgical group, 70% reported improvement of their predominant complaint at four years. This study showed deterioration from one-year results presented in their previous study.

Atlas et al[9] reported the 8- to 10-year follow-up results of the above two studies. Long-term follow-up (8-10 years) results were available for 79% (97 of 123) of patients (including 11 pa-

tients who died before the 10-year follow-up but completed an eight- or nine-year survey); 89% (56 of 63) initially treated surgically and 68% (41 of 60) initially treated medically/interventionally.

After eight to 10 years, a similar percentage of surgical and medical/interventional patients reported that their low back pain was improved (53% versus 50%, $p < 0.8$), their predominant symptom (either back or leg pain) was improved (54% versus 42%, $p < 0.3$) and that they were satisfied with their current status (55% versus 49%, $p < 0.5$). These treatment group findings persisted after adjustment for other determinants of outcome in multivariate models. However, patients initially treated surgically reported less severe leg pain symptoms and greater improvement in back-specific functional status after eight to 10 years than medically/interventionally treated patients.

By 10 years, 23% of surgical patients had undergone at least one additional lumbar spine operation, and 39% of medical/interventional patients underwent at least one lumbar spine operation. Patients undergoing subsequent surgical procedures experienced worse outcomes than those continuing with their initial treatment. Outcomes according to actual treatment received at 10 years did not differ because individuals undergoing additional surgical procedures experienced worse outcomes than those continuing with their initial treatment. The authors concluded that among patients with lumbar spinal stenosis completing 8- to 10-year follow-up, low back pain relief, predominant symptom improvement and satisfaction with the current state were similar in patients initially treated surgically or medically/interventionally. However, leg pain relief and greater back-related functional status continued to favor those initially receiving surgical treatment.

In critique of this study, there was a high re-operation rate in the surgical group at 10 years, with 23% of the surgical patients undergoing at least one additional spine operation. There was a high crossover rate in the medical/interventional group with 39% of medical/interventional patients having at least one lumbar spine operation.

This study provides Level II therapeutic evidence that at 8- to 10-year follow-up, surgical treatment was similar to medical/interventional treatment with regard to low back pain relief, predominant symptom improvement and satisfaction with the current state. The surgically treated patients, however, reported greater improvement in leg pain symptoms and greater improvement in back-specific functional status.

Thome et al[47] conducted a randomized, controlled trial comparing surgical techniques for lumbar spinal stenosis using 120 patients. There were three separate groups. Group 1 had bilateral laminotomies, Group 2 had unilateral laminotomy and Group 3 had laminectomies performed. At one-year follow-up, 94% of patients were assessed with VAS, Roland Morris Disability Questionnaire (RMDQ) and SF-36. Residual pain was lower in patients undergoing bilateral

laminotomies or unilateral laminotomy compared to laminectomy ($p < 0.05$). The RMDQ score significantly improved in all groups ($p<0.001$) corresponding to a dramatic increase in walking distance. SF-36 scores demonstrated marked improvement most pronounced in bilateral laminotomies. The number of repeated operations did not differ among groups. Patient satisfaction was significantly superior in patients treated with bilateral laminotomy, with 3%, 27% and 26% of patients unsatisfied in groups 1, 2 and 3 respectively ($p < 0.01$). In conclusion, bilateral laminotomy had the best outcomes. Overall complication rate was lowest with bilateral laminotomy and highest with laminectomies.

In critique, this study had very good follow-up of 94%. Bilateral and unilateral laminotomies allowed adequate and safe decompression of lumbar stenosis and resulted in a highly significant reduction of symptoms and disability and improved health related quality of life. There was an improvement in the SF-36, VAS score and RMDQ score but the standard deviations were high for the VAS and RMDQ. This study provides Level II evidence that patients who received bilateral laminotomies or unilateral laminotomies experienced better outcomes than those undergoing laminectomies, but only Level IV evidence that decompression provided relief in patients with spinal stenosis.

Arinzon et al[3] performed a prognostic case control study investigating the effect of decompression for lumbar spinal stenosis in elderly diabetic patients. The study included 62 diabetic patients and 62 gender- and age-matched nondiabetic controls. The mean follow-up was 40.3 months. Comorbidities were assessed and outcomes were measured using the visual analog scale (VAS), basic activities of daily living (BADL) and walking distance. The authors concluded that decompression for symptomatic spinal stenosis is beneficial in elderly diabetic patients. However, the results are related to successful pain reduction, physical and mental health status, severity of clinical presentation, insulin treatment and duration of diabetes. The benefits in diabetic patients are low as compared with nondiabetic patients with regard to symptom relief, satisfaction, BADL function and rate of complications.

In critique of this study, it highlights the clinical results of lumbar decompression in diabetic patients. Conclusions regarding mental health status were not supported with appropriate outcome tools to assess mental health. They failed to address the degree of stenosis in both the diabetic and control cohort. This study provides Level III prognostic evidence to support decompressive surgery for lumbar spinal stenosis in elderly diabetic patients. It also highlights the higher complication rate ($p<0.0001$) and less successful pain relief compared with nondiabetic patients ($p=0.0067$).

Arinzon et al[4] conducted a retrospective, prognostic study of the effects of age on decompressive surgery for lumbar spinal stenosis. Two hundred and eighty-three patients were grouped according to age. One group was aged 65-74 years old and the second group was > 75 years old. Follow-up was up to 42 months with a minimum of nine months. Within both treatment

groups there was a significant ($p<0.0001$) subjective improvement in low back and radicular pain as well as the ability to perform daily activities. When compared to preoperative levels, the oral scores for pain while performing daily activities were significantly improved ($p<0.001$) in both treatment groups. The authors concluded that the overall postoperative complication rate was similar between the groups and that age is not a contraindication for surgical decompression of lumbar spinal stenosis. Both groups are equally likely to suffer minor perioperative complications.

In critique of this study, there were no validated outcome tools and a lack of standardized surgical procedures, thus this paper provides Level III prognostic evidence that age greater than 75 years is not a contraindication for lumbar decompression compared with patients 65-74 years old.

Mariconda et al[34] reported an incompletely randomized, prospective study of 44 patients comparing single or multilevel laminectomy in patients with mild to moderate leg pain to patients treated with medical/interventional therapy. Outcomes were assessed using the Beaujon Scoring System. Twenty-two patients were assigned to each group. Only 32 of 44 patients were randomly assigned into each group. The mean functional status at one year was improved in both groups. Conservative treatment consisted of bed rest, use of a semirigid orthosis, physical therapy and appropriate exercise program. At four years, the good results were 68% in the surgical group and 33% in the medical/interventional group. Only 2.6% of patients experienced an increase in their spondylolisthesis. There was a reoperation rate of 9% and a cross over rate of 9%.

In critique of this study, patients were relatively young with a mean age of 61 years and an inclusion criterion as young as 40 years of age. Validated outcome measures were not used. The patient sample size was small. There was a mixed surgical technique with occasional undercutting of the contralateral lamina. There was partial randomization in the study with only 73% of the patients randomized. Finally, it is not known how long medical/interventional management was continued. Because of these deficiencies, this study was classified as providing Level III evidence.

This study provides Level III therapeutic evidence to support good outcomes in 68% of patients undergoing decompression for lumbar spinal stenosis compared with medical/interventional management.

More than 30 articles were identified in the literature search that provided Level IV evidence to support surgical decompression in the treatment of lumbar stenosis (see references). Within this group, less invasive decompressive procedures were also shown to be beneficial. Although a systematic review of the spinal stenosis literature requires evaluation and recommendations based on the highest levels of available evidence, it is noted that these Level IV studies

consistently supported lumbar decompression in the treatment of lumbar spinal stenosis and served to support further the conclusions of the higher levels of evidence.

Patients aged 75 or greater with lumbar spinal stenosis show the same benefit from lumbar decompression as younger patients aged 65-74.

Grade of Recommendation: C

Arinzon et al[4] performed a retrospective, prognostic study of the effects of age on decompressive surgery for lumbar spinal stenosis in 283 patients grouped according to age. One group included ages 65-74 and the second group was greater than 75 years old. Follow-up was up to 42 months with a minimum of nine months. Within both treatment groups there was a significant ($p<0.0001$) subjective improvement in low back and radicular pain as well as the ability to perform daily activities. When compared to preoperative levels, the oral scores for pain while performing daily activities were significantly improved ($p<0.001$) in both treatment groups. The authors concluded that the overall postoperative complication rate was similar between the groups and that age is not a contraindication for surgical decompression of lumbar spinal stenosis. Both groups are equally likely to suffer minor perioperative complications.

In critique of this study, there were no validated outcome tools and a lack of standardized surgical procedures, thus this paper provides Level III prognostic evidence that age greater than 75 years is not a contraindication for lumbar decompression compared with patients 65-74 years old.

Diabetic patients, 65 and older, with lumbar spinal stenosis benefit from lumbar decompression.

Grade of Recommendation: C

Arinzon et al[3] conducted a prognostic, case control study investigating the effect of decompression for lumbar spinal stenosis in elderly diabetic patients. The study included 62 diabetic patients and 62 gender and age matched nondiabetic controls. The mean follow-up was 40.3 months. Comorbidities were assessed and outcomes were measured using the visual analog scale (VAS), basic activities of daily living (BADL) and walking distance. The authors concluded that decompression for symptomatic spinal stenosis is beneficial in elderly diabetic patients. However, the results are related to successful pain reduction, physical and mental health status, severity of clinical presentation, insulin treatment and duration of diabetes. The benefits

in diabetic patients are low as compared with nondiabetic patients with regard to symptom relief, satisfaction, BADL function and rate of complications.

In critique of this study, it highlights the clinical results of lumbar decompression in diabetic patients. Conclusions regarding mental health status were not supported with appropriate outcome tools to assess mental health. They failed to address the degree of stenosis in both the diabetic and control cohort. This study provides Level III prognostic evidence to support decompressive surgery for lumbar spinal stenosis in elderly diabetic patients. It also highlights the higher complication rate ($p<0.0001$) and less successful pain relief compared with nondiabetic patients ($p=0.0067$).

Future Directions for Research

The work group identified the following potential study, which would generate meaningful evidence to assist in further defining the role of decompression for lumbar spinal stenosis.

Recommendation:

> A multicenter, randomized, controlled trial with sufficient power and appropriate validated outcome tools to determine the effectiveness of lumbar decompression as compared to medical/interventional management for moderate to severe lumbar stenosis. This study could include stratification of patients based on demographics and comorbidities.

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Does surgical decompression alone improve surgical outcomes in the treatment of spinal stenosis compared to medical/interventional treatment alone or the natural history of the disease?

In patients with severe symptoms of lumbar spinal stenosis, decompressive surgery alone is effective about 80% of the time and medical/interventional treatment alone is effective about 33% of the time.

Grade of Recommendation: C

In patients with moderate to severe symptoms of lumbar spinal stenosis, surgery is more effective than medical/interventional treatment.

Grade of Recommendation: C

In patients with mild to moderate symptoms of lumbar spinal stenosis, medical/interventional treatment is effective up to 70% of the time.

Grade of Recommendation: C

Amundsen et al[1] conducted a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 patients with moderate to severe symptoms were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent).

With medical/interventional treatment, a good result was reported by 70% (35 of 50) of patients at six months, 64% (32 of 50) at one year and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year and 84% (16 of 19) at four years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (7 of 18) at six months, 33% (6 of 18) at one year and 47% (8 of 17) at four years. Of these patients 56 % (10 of 18) reported being worse at six months. Of the patients randomly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (9 of 13) at one year and 92% (11 of 12) at four years.

At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.

In critique, no standardized outcome measures were utilized, and there was a substantial number of patient deaths and patients crossing over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment differed from the natural history of spinal stenosis. Also, the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc). The surgically treated group improved more than the medically/interventionally treated group, though of the group with medical/interventional treatment, a large number of patients did quite well.

When analyzing the small subset of randomized patients, this study provides Level II treatment evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result about 40% of the time. Analysis of the surgically treated cohort of severely symptomatic patients provides Level IV evidence that a good outcome with decompression can be expected in 80-90% of patients. Analysis of the cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.

Johnsson et al[11] studied a case series of 63 patients with moderate to severe lumbar stenosis as diagnosed by myelography (partial block was diagnostic of moderate stenosis, a total block of severe stenosis) and symptoms of neurogenic claudication, radiculopathy or mixed symptoms. All patients were offered surgery. Patients that were too ill to have surgery as determined by anesthesia or declined surgery were placed in the no care group (19 patients); the remaining 44 patients underwent decompressive surgery without fusion. Outcomes included a four-level pain scale, a 100 mm VAS for degree of improvement or deterioration, a measure of walking capacity and electrodiagnostic studies.

At follow-up, 42% (8 of 19) of the patients not operated upon, 33% (10 of 30) of the surgical patients with moderate stenosis and 57% (8 of 14) of the surgical patients with severe stenosis were symptom free. With regard to patient pain rating at follow-up, in the nontreatment group, 32% (6 of 19) noted improvement in pain, compared with 57% (17 of 30) in the surgical group with moderate stenosis and 64% (9 of 14) in the surgical group with severe stenosis. Patients who felt their pain was worse at follow-up included 10% (2 of 19) in the nontreated group compared with 20% (6 of 30) in the surgical group with moderate stenosis and 36% (5 of 14) in

the surgical group with severe stenosis. *Severe deterioration was not found in untreated patients.* Electrophysiologic parameters seemed to worsen equally in both groups.

In critique, the authors used nonvalidated outcome measures as their VAS for pain was divided into only four strata. Length of follow-up was not clearly listed and some data were ambiguous. In this study, no surgery appears to be the same as no treatment other than pain medication, although treatment for this group is not clearly defined. This study demonstrates Level IV treatment evidence that decompression provides improvement in pain 50-60% of the time; however 20-36% of patients are likely to worsen. This study also demonstrates Level IV evidence that medical/interventional management will provide pain relief about 33% of the time, whereas about 10% of the time, pain is likely to worsen.

The work group evaluated three other studies which have been included in a secondary evidentiary table, but excluded from the guideline recommendations for the following reasons: (1) Atlas et al[3] included a mixed diagnostic group of patients with degenerative stenosis and herniated discs; (2) Gibson et al[9] is a Cochrane review that discussed the broader topic of lumbar spondylosis which included a wider variety of diagnoses than this work group is addressing. The appropriate articles included in this Cochrane review have been evaluated separately here by the work group and are included in this guideline; and (3) the analysis by Turner et al[16] included only low quality studies published before 1992 which were individually discarded from the evidentiary table.

In patients with mild to moderate symptoms of lumbar spinal stenosis, placement of an interspinous process spacing device is more effective than medical/interventional treatment at two-year follow-up.

Grade of Recommendation: I (Insufficient Evidence)

Although the study cited in support of this recommendation is a Level I study, it is a single study. Therefore, until further evidence is published, evidence remains insufficient to make a recommendation.

The following study presents a recent approach to one-or two-level lumbar spinal stenosis that results in an indirect decompression of the spinal canal. This differs from more traditional surgical decompressions accomplished by laminectomy or laminotomy. In this approach, a device is placed between two spinous processes with the back in flexion. The device is reported to thereby increase canal size during weight bearing and maintain canal size in extension, effectively, but indirectly, decompressing the canal with this surgical procedure. Because this

procedure results in a surgical decompression of the lumbar spinal canal, the work group chose to place this study in this section of this Guideline.

Zucherman et al[19] conducted a prospective, randomized, controlled trial of 191 patients with mild to moderate symptoms of lumbar stenosis. Diagnostic criteria were an age of at least 50 years, the presence of leg, buttock or groin pain with or without back pain that was relieved during flexion, the ability to sit for 50 minutes without pain, the ability to walk at least 50 feet and stenosis at one or two levels as seen on CT or MRI. The surgery group included 100 patients which had placement of the X STOP. The control group consisted of 91 patients who were medically/interventionally managed. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years.

The primary outcome measure was the Zurich Claudication Questionnaire, a validated outcome measure for lumbar spinal stenosis. Secondary outcomes included the SF-36 and range of motion.

At two years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X STOP group and by 7.4% in the control group. At the same point, the mean Physical Function scores improved by 44.3% in the X STOP group and by -0.4% in the control group. At the two-year evaluation, 60% (56 of 93) of surgical patients reported a clinically significant improvement in the Symptom Severity domain compared with 19% (15 of 81) of patients in the control group, 57% (53 of 93) of patients reported clinically significant improvement in the Physical Function domain compared with 15% (12 of 81) of patients in the control group, and 73% (68 of 93) of patients were at least somewhat satisfied compared with 36% (28 of 78) of patients in the control group.

In critique, medical/interventional treatment was not controlled and secondary outcome measures were not available. Data on two-year outcomes of the medical/interventional group showed poorer results than other medical/interventional studies. This initial evaluation of the X STOP provided Level I therapeutic evidence that in patients with mild to moderate stenosis, this procedure was more effective than a medical/interventional treatment regimen in similar patients.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of decompression, as compared to a medical/interventional treatment and natural history, for lumbar spinal stenosis.

Recommendation #1:

A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with moderate clinically symptomatic stenosis, comparing lumbar decompression to a well-defined medical/interventional treatment program and a natural history group of untreated patients.

Recommendation #2:

A large, multicenter, three-arm, randomized, controlled trial using a well-defined group of patients with mild to moderate clinically symptomatic stenosis, comparing the use of X STOP to a microlaminotomy decompression and a well-defined medical/interventional treatment program.

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Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of spinal stenosis compared to treatment by decompression alone?

In patients with lumbar spinal stenosis and spondylolisthesis, decompression with fusion results in better outcomes than decompression alone.

Grade of Recommendation: B

Herkowitz et al[19] performed a randomized, controlled trial of a homogeneous group of 50 patients with symptoms of degenerative stenosis and spondylolisthesis. Patients were randomized by alternating selection into two groups, one group (25 patients) underwent decompression alone and one group (25 patients) underwent decompression and intertransverse process arthrodesis. Patients were followed between 2.4 and four years. Outcome measures were a five-point pain scale and assessment of operative result (excellent, good, fair, poor). The decompression and arthrodesis group experienced a significantly higher number of excellent and good results (96%, 24 of 25) compared with the group that had decompression alone (44%, 11 of 25) ($p<0.001$). Pseudarthosis occurred in 36% (9 of 25) of patients who underwent arthrodesis, but this presence did not alter outcomes. Progression of slip was noted in 96% (24 of 25) of patients with decompression alone compared with 28% (7 of 25) in the decompression and arthrodesis group.

In critique, nonvalidated outcome measures were used and the sample size in this study was small; however the results of the study were nonetheless statistically significant. Because of the small sample size and the use of nonvalidated outcome measures along with incomplete masking, this potentially Level I study was downgraded to a Level II study. This study provides Level II therapeutic evidence that decompression and intertransverse process arthrodesis provides better outcomes than decompression alone in the treatment of symptomatic degenerative stenosis with spondylolisthesis at three-year follow-up.

Bridwell et al[7] conducted a nonmasked, incompletely randomized trial of 44 patients with spinal stenosis and spondylolisthesis. Patients were randomized to three groups: (1) decompression alone (nine patients), (2) decompression with in situ fusion (11 patients) and (3) decompression with instrumented fusion (24 patients). Patients with greater than 10° or 3 mm of motion on preoperative flexion/extension radiographs were assigned to Group 3, accounting for larger numbers in this group. Outcome measures were patient assessment of ability to walk, patient assessment of surgical benefit and progression to further spondylolisthesis. Patients were followed for greater than two years. Fusion was evaluated by plain radiographs. Progression of spondylolisthesis was seen in 44% (4 of 9) of the group with decompression alone, 70% (7 of

10) of the group with in situ fusion and 4% (1 of 24) of the group with decompression with instrumented fusion. Patient symptoms were associated with progression of slip. Thus the group with instrumentation experienced significantly less slip progression and significantly better fusion rate and outcome.

In critique, the sample size was small, randomization was poor, there was no masking and no validated outcome measures were used. For these reasons this study provides Level III therapeutic evidence that instrumented fusion in the treatment of degenerative spondylolisthesis with lumbar spinal stenosis decreases progression of spondylolisthesis and patient symptoms as compared with decompression alone or decompression with in situ fusion.

Ghogawala et al[13] performed a prospective, cohort study of 34 patients with stenosis and Grade I spondylolisthesis without gross instability (less than 3 mm translation on flexion/extension radiographs). Patients were divided, based on surgeon discretion, into a group who received laminectomy (20 patients) or laminectomy and fusion with pedicle screw fixation (14 patients). Outcome measures were the ODI and SF-36. At one year, ODI improved 13.6 points with the decompression group versus 27.5 points for the decompression and fusion group. SF-36 scores improved 6.5 in the decompression group versus 15.9 in the decompression and fusion group. While improvement in both groups was statistically significant, the decompression and fusion group improved significantly more than decompression alone ($p<0.002$ on PCS and $p<0.003$ on ODI).

In critique, the sample size of this study was small and group assignment could have been highly biased. Both groups showed improvement. This study provides Level III therapeutic evidence that decompression with fusion is more effective than decompression alone in patients with Grade I spondylolisthesis without instability.

Katz et al[21] conducted a prospective, observational study of 310 consecutive patients with spinal stenosis. Inclusion criteria included age greater than or equal to 50 years, the presence of back, buttock and/or lower extremity pain; radiographic evidence of stenosis and the surgeon's judgment that patients had clinically significant degenerative lumbar spinal stenosis. A total of 279 patients participated and 199 were available at follow-up (71%). Outcome measures were health status (including Sickness Impact Profile and Zung Depression Questionnaire), walking capacity, back and leg pain, and satisfaction with surgery. At follow-up no radiographs were obtained. Of patients in the study, 71% underwent decompression, 14% had decompression with fusion and 15% had decompression with fusion and instrumentation. The minimum follow-up was two years.

Noninstrumented arthrodesis was associated with superior relief of low back pain at six months ($p< 0.004$) and 24 months ($p< 0.01$). There were no significant differences in the other outcomes across treatment groups.

In critique, the groups of patients were not homogeneous, a large number of patients were lost to follow-up and the numbers of patients in the fusion groups were very small. This study provides Level III therapeutic evidence that noninstrumented decompression and fusion provides better relief of low back pain at two-year follow-up than decompression alone or decompression and fusion with instrumentation.

Mardjetko et al[27] performed a meta-analysis of literature prior to 1993 regarding degenerative spondylolisthesis with radicular symptoms. Most of the included studies are Level IV data. There is a high degree of heterogeneity in analysis because of the variety of reporting methods for results and outcomes data. Overall, surgical groups appeared to do better than no treatment at all, and decompression with fusion did better than decompression alone. There is no clear advantage clinically to instrumentation, although fusion rates are higher with instrumentation.

In critique, the data analyzed in this meta-analysis is mainly Level IV data and because of the heterogeneity of outcome measures used in the study, it is more difficult to draw conclusions. This study provides Level III therapeutic evidence that in patients with degenerative spondylolisthesis, decompression and fusion is more effective than decompression alone. The use of instrumentation increases the likelihood of fusion, although does not appear to influence clinical outcomes.

Matsudaira et al[28] conducted a retrospective comparative study of 53 patients with single-level Grade I spondylolisthesis and spinal stenosis at L4-5. These patients were divided (not randomized) into three groups. One group of 19 patients underwent decompressive laminectomy with fusion and instrumentation. A second group of 19 patients underwent decompression of the canal using a laminoplasty technique to preserve the integrity of the midline structure. The last group (16 patients) refused surgery and was treated with an undefined, medical/interventional program. Clinical outcomes were measured using the Japanese Orthopedic Association (JOA) score.

Subjective LBP as well as the JOA score was significantly higher in the control group than in either surgical group. There were no significant differences in percent of slip or demographics.

At two-year follow-up, the JOA scores showed no improvement in the control group, but significant improvement in the surgical groups ($p < 0.0001$). Alleviation of all symptoms including back pain was significantly better in the two surgical groups compared with the control group. There was no significant difference between the two surgical groups. Back pain improved in all three groups with greater improvement in the surgical groups. Degree of satisfaction was slightly higher in the decompression alone group. The fusion group experienced a higher complication rate. Slip progression was higher in the medical/interventional group and the decompression alone group compared with the fusion group.

In critique, the sample size was small, medical/interventional treatment was not defined and the reasons for surgical refusal were not explained. This study provides Level III therapeutic evidence that in patients with single level stenosis at L4-5 and Grade I spondylolisthesis there is no difference in outcomes between laminoplasty and decompression with fusion at two-year follow-up. Progression of slip was more likely to occur in patients undergoing laminoplasty or no treatment as compared with patients undergoing fusion, although this did not influence outcomes at two years. Both of these surgical treatments offered better outcomes than medical/interventional treatment.

In addition to the studies noted above, a number of case series (Level IV evidence) supported this recommendation as well. [4,8,11,18,22,29,30,35]

The presence of pseudarthrosis on radiographs following lumbar fusion for lumbar spinal stenosis with spondylolisthesis does not affect outcomes at two years.

Grade of Recommendation: B

Herkowitz et al[19] performed a randomized, controlled trial of a homogeneous group of 50 patients with symptoms of degenerative stenosis and spondylolisthesis. Patients were randomized by alternating selection into two groups, one group (25 patients) underwent decompression alone and one group (25 patients) underwent decompression and intertransverse process arthrodesis. Patients were followed between 2.4 and four years. Outcome measures were a five-point pain scale and assessment of operative result (excellent, good, fair, poor). The decompression and arthrodesis group reported a significantly higher number of excellent and good results (96%, 24 of 25) compared with the group that had decompression alone (44%, 11 of 25) ($p<0.001$). Pseudarthosis occurred in 36% (9 of 25) of patients who underwent arthrodesis, but this presence did not alter outcomes. Progression of slip was noted in 96% (24 of 25) of patients with decompression alone compared with 28% (7 of 25) in the decompression and arthrodesis group.

In critique, nonvalidated outcome measures were used and the sample size in this study was small; however, the results of the study were nonetheless statistically significant. Because of the small sample size and the use of nonvalidated outcome measures along with incomplete blinding, this potentially Level I study was downgraded to a Level II study. This study provides Level II therapeutic evidence that decompression and intertransverse process arthrodesis provides better outcomes than decompression alone in the treatment of symptomatic degenerative stenosis with spondylolisthesis at three-year follow-up, and that the presence of pseudarthrosis does not affect the outcome in the fusion group.

Fischgrund et al[10] conducted a nonmasked, prospective, randomized, controlled trial comparing instrumented to noninstrumented fusion in patients with symptomatic spinal stenosis and associated spondylolisthesis. Inclusion criteria were a clinical diagnosis of stenosis (leg pain, claudication), failure of at least three months of medical/interventional care, plain radiographs showing single-level spondylolisthesis and MRI or CT confirmed spinal stenosis at the level of listhesis. Outcome measures were a five-point VAS for back and leg pain and an operative result rating (excellent, good, fair or poor) based on examiner assessment of pain and functional level.

Seventy-six patients underwent posterior decompression with concomitant posterolateral intertransverse process arthrodesis. The patients were randomized to a segmental transpedicular instrumented or noninstrumented group. Sixty-seven patients were available for a two-year follow-up. Clinical outcome was excellent or good in 76% of the patients in whom instrumentation was placed and in 85% of those in whom no instrumentation was placed. Successful arthrodesis occurred in 82% of the instrumented cases versus 45% of the noninstrumented cases. Overall, successful fusion did not influence patient outcome.

In critique, standardized outcome measures were not used and follow-up may not be long enough to see the effects of pseudarthrosis. This study provides Level II evidence that instrumented fusion increases the likelihood of obtaining a solid arthrodesis; however, this does not correlate with improved outcomes at two years.

Bridwell et al[7] conducted a nonmasked, incompletely-randomized trial of 44 patients with spinal stenosis and spondylolisthesis. Patients were randomized to three groups: (1) decompression alone (nine patients), (2) decompression with in situ fusion (11 patients) and (3) decompression with instrumented fusion (24 patients). Patients with greater than 10° or 3 mm of motion on preoperative flexion/extension radiographs were assigned to Group 3, accounting for larger numbers in this group. Outcome measures were patient assessment of ability to walk, patient assessment of surgical benefit and progression to further spondylolisthesis. Patients were followed for greater than two years. Fusion was evaluated by plain radiographs. Progression of spondylolisthesis was seen in 44% (four of nine) of the group with decompression alone, 70% (seven of 10) of the group with in situ fusion and 4% (one of 24) of the group with decompression with instrumented fusion. Patient symptoms were associated with progression of slip. Thus the group with instrumentation experienced significantly less slip progression and significantly better fusion rate and outcome.

In critique, the sample size was small, randomization was poor and no validated outcome measures were used. For these reasons, this study provides Level III evidence that instrumented fusion in the treatment of degenerative spondylolisthesis with lumbar spinal stenosis decreases progression of spondylolisthesis, increases fusion rates and improves outcomes as compared with decompression alone or decompression with in situ fusion.

The presence of pseudarthrosis on radiographs following lumbar fusion for lumbar spinal stenosis with spondylolisthesis negatively affects outcomes at greater than five-year follow-up.

Grade of Recommendation: I (Insufficient Evidence)

Kornblum et al[23] reported on 58 patients with symptomatic lumbar stenosis and spondylolisthesis that had been studied prospectively in two prior studies. Patients were treated with a posterior decompression and bilateral posterior arthrodesis with bone graft. Radiographic evaluation was used to determine if fusion or pseudarthrosis was present. Forty-seven patients were available for follow-up for a range of five to 14 years. Outcome measures were VAS for leg and back pain, and a questionnaire about surgical outcome. Patients were divided into two cohorts based on presence or absence of pseudarthrosis. The success was good in 86% of patients with solid fusion and good in only 56% of patients with radiographically suggested pseudarthrosis.

In critique, the sample size is small, only patients with noninstrumented fusions were included, 19% of patients were lost to follow-up and whereas initial data was collected prospectively, for this study, selective data was retrospectively extracted from two prior studies. Pseudarthrosis was diagnosed by routine lumbar spine films. This study provides Level III prognostic evidence that pseudarthrosis is a poor prognostic indicator of good outcomes in patients undergoing decompression and noninstrumented fusion for stenosis with spondylolisthesis at long-term follow-up.

The addition of instrumentation to posterior fusion for treatment of spinal stenosis with spondylolisthesis increases the radiographic fusion rate.

Grade of Recommendation: B

Fischgrund et al[10] conducted a nonmasked, prospective, randomized, controlled trial comparing instrumented to noninstrumented fusion in patients with symptomatic spinal stenosis and associated spondylolisthesis. Inclusion criteria were a clinical diagnosis of stenosis (leg pain, claudication), failure of at least three months of medical/interventional care, plain radiographs showing single-level spondylolisthesis and MRI- or CT-confirmed spinal stenosis at the level of listhesis. Outcome measures were a five-point VAS for back and leg pain and an operative result rating (excellent, good, fair or poor) based on examiner assessment of pain and functional level.

Seventy-six patients underwent posterior decompression with concomitant posterolateral intertransverse process arthrodesis. The patients were randomized to a segmental transpedicular instrumented or noninstrumented group. Sixty-seven patients were available for a two-year follow-up. Clinical outcome was excellent or good in 76% of the patients in whom instrumentation was placed and in 85% of those in whom no instrumentation was placed. Successful arthrodesis occurred in 82% of the instrumented cases versus 45% of the noninstrumented cases. Overall, successful fusion did not influence patient outcome.

In critique, investigators assumed that two-year follow-up is adequate time to determine the presence of a pseudarthrosis. Additionally, only routine lumbar radiographs were utilized to assess the presence of pseudarthrosis. This study provides Level II evidence that instrumented fusion increases the likelihood of obtaining a solid arthrodesis.

Zdeblick[43] performed a prospective, randomized controlled trial of 124 patients with multiple diagnoses, including a small cohort of degenerative spondylolisthesis or degenerative scoliosis with stenosis. These patients were treated with decompression plus fusion, fusion with semirigid instrumentation or fusion with rigid instrumentation. Outcome was measured using a four-grade clinical scale (excellent, good, fair or poor).

Patients were followed for a minimum of two years and only one patient was lost to follow-up. Because of poor bone quality, nine patients crossed from implant to nonimplant group at the time of surgery. Several diagnoses and outcomes data were not presented in detail. Overall fusion rates were better with instrumentation and better with rigid than semirigid instrumentation. This held true for the subset of patients with degenerative spondylolisthesis. Overall outcomes were better for groups with instrumented fusion but this was not detailed by diagnoses. Good or excellent clinical results were reported in 95% of the group with rigid instrumentation and in 89% of the group with semirigid instrumentation.

In critique, this study included a heterogeneous group of patient diagnoses, nonvalidated outcome measures and incomplete reporting of outcome data. Fusion was assessed by routine lumbar spine X-ray studies but these did include flexion and extension films. This study provides Level II therapeutic evidence that at two-year follow-up, radiographically assessed fusion results are better for rigidly instrumented fusion than for semirigid instrumentation which in turn was better than for no instrumentation in this patient population.

Bridwell et al[7] performed a nonmasked, incompletely-randomized trial of 44 patients with spinal stenosis and spondylolisthesis. Patients were randomized to three groups: (1) decompression alone (nine patients), (2) decompression with in situ fusion (11 patients) and (3) decompression with instrumented fusion (24 patients). Patients with greater than 10° or 3 mm of motion on preoperative flexion/extension radiographs were assigned to Group 3, accounting for larger numbers in this group. Outcome measures were patient assessment of ability to walk, pa-

tient assessment of surgical benefit and progression to further spondylolisthesis. Patients were followed for greater than two years. Fusion was evaluated by plain radiographs. Progression of spondylolisthesis was seen in 44% (four of nine) of the group with decompression alone, 70% (seven of 10) of the group with in situ fusion and 4% (one of 24) of the group with decompression with instrumented fusion. Patient symptoms were associated with progression of slip. Thus the group with instrumentation experienced significantly less slip progression and significantly better fusion rate and outcome.

In critique, the sample size was small, randomization was poor and no validated outcome measures were used. Fusions were assessed with routine radiographs including flexion and extension films. For these reasons, this study provides Level III therapeutic evidence that instrumented fusion in the treatment of degenerative spondylolisthesis with lumbar spinal stenosis decreases progression of spondylolisthesis and increases fusion rates as compared to decompression with in situ fusion.

Of patients with lumbar spinal stenosis meeting Posner's criteria of instability, decompression with fusion provides better outcomes than decompression alone at greater than two-year follow-up.

Grade of Recommendation: I (Insufficient Evidence)

Yone et al[41] conducted a prospective, comparative study of 60 patients with lumbar stenosis. Inclusion criteria were the presence of back pain, leg pain or claudication which failed to improve with medical/interventional care and stenosis on imaging though criteria were not clearly defined. Patients were assessed as to whether they had instability based on Posner's definition. Of these 60 patients, 33 met the criteria for instability. Of these 33 patients with instability, all were offered decompression and fusion. Decompression and instrumented fusion was performed in 19 patients while the remaining 14 refused fusion and underwent decompression alone. The 27 patients without instability also underwent decompression without fusion. The primary outcome measure was the JOA score. Of the patients determined to have instability who underwent decompression and instrumented fusion as well as the group that was determined to have no instability and thus underwent decompression alone, 80% of the patients experienced good outcomes. Conversely, in the group determined to have instability that refused arthrodesis and thus underwent decompression alone, only 43% of the patients experienced good outcomes.

In critique, the sample size of patients undergoing fusion in this study was small. This study provides Level II therapeutic evidence that, in patients with lumbar spinal stenosis meeting Posner's criteria of instability, decompression and fusion is more effective than decompression alone.

Of patients with lumbar spinal stenosis without spondylolisthesis or instability, there is no evidence to support the addition of a fusion.

Grade of Recommendation: I (Insufficient Evidence)

Grob et al[17] conducted a randomized, controlled trial of 45 patients with symptomatic lumbar stenosis with less than 5 mm of intervertebral translation who were randomly assigned to three groups: (1) decompression with laminotomy and medial facetectomy, (2) decompression with arthrodesis of the most stenotic segment and (3) decompression with arthrodesis of all the effected segments. Inclusion criteria included a clinical diagnosis of stenosis and confirmation with CT, myelogram or MRI scan to have a mid sagittal diameter of less than 11 mm. Outcome measure was a result classification (very good, good, fair or poor) based on percentage of subjective pain relief, use of analgesics and reported impairment of daily activities.

Average follow-up duration was 28 months. At this point in follow-up, all groups showed an increase in walking ability and a decrease in pain. There was no difference between the groups noted.

In critique, the sample size of patients is small and no validated outcome measures were used. Intervertebral translation data were not presented in detail. This study provides Level II therapeutic evidence that there is no difference between decompression and decompression with fusion in patients with stenosis and less than 5 mm of intervertebral translation.

Yone et al[41] performed a prospective, comparative study of 60 patients with lumbar stenosis. Inclusion criteria were the presence of back pain, leg pain or claudication which failed to improve with medical/interventional care and stenosis on imaging though criteria were not clearly defined. Patients were assessed as to whether they had instability based on Posner's definition. Of these 60 patients, 33 met the criteria for instability. Of these 33 patients with instability, all were offered decompression and fusion. Decompression and fusion was performed in 19 patients while the remaining 14 refused fusion and underwent decompression alone. The 27 patients without instability also underwent decompression without fusion. The primary outcome measure was the JOA score. Of the patients who underwent instrumented fusion and the group that had no instability with decompression, 80% of the patients experienced good outcomes. Only 43% of the patients in the group with instability and decompression without fusion experienced good outcomes.

In critique, the sample size of patients undergoing fusion in this study was small. This study provides Level II therapeutic evidence that, in patients with lumbar spinal stenosis meeting Posner's criteria of instability, decompression and fusion is more effective than decompression

alone. The results of decompression and fusion in the instability group were comparable to results of decompression alone in the group without instability. However, no fusions were done in this latter group, thus, this study does not directly address the efficacy of decompression versus decompression and fusion in spinal stenosis without instability.

Future Directions for Research

The work group would like to point out that a number of these papers were downgraded because of lack of disease-specific outcome measures, and that future research including validated outcome measures could improve the level of evidence.

Recommendation:

> A randomized, controlled trial of sufficient power is proposed with validated outcome instruments and long-term follow-up evaluating the results of decompression, decompression with fusion and decompression with fusion and instrumentation.

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What is the long-term result (four+ years) of surgical management of spinal stenosis?

The long-term results of surgical management of spinal stenosis are good or excellent in 50-79% of patients.

Grade of Recommendation: C

Airaksinen et al[1] conducted a retrospective review of surgical outcomes for lumbar spinal stenosis. Of the 497 patients, 438 were available for follow-up at a mean of 4.3 years. The ODI was used as an outcome measure and a masked review was performed. Overall, there were good or excellent results in 62 % of patients. This study provides Level IV therapeutic evidence that surgery offers a 62% good or excellent result at four-year follow-up.

Amundsen et al[2] performed a prospective, comparative study of 100 patients with lumbar spinal stenosis. Patients were assigned to four groups. Those with severe symptoms underwent decompression (surgical group, S, n=19). Those with mild symptoms were treated medically/interventionally (conservative group, C, n=52). Those with moderate symptoms were randomized to medical/interventional (randomized conservative, RC, n=18) or operative care (randomized surgical, n=13). Follow-up was assessed at four and 10 years. All follow-up assessments were performed by the lead author, who also determined the overall treatment result. An intent-to-treat analysis was performed on the randomized groups at four years (ie, crossovers from medical/interventional to operative care were treated as failures). For the 10-year analysis, all surgical patients and all medically/interventionally treated patients were grouped together.

At the four-year follow-up, 84% of the nonrandomized surgical group reported good results; 57% of the nonrandomized, medical/interventional group reported good results; 47% of the randomized, medical/interventional group reported good results; and 92% of the randomized surgical group reported good results. The operative group tended to deteriorate somewhat over time while the medical/interventional group tended to improve, such that at final follow-up there were good outcomes in 70 to 75% of both groups. Those operated on a delayed basis (crossovers) did not have worse results than those operated on early.

In critique, the method used for assigning patients to treatment groups was biased. Thus, although they characterize one of the arms of their study as randomized, the bias limits the ability to draw conclusions from the data on these patients. Furthermore, the numbers assigned to the randomized groups were small, the numbers were unequal (suggesting bias in the randomization process) and no statistical tests for significance were applied. Outcome assessment by the treating physician using nonvalidated outcome measures introduces further bias.

This study offers Level IV therapeutic evidence that surgery for severe spinal stenosis provides good or excellent results in approximately 80% of patients at four-year follow-up and the results were relatively stable at 70% good or excellent results at 10 years. It also offers Level IV evidence that patients who have medical/interventional therapy first but then cross over to surgery will not harm their chances of success with surgery.

Atlas et al[4] conducted a prospective outcome study of 148 patients comparing the results between patients treated surgically for spinal stenosis and those treated medically/interventionally. There was a 33% drop rate, primarily due to death. The surgical group experienced worse symptoms initially. There was a 39% crossover to the surgical group. Validated outcome measures were used. At four-year follow-up, the results favored surgery. Over time the surgical results deteriorated, with the two groups converging at final follow-up. At eight- to 10-year follow-up, 50% of surgical patients reported improved back pain, 67% reported improved leg pain, 54% reported improvement in their predominant symptom, 55% were satisfied with their current state and 82% would choose the same treatment.

In critique, there was a high dropout rate in this study, primarily due to death. This is expected in this age group, but nonetheless complicates data interpretation. This study provides Level IV therapeutic evidence that at eight to 10 years, 50-67% of patients undergoing surgical treatment demonstrated improvements in pain and satisfaction, although this represents a deterioration relative to their short- and intermediate-term results.

Cornefjord et al[10] studied a retrospective case series of 124 patients having surgery for lumbar spinal stenosis, with a four- to 12-year follow-up. Ninety-six patients (77%) were available for follow-up. A masked observer assessed nonvalidated measures of lower extremity pain, low back pain and walking distance. There were significant improvements (all $p < 0.001$) in all three outcome measures and patient satisfaction was 65%.

In critique, validated outcome measures were not used. This study provides Level IV therapeutic evidence that 65% of patients treated surgically for spinal stenosis will have a satisfactory outcome at four- to 12-year follow-up.

Herno et al[19] conducted a retrospective case series of the results from surgical decompression for lumbar spinal stenosis. Of the 146 patients studied, 119 were available for follow-up at a mean of 6.8 years and 108 were available at a mean of 12.8 years. The ODI and other outcome measures were used. At six years, the average ODI was 34.5 and overall good and excellent results were 67%. At 12 years, these results were 30.2 and 69% respectively.

In critique, there was no masked outcome measurement. There was a 26% drop-out rate. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis

will have 67% good or excellent results at seven years and that the results will be maintained at 13 years.

Hurri et al[21] performed a retrospective review of the long-term outcomes on 134 patients diagnosed with lumbar spinal stenosis. At twelve-year follow-up, 48 had died, and of the remaining 86 patients, 75 were available. Of the remaining 75 patients, 57 were treated surgically and 18 medically/interventionally. Patients were evaluated by telephone with nonvalidated outcome measures as well as the ODI. Sixty-three percent of the operative group improved, while 18% actually worsened. The final ODI was 29.

In critique, there was a high drop out rate, even for studies in this population. Furthermore, a validated outcome measure was only implemented at follow-up. This study provides Level IV therapeutic evidence that 63% of patients treated surgically for spinal stenosis will improve at long-term follow-up.

Javid et al[23] conducted a prospective study of 170 patients with lumbar spinal stenosis that underwent surgery. Of the 170 patients, 83 had central stenosis, 61 had stenosis and HNP and 23 had lateral recess stenosis. Follow-up was performed anywhere from one to 11 years, with a mean of five years. Twenty-four patients were lost to follow-up. Among the spinal stenosis patients, 64-70% experienced good results.

In critique, there was no masked outcome measurement, nonvalidated measures were used and there was large variability in the length of outcome. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 64-70% good or excellent results.

Jolles et al[24] performed a retrospective review of 155 patients treated surgically for lumbar spinal stenosis, with five- to eight-year follow-up. Of the 155 patients, 77 were available for follow-up. Validated outcome measures were used. Seventy-nine percent experienced good or excellent results.

In critique, there was a high drop out rate, even for studies in this population. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 79% good or excellent results at a five-year follow-up.

Jonsson et al[25] conducted a prospective study of 105 patients with lumbar spinal stenosis treated surgically. Of the 105 patients, 88 were available for five-year follow-up. The reviewer was masked, and outcomes were measured with a nonvalidated four-point scale (excellent, fair, no change or poor). Sixty-four percent experienced good or excellent results.

In critique, a nonvalidated outcome measure was used. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 64% good or excellent results at a five-year follow-up.

Katz et al[26] performed a retrospective review of 88 patients who underwent surgery for lumbar spinal stenosis. Follow-up data were available in 55 patients. Of these patients, 85% experienced some initial improvement. Thirty-three percent reported severe low back pain at final follow-up and 20% experienced severe lower extremity pain. Overall, 75% of patients were satisfied at final follow-up.

In critique, a nonvalidated outcome measure was used. 37% were lost to follow-up, most due to death. This study provides Level IV therapeutic evidence that 75% of patients treated surgically for spinal stenosis will be satisfied at seven- to 10-year follow-up, although 33% experienced severe low back pain.

Tuite et al[40] retrospectively reviewed 119 patients undergoing decompression surgery for lumbar spinal stenosis with a mean follow-up of 4.6 years. Seventy-nine percent reported improvement at one year and 66% at final follow-up.

In critique, nonvalidated outcome measures were used and were only collected at follow-up. This study provides Level IV therapeutic evidence that 79% of patients treated surgically for spinal stenosis will have a good result at one year, declining to 66% at mean 4.6-year follow-up.

There were many additional Level IV studies, the results of which were consistent with those cited above. Although they are not addressed in the text of the guideline, information is available on the evidentiary table.[8,16,28,31,33,35,37] The committee did note that there was no better than level IV evidence for long-term effects of surgical treatment for spinal stenosis. However, it was further acknowledged that owing to the definition of long-term, specifically five years or beyond, it is unlikely that there will ever be high level evidence when studying this question. Thus, even studies that are retrospective and without control groups still offer important and valuable information if other features are of good quality, such as drop outs, valid outcome measures and well defined patient populations and interventions.

Future Directions for Research

The work group identified the following suggestions for future studies, which would generate meaningful evidence to assist in further defining the role of medical treatment for lumbar spinal stenosis. It is acknowledged that the opportunity for assessing long-term outcomes in this group of patients is severely limited by the age-related morbilities in this patient group, thus it is unlikely that outcome studies longer than those noted above are practically feasible.

Recommendation #1:

Future long-term studies of the effects of surgical interventions for lumbar spinal stenosis should include an untreated control group, when ethically feasible.

Recommendation #2:

Future long-term outcome studies of lumbar spinal stenosis should include results specific to each of the surgical treatment methods.

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V. APPENDICES

APPENDIX A:
Acronyms

AP	antero-posterior
BADL	basic activities of daily living
CT	computed tomography
CTM	CT myelography
DM	distraction manipulation
DSA	dural sac area
DSEP	dermatomal somatosensory evoked potential
EBM	evidence-based medicine
ESI	epidural steroid injection
ETT	exercise treadmill test
HNP	herniated nucleus pulposus
JOA	Japanese Orthopaedic Association
LBOS	low back outcome score
LR	likelihood ratio
LSO	lumbosacral orthosis
MR	magnetic resonance
MRI	magnetic resonance imaging
MSBQ	Maine Seattle Back Questionnaire
NASS	North American Spine Society
NM	neural mobilization
NSAIDs	nonsteroidal anti-inflammatory drugs
OCS	Oxford Claudication Score
ODI	Oswestry Disability Index
QALY	quality of life years
RCT	randomized clinical rrial
RMDQ	Roland Morris Disability Questionnaire
SIP	sickness impact profile
SLR	straight leg raise
SSS	Swiss Spinal Stenosis Questionnaire
SWT	shuttle walking test
TENS	transcutaneous electrical nerve stimulation
VAS	visual analog scale
ZCQ	Zurich Claudication Questionnaire

APPENDIX B:
Levels of Evidence For Primary Research Question[1]

	Types of Studies			
	Therapeutic Studies – Investigating the results of treatment	Prognostic Studies – Investigating the effect of a patient characteristic on the outcome of disease	Diagnostic Studies – Investigating a diagnostic test	Economic and Decision Analyses – Developing an economic or decision model
Level I	• High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals • Systematic review[2] of Level I RCTs (and study results were homogenous[3])	• High quality prospective study[4] (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients) • Systematic review[2] of Level I studies	• Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level I studies	• Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses • Systematic review[2] of Level I studies
Level II	• Lesser quality RCT (eg, < 80% follow-up, no blinding, or improper randomization) • Prospective[4] comparative study[5] • Systematic review[2] of Level II studies or Level 1 studies with inconsistent results	• Retrospective[6] study • Untreated controls from an RCT • Lesser quality prospective study (eg, patients enrolled at different points in their disease or <80% follow-up) • Systematic review[2] of Level II studies	• Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard) • Systematic review[2] of Level II studies	• Sensible costs and alternatives; values obtained from limited studies; with multiway sensitivity analyses • Systematic review[2] of Level II studies
Level III	• Case control study[7] • Retrospective[6] comparative study[5] • Systematic review[2] of Level III studies	• Case control study[7]	• Study of non-consecutive patients; without consistently applied reference "gold" standard • Systematic review[2] of Level III studies	• Analyses based on limited alternatives and costs; and poor estimates • Systematic review[2] of Level III studies
Level IV	Case Series[8]	Case series	• Case-control study • Poor reference standard	• Analyses with no sensitivity analyses
Level V	Expert Opinion	Expert Opinion	Expert Opinion	Expert Opinion

1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (eg, cemented hip arthroplasty) compared with a group of patients treated in another way (eg, uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called "cases" (eg, failed total arthroplasty) are compared to those who did not have outcome, called "controls" (eg, successful total hip arthroplasty).
8. Patients treated one way with no comparison group of patients treated in another way.

APPENDIX C:

Grades of Recommendation for Summaries or Reviews of Studies

A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.

B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.

C: Poor quality evidence (Level IV or V Studies) for or against recommending intervention.

I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

APPENDIX D:

Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care or use of new technologies is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities.

Background
It has become apparent that the number of literature searches being conducted at NASS is increasing and that they are not necessarily conducted in a consistent manner between committees/projects. Because the quality of a literature search directly affects the quality of recommendations made, a comparative literature search was undertaken to help NASS refine the process and make recommendations about how to conduct future literature searches on a NASS-wide basis.

In November-December 2004, NASS conducted a trial run at new technology assessment. As part of the analysis of that pilot process, the same literature searches were conducted by both an experienced NASS member and a medical librarian for comparison purposes. After reviewing the results of that experiment and the different strategies employed for both searches, it was the recommendation of NASS Research staff that a protocol be developed to ensure that all future NASS searches be conducted consistently to yield the most comprehensive results. While it is recognized that some searches occur outside the Research and Clinical Care Councils, it is important that all searches conducted at NASS employ a solid search strategy, regardless of the source of the request. To this end, this protocol has been developed and NASS-wide implementation is recommended.

Protocol for NASS Literature Searches
The NASS Research Department has a relationship with Northwestern University's Galter Health Sciences Library. When it is determined that a literature search is needed, NASS research staff will work with the requesting parties and Galter to run a comprehensive search employing *at a minimum* the following search techniques:

1. A preliminary search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). The following parameters are to be provided to research staff to facilitate this search.

    - Time frames for search
    - Foreign and/or English language
    - Order of results (chronological, by journal, etc.)
    - Key search terms and connectors, with or without MeSH terms to be employed
    - Age range
    - Answers to the following questions:
        - Should duplicates be eliminated between searches?
        - Should searches be separated by term or as one large package?
        - Should human studies, animal studies or cadaver studies be included?

    This preliminary search should encompass a search of the Cochrane database when access is available.

2. Search results with abstracts will be compiled by Galter in Endnote software. Galter typically responds to requests and completes the searches within two to five days. Results will be forwarded to the research

staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff hasve access to EndNote software and will maintain a database of search results for future use/documentation.)

3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review and on which to run a "related articles" search.

4. Based on content expert's review, NASS research staff will then coordinate with the Galter medical librarian the second level searching to identify relevant "related articles."

5. Galter will forward results to research staff to share with appropriate NASS staff member.

6. NASS staff share related articles search results with an appropriate content expert (NASS Committee member or other) to assess relevance of this second set of articles, and identify appropriate articles to review and on which to run a second "related articles" search.

7. NASS research staff will work with Galter library to obtain the 2nd related articles search results and any necessary full-text articles for review.

8. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

Protocol for Expedited Searches
At a minimum, numbers 1, 2 and 3 should be followed for any necessary expedited search. Following #3, depending on the time frame allowed, deeper searching may be conducted as described by the full protocol or request of full-text articles may occur. If full-text articles are requested, #8 should also be included. Use of the expedited protocol or any deviation from the full protocol should be documented with explanation.

Following these protocols will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. Research staff will maintain a search history in EndNote for future use or reference.

APPENDIX E:

Literature Search Parameters

Natural History of Degenerative Lumbar Spinal Stenosis (Work Group 1) Search Strategies

Notes about the following searches: (1) Animal studies have been excluded. (2) Restricting to 18 or older may result in the elimination of important articles because age tags are not applied consistently to this literature; therefore, you may come across a few articles about subjects under 18.

Search Strategies by Clinical Question:

1. What is the best working definition of spinal stenosis?

   Reviewed three book chapters (see reference section).

2. What is the natural history of spinal stenosis?

   Spinal Stenosis – natural hx – broad
   ("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND (natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR non-operative[All Fields] OR (conservative[All Fields] AND ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics"[MeSH Terms] OR treatment[Text Word] OR therapy[Text Word])) OR untreated[All Fields]) AND English[lang]

   Spinal Stenosis – natural hx – narrow
   ("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ((natural history[Text Word] OR natural course[Text Word] OR untreated[Text Word]) AND English[lang])

Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials

Diagnosis/Imaging of Degenerative Lumbar Spinal Stenosis (Work Group 2) Search Strategies

Notes about the following searches: (1) Animal studies have been excluded. (2) It is *not possible* to exclude basic science and surgical technique papers. (3) Restricting to 18 or older may result in the elimination of important articles because age tags are not applied consistently to this literature, therefore you may come across a few articles about subjects under 18.

Search Strategies by Clinical Question:

1. What are the most reliable historical and physical findings consistent with the diagnosis of spinal stenosis?

Spinal Stenosis – diagnosis – broad

("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Diagnosis"[MeSH:noexp] OR "Diagnosis, Differential"[MeSH] OR "Diagnostic Imaging"[MeSH] OR "Diagnostic Techniques, Neurological"[MeSH] OR "Physical Examination"[MeSH] OR "Myography"[MeSH] OR "Disability Evaluation"[MeSH] OR "Medical History Taking"[MeSH] OR "diagnosis"[Subheading] AND English[lang]) AND English[lang] AND "humans"[MeSH Terms]

Spinal Stenosis – diagnosis – narrow

"spinal stenosis/diagnosis"[MAJR] AND English[lang] AND "humans"[MeSH Terms]

2. What are the most reliable diagnostic tests for spinal stenosis?

Spinal Stenosis – dx tests – sensitivity and specificity

("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Diagnostic Techniques and Procedures"[MeSH] AND ("Sensitivity and Specificity"[MeSH] OR (accura[text word] OR accuracies[text word] OR accuracte[text word] OR accuracy[text word] OR accuracy/az[text word] OR accuracy/consistency[text word] OR accuracy/cost[text word] OR accuracy/defects[text word] OR accuracy/efficacy[text word] OR accuracy/error[text word] OR accuracy/inaccuracy[text word] OR accuracy/pitfalls[text word] OR accuracy/planning/speed[text word] OR accuracy/precision[text word] OR accuracy/prediction[text word] OR accuracy/recovery[text word] OR accuracy/reliability[text word] OR accuracy/sensitivity[text word] OR accuracy/speed[text word] OR accuracy/stability[text word] OR accuracy/time[text word] OR accuracy/timeliness[text word] OR accuracy/trueness[text word] OR accuracy/validity[text word] OR accuracy'[text word] OR accuracy's[text word] OR accuracyobtainable[text word] OR accuracyof[text word] OR accuracysuperior[text word] OR accuracyto[text word] OR accuracywise[text word] OR accurad[text word] OR accurage[text word] OR accural[text word] OR accurance[text word] OR accurancy[text word] OR accurary[text word] OR accurasee[text word] OR accurat[text word] OR accuratam[text word] OR accuratc[text word] OR accurate[text word] OR accu-

rate/adequate[text word] OR accurate/complete[text word] OR accurate/incomplete[text word] OR accurate/reliable[text word] OR accurate/timely[text word] OR accurate'[text word] OR accurateand[text word] OR accurated[text word] OR accuratedly[text word] OR accurateestimation[text word] OR accurately[text word] OR accurately/consistently[text word] OR accurately/efficiently[text word] OR accurately'[text word] OR accuratelytermed[text word] OR accuratelythan[text word] OR accurateness[text word] OR accurater[text word] OR accurates[text word] OR accuratest[text word] OR accuration[text word] OR accurative[text word] OR accuratized[text word] OR accuratly[text word] OR accuraty[text word] OR accuray[text word]) OR (valid[Text word] OR valid/analog[Text word] OR valid/endogenous[Text word] OR valid/invalid[Text word] OR valid'[Text word] OR valida[Text word] OR validable[Text word] OR validacion[Text word] OR validade[Text word] OR validado[Text word] OR validamine[Text word] OR validamines[Text word] OR validamycin[Text word] OR validamycins[Text word] OR validat[Text word] OR validata[Text word] OR validatability[Text word] OR validatable[Text word] OR validate[Text word] OR validate'[Text word] OR validated[Text word] OR validated/discovered[Text word] OR validated/extended[Text word] OR validated/phenotyped[Text word] OR validated'[Text word] OR validatedfurther[Text word] OR validates[Text word] OR validatibility[Text word] OR validatible[Text word] OR validating[Text word] OR validating/determining[Text word] OR validating/sustaining[Text word] OR validating'[Text word] OR validation[Text word] OR validation/adaptation[Text word] OR validation/calibration[Text word] OR validation/characterization[Text word] OR validation/evaluation[Text word] OR validation/feedback[Text word] OR validation/process[Text word] OR validation/refinement[Text word] OR validation/revision[Text word] OR validation/standardisation[Text word] OR validation/testing[Text word] OR validation/verification[Text word] OR validation/vindication[Text word] OR validation'[Text word] OR validation's[Text word] OR validational[Text word] OR validationinebreak[Text word] OR validations[Text word] OR validative[Text word] OR validatol[Text word] OR validator[Text word] OR validator's[Text word] OR validators[Text word] OR validatory[Text word] OR validaty[Text word] OR validazione[Text word] OR valide[Text word] OR valided[Text word] OR validee[Text word] OR validees[Text word] OR validfor[Text word] OR validiated[Text word] OR validiert[Text word] OR validierung[Text word] OR validierungsversuch[Text word] OR validified[Text word] OR validimax[Text word] OR validipes[Text word] OR validire[Text word] OR validisation[Text word] OR validised[Text word] OR validitate[Text word] OR validitates[Text word] OR validitation[Text word] OR validite[Text word] OR validited[Text word] OR validities[Text word] OR validiting[Text word] OR validition[Text word] OR validitiy[Text word] OR validity[Text word] OR validity/accuracy[Text word] OR validity/applicability[Text word] OR validity/credibility[Text word] OR validity/effective[Text word] OR validity/invalidity[Text word] OR validity/no[Text word] OR validity/quality[Text word] OR validity/reliability[Text word] OR validity/representativity[Text word] OR validity/screening[Text word] OR validity/test[Text word] OR validity/utility[Text word] OR validity'[Text word] OR validity's[Text word] OR validityof[Text word] OR validiy[Text word] OR validization[Text word] OR validly[Text word] OR validness[Text word] OR validol[Text word] OR validone[Text word] OR validoxylamine[Text word] OR validoxylamines[Text word] OR validty[Text word] OR validum[Text word] OR validus[Text word] OR validus'[Text word] OR validy[Text word] OR validyne[Text word]) OR (reliab[Text word] OR reliabaly[Text word] OR reliabe[Text word] OR reliabel[Text word] OR reliabiities[Text word] OR reliabiity[Text word] OR reliabile[Text word] OR reliabiligy[Text word] OR reliabiliity[Text word] OR reliabilism[Text word] OR reliabilists[Text word] OR reliabilit[Text word] OR reliabilitat[Text word] OR reliabilities[Text word] OR reliabilities/precisions[Text word] OR reliabilitiy[Text word] OR reliability[Text word] OR reliability/agreement[Text word] OR reliability/durability[Text word] OR reliability/generalisability[Text word] OR reliability/internal[Text word] OR reliability/practicability[Text word] OR reliability/quality[Text word] OR reliability/repeatability[Text word] OR reliability/reproducibility[Text word] OR reliability/responsibility[Text word] OR reliability/sensitivity[Text word] OR reliability/significance[Text word] OR reliability/stability[Text word] OR reliability/usefulness[Text word] OR reliability/validity[Text word] OR reliability/value[Text word] OR reliability'[Text word] OR reliabillty[Text word] OR reliabiltiy[Text word] OR reliabilty[Text word] OR reliabily[Text word] OR reliabity[Text word]

OR reliabl[Text word] OR reliable[Text word] OR reliable/repeatable[Text word] OR reliable/valid[Text word] OR reliable'[Text word] OR reliablefor[Text word] OR reliables[Text word] OR reliablility[Text word] OR reliablitity[Text word] OR reliablity[Text word] OR reliablity'[Text word] OR reliably[Text word] OR reliaby[Text word])) AND English[lang] AND "humans"[MeSH Terms])

Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials

Medical/Interventional Treatment of Degenerative Lumbar Spinal Stenosis (Work Group 3) Search Strategies

Notes about the following searches: (1) Both human and animal studies are included. (2) Case studies and reports have been eliminated. (3) It is *not possible* to eliminate "surgical technique" papers. (4) Restricting to 18 or older may result in the elimination of important articles because age tags are not applied consistently to this literature, therefore you may come across a few articles about subjects under-18.

Search Strategies by Clinical Question:

1. What are the appropriate outcome measures for the medical/interventional treatment of spinal stenosis?

   Spinal Stenosis – med treatment – outcome measures – no case reports

   (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("therapy"[Subheading] OR "Therapeutics"[MeSH] OR medical management[Text word] OR non-operative[Text word] OR nonsurgical[text word] OR conservative[text word]) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR treatment outcome[text word] OR outcome measures[text word]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("therapy"[Subheading] OR "Therapeutics"[MeSH] OR medical management[Text word] OR non-operative[Text word] OR nonsurgical[text word] OR conservative[text word]) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR treatment outcome[text word] OR outcome measures[text word]) AND Case Reports[ptyp] AND English[lang])

2. Do medical, noninvasive treatments improve outcomes in the treatment of spinal stenosis compared to the natural history of the disease?

   Spinal Stenosis – medical treatment vs natural hx – no case reports

   (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND (natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR non-operative[All Fields] OR (conservative[All Fields] AND ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics"[MeSH Terms] OR treatment[Text Word] OR therapy[Text Word])) OR untreated[All Fields]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND (natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR non-operative[All Fields] OR

(conservative[All Fields] AND ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics"[MeSH Terms] OR treatment[Text Word] OR therapy[Text Word])) OR untreated[All Fields]) AND Case Reports[ptyp])

3. What is the role of pharmacological treatment in the management of spinal stenosis?

Spinal Stenosis – Pharm treatment – no case reports

((("Narcotics"[MeSH] OR "Narcotics"[Pharmacological Action] OR "Analgesics, Non-Narcotic"[MeSH]) OR ("Drug Therapy"[MeSH] OR "drug therapy"[Subheading]) OR "Adrenal Cortex Hormones"[MeSH] OR "Steroids"[MeSH] OR ("Anti-Inflammatory Agents, Non-Steroidal"[MeSH] OR "Anti-Inflammatory Agents, Non-Steroidal"[Pharmacological Action]) OR "Anti-Inflammatory Agents"[MeSH]) AND ("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND English[lang]) NOT ((("Narcotics"[MeSH] OR "Narcotics"[Pharmacological Action] OR "Analgesics, Non-Narcotic"[MeSH]) OR ("Drug Therapy"[MeSH] OR "drug therapy"[Subheading]) OR "Adrenal Cortex Hormones"[MeSH] OR "Steroids"[MeSH] OR ("Anti-Inflammatory Agents, Non-Steroidal"[MeSH] OR "Anti-Inflammatory Agents, Non-Steroidal"[Pharmacological Action]) OR "Anti-Inflammatory Agents"[MeSH]) AND ("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND Case Reports[ptyp] AND English[lang])

4. What is the role of physical therapy/exercise therapy in the treatment of spinal stenosis?

Spinal Stenosis – PT, exercise – no case reports

(("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Physical Therapy Modalities"[MeSH] OR "Exercise Movement Techniques"[MeSH] OR "Exercise"[MeSH] OR "Physical Fitness"[MeSH] OR "Exercise Test"[MeSH] OR treadmill[text word] OR physical therapy[text word] OR exercise[text word]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Physical Therapy Modalities"[MeSH] OR "Exercise Movement Techniques"[MeSH] OR "Exercise"[MeSH] OR "Physical Fitness"[MeSH] OR "Exercise Test"[MeSH] OR treadmill[text word] OR physical therapy[text word] OR exercise[text word]) AND Case Reports[ptyp] AND English[lang])

5. What is the role of manipulation in the treatment of spinal stenosis?

Spinal Stenosis – manipulation, chiropractic – no case reports

(("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Musculoskeletal Manipulations"[MeSH] OR manipulation[text word] OR "Chiropractic"[MeSH] OR chiropractic[text word]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Musculoskeletal Manipulations"[MeSH] OR manipulation[text word] OR "Chiropractic"[MeSH] OR chiropractic[text word]) AND Case Reports[ptyp] AND English[lang])

6. What is the role of injections in the treatment of spinal stenosis? (exclude subcutaneous and intramuscular if possible)

Spinal Stenosis – injections, not subcut or intramuscu – no case reports

(("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Injections"[MeSH] NOT ("Injections, Intramuscular"[MeSH] OR "Injections, Subcutaneous"[MeSH])) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Injections"[MeSH] NOT ("Injections, Intramuscular"[MeSH] OR "Injections, Subcutaneous"[MeSH])) AND Case Reports[ptyp] AND English[lang])

7. What is the role of other modalities such as traction, electrical stimulation and TENS in the treatment of spinal stenosis?

Spinal Stenosis – traction, acupunc, elec stim, TENS – no case reports

(("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Electric Stimulation Therapy"[MeSH] OR "electric stimulation"[MeSH Terms] OR electrical stimulation[text word] OR TENS[text word] OR "Traction"[MeSH] OR traction[text word] OR "Acupuncture"[MeSH] OR "Acupuncture Therapy"[MeSH] OR acupuncture[text word]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Electric Stimulation Therapy"[MeSH] OR "electric stimulation"[MeSH Terms] OR electrical stimulation[text word] OR TENS[text word] OR "Traction"[MeSH] OR traction[text word] OR "Acupuncture"[MeSH] OR "Acupuncture Therapy"[MeSH] OR acupuncture[text word]) AND Case Reports[ptyp] AND English[lang])

8. What is the long term result (10+ years) of medical/interventional management of spinal stenosis?

Spinal Stenosis – med mgt, outcome measures, long-term – no case reports

((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("therapy"[Subheading] OR "Therapeutics"[MeSH] OR medical management[Text word] OR non-operative[Text word] OR nonsurgical[text word] OR conservative[text word]) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR treatment outcome[text word] OR outcome measures[text word]) AND English[lang]) AND ("Longitudinal Studies"[MeSH] OR long-term[All Fields]) AND English[lang]) NOT ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("therapy"[Subheading] OR "Therapeutics"[MeSH] OR medical management[Text word] OR non-operative[Text word] OR nonsurgical[text word] OR conservative[text word]) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR treatment outcome[text word] OR outcome measures[text word]) AND English[lang]) AND ("Longitudinal Studies"[MeSH] OR long-term[All Fields]) AND Case Reports[ptyp] AND English[lang])

Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials
- EMBASE Drugs and Pharmacology

Surgical Treatment of Degenerative Lumbar Spinal Stenosis (Work Group 4) Search Strategies

Notes about the following searches: (1) Both human and animal studies are included. (2) Restricting to 18 or older may result in the elimination of important articles because age tags are not applied consistently to this literature, therefore you may come across a few articles about subjects under 18.

General search on surgical management:
Spinal Stenosis – surgical mgt. – all

(((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp])) OR ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp]) AND (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "humans"[MeSH Terms]))

Search Strategies by Clinical Question:

1. What are the appropriate outcome measures for the surgical treatment of spinal stenosis?

Spinal Stenosis – surgical mgt. – outcome measures

((((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp])) OR ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar steno-

sis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp]) AND (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "humans"[MeSH Terms])) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR treatment outcome[text word] OR outcome measures[text word])

2. Do surgical treatments improve outcomes in the treatment of spinal stenosis compared to the natural history of the disease?

Spinal Stenosis – surgical mgt. vs natural hx

((((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp])) OR ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp]) AND (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "humans"[MeSH Terms]))) AND ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR non-operative[All Fields] OR (conservative[All Fields] AND ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics"[MeSH Terms] OR treatment[Text Word] OR therapy[Text Word])) OR untreated[All Fields]) AND English[lang]) AND English[lang]

3. What is the role of decompression in the treatment of spinal stenosis?

Spinal Stenosis – surg decompression or laminectomy

(("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH])) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields])

AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH]) AND "animals"[MeSH Terms:noexp])

4. Does surgical decompression alone improve surgical outcomes in the treatment of spinal stenosis compared to medical/interventional treatment alone or the natural history of the disease?

   Spinal Stenosis - decompression vs (natural hx or med mgt)

   ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR non-operative[All Fields] OR (conservative[All Fields] OR ("therapy"[Subheading] OR ("therapeutics"[TIAB] NOT Medline[SB]) OR "therapeutics"[MeSH Terms] OR treatment[Text Word] OR therapy[Text Word])) OR untreated[All Fields]) AND English[lang]) AND ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH])) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH]) AND "animals"[MeSH Terms:noexp]))

5. Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of spinal stenosis compared to treatment by decompression alone?

   Spinal Stenosis – spinal fusion and decompression

   ("Decompression, Surgical"[MeSH] OR "Laminectomy"[MeSH]) AND "Arthrodesis"[MeSH] AND ("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND English[lang] AND "humans"[MeSH Terms]

6. What is the long-term result (10+ years) of surgical management of spinal stenosis?

   Spinal Stenosis – surg mgt. and long-term (broader search)

   ("Longitudinal Studies"[MeSH] OR long-term[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND ("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND English[lang] AND "humans"[MeSH Terms]

   Spinal Stenosis – surg mgt. and outcomes – long-term (narrow search)

("Longitudinal Studies"[MeSH] OR long-term[All Fields]) AND (((((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang]) NOT (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp])) OR ((("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "animals"[MeSH Terms:noexp]) AND (("Spinal Stenosis"[MeSH] OR spinal stenosis[Text Word] OR ((lateral recess[All Fields] OR foraminal[All Fields]) AND ("pathologic constriction"[Text Word] OR "constriction, pathologic"[MeSH Terms] OR stenosis[Text Word])) OR lumbar stenosis[All Fields] OR lumbar spinal stenosis[All Fields] OR spinal canal stenosis[All Fields]) AND ("Surgical Procedures, Operative"[MeSH] OR "surgery"[Subheading]) AND English[lang] AND "humans"[MeSH Terms]))) AND ("Outcome Assessment (Health Care)"[MeSH] OR "Treatment Outcome"[MeSH] OR treatment outcome[text word] OR outcome measures[text word]))

Databases Searched:

- MEDLINE (PubMed)
- ACP Journal Club
- Cochrane Database of Systematic Reviews
- Database of Abstracts of Reviews of Effectiveness (DARE)
- Cochrane Central Register of Controlled Trials

APPENDIX F:
Evidentiary Tables

Degenerative Lumbar Spinal Stenosis
Natural History

-Primary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusions
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleas F. Lumbar spinal stenosis: conservative or surgical management? A prospective 10-year study. *Spine.* 2000;25(11): 1424-1435; discussion 1435-1436.	II	This is an evaluation of an observational cohort of 18 patients (the randomized control group from a prospective surgical study) with moderate symptoms of lumbar stenosis and 50 patients (the nonrandomized, medical/interventional treatment group) with mild symptoms who were followed for 10 years. Outcome measures included: subjective patient rated outcomes; opinion of examining physician; pain, working ability and walking ability; level of physical activity at leisure; and change in physical findings. Claudication was defined by median walking distance using four-tiered classification system. Of the 18 moderate patients, 56% (10 of 18) were worse at six months. At the 10-year mark, of the patients randomized to medical/interventional treatment, 75% (six of eight) experienced moderate to severe pain and 25%(2 of eight) experienced light to mild pain. Of the original 50 patients with mild disease, 56% (15 of 27) experienced moderate to severe pain and 44% (12 of 27) experienced light to mild pain at 10 years. There was a significant crossover of patients in both groups.	In critique, this study did not use validated outcome measures; it contained both randomized and non-randomized patient groups; the dropout rate was greater than 80% over the long follow-up period and; there was a good deal of crossover between surgical and medical/interventional treatment groups. As a prospective study with less than 80% follow-up, this study provides Level II prognostic evidence for the natural history of patients with lumbar stenosis.

		The authors did not note an association between radiographic findings and ultimate outcome.	
Atlas S J, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III. 1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis. *Spine.* 1996;21(15): 1787-1794; discussion 1794-1795.	See description	This is an evaluation of a medical/interventional control group from a study comparing surgical and medical/interventional treatment of patients with radiculopathy. The patient sample included both spinal stenosis and those with disc herniations. Data are not presented to allow for subgroup analysis of lumbar stenosis.	In critique, although these papers clearly document the natural history of a group of patients who did not receive surgical intervention for lumbar spinal stenosis, these patient samples contain both patients with stenosis and patients with disc herniation. As a result, these reports do not allow subgroup analysis and could not be used as evidence regarding the natural history of patients with lumbar spinal stenosis. The guideline work group concluded that the natural history of spinal stenosis cannot be objectively extrapolated from this study.
Atlas S J, Deyo RA, Keller RB, et al. "The Maine Lumbar Spine Study, Part II. 1-year outcomes of surgical and nonsurgical management of sciatica." *Spine.* 1996;21(15): 1777-1786.	See description	This is an evaluation of a medical/interventional control group from a study comparing surgical and medical/interventional treatment of patients with radiculopathy. The patient sample included both spinal stenosis and those with disc herniations. Data are not presented to allow for subgroup analysis of lumbar stenosis.	In critique, although these papers clearly document the natural history of a group of patients who did not receive surgical intervention for lumbar spinal stenosis, these patient samples contain both patients with stenosis and patients with disc herniation. As a result, these reports do not allow subgroup analysis and could not be used as evidence regarding the natural history of patients with lumbar spinal stenosis. The guideline work group concluded that the natural history of spinal stenosis cannot be objectively extrapolated from this study.
Atlas S.J, Keller RB, Robson D, Deyo RA, Singer DE. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the Maine lumbar spine study. *Spine.*	See description	This is an evaluation of a medical/interventional control group from a study comparing surgical and medical/interventional treatment of patients with radiculopathy. The patient sample included both spinal stenosis and those with disc herniations. Data are not presented to allow for subgroup analysis of	In critique, while these papers clearly document the natural history of a group of patients who did not receive surgical intervention for lumbar spinal stenosis, these patient samples contain both patients with stenosis and patients with disc herniation. As a result, these reports do not allow subgroup analysis and

2000;25(5): 556-562.		lumbar stenosis.	could not be used as evidence regarding the natural history of patients with lumbar spinal stenosis. The guideline work group concluded that the natural history of spinal stenosis cannot be objectively extrapolated from this study.
Atlas SJ, Keller RB, Wu YA, Deyo RA, Sinder DE. Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the Maine lumbar spine study. *Spine.* 2005;30(8): 936-943.	See description	This is an evaluation of a medical/interventional control group from a study comparing surgical and medical/interventional treatment of patients with radiculopathy. The patient sample included both spinal stenosis and those with disc herniations. Data are not presented to allow for subgroup analysis of lumbar stenosis.	In critique, while these papers clearly document the natural history of a group of patients who did not receive surgical intervention for lumbar spinal stenosis, these patient samples contain both patients with stenosis and patients with disc herniation. As a result, these reports do not allow subgroup analysis and could not be used as evidence regarding the natural history of patients with lumbar spinal stenosis. The guideline work group concluded that the natural history of spinal stenosis cannot be objectively extrapolated from this study.
Gibson JN, G. Waddell G. Surgery for degenerative lumbar spondylosis; *Cochrane Database Syst Rev.* 2006 ;(3): CD001352.	See description	The only papers reviewed related to the natural history of spinal stenosis were Amundsen et al and Zucherman et al.	See Amundsen and Zucherman.
Herno A, Airaksinen O, Saari T, Luukkonen M. Lumbar spinal stenosis: a matched-pair study of operated and non-operated patients. *Br J Neurosurg.* 1996;10(5): 461-465.	IV	This is an evaluation of a matched control group of 54 patients from a surgical series of patients studied respectively and diagnosed with spinal stenosis by myelography.	In critique, the initial clinical status of these patients at the time of the index myelogram was unknown. This case series was judged to provide Level IV prognostic evidence. No definitive conclusions regarding the natural history of lumbar stenosis can be drawn from this Level IV study. This study provides Level IV prognostic evidence that patients with mild or moderate stenosis and severe comorbidities may be managed

			medically/interventionally.
Hurri H, Slatis P, Soini J. Lumbar spinal stenosis: assessment of long-term outcome 12 years after operative and conservative treatment. *J Spinal Disord.* 1998;11(2): 110-115.	IV	This is a case series of 18 patients with lumbar stenosis diagnosed by functional myelography, treated medically/interventionally and followed for 12 years using the Oswestry Disability Index (ODI). Details of medical/interventional treatment were nonspecified. 44% (8 of 18) reported at least slight improvement of the 12 years while 11% (2 of 18) worsened over this same time period.	In critique, this paper is limited by the nonstandardized medical/interventional treatment and failure to stratify outcomes such as claudication, neurologic function and pain. The only reported outcome that allowed subgroup analysis of the medical/interventional group was the ODI, a validated outcome measure. The strengths of this study include its long follow-up and use of the ODI as an outcome measure. As a case series, this study provides Level IV prognostic evidence for the natural history of patients with lumbar stenosis.
Johnsson KE, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis. A comparison of surgically treated and untreated patients. *Spine.* 1991;16(6): 615-9.	IV	This is an evaluation of a control group for a retrospective surgical study consisting of 19 symptomatic patients with myelographically defined lumbar stenosis treated medically/interventionally due to medical comorbidities or patient refusal of surgery. Of the 16 patients with neurogenic claudication treated medically/interventionally, approximately 31% (6 of 16) were improved at three to four years follow-up.	In critique of this study, the population was identified retrospectively based on their final outcome of not having undergone surgery. With this inherent bias, it is not possible to determine how many patients had initially refused surgery but eventually underwent an operation. In addition, the investigators did not employ a disease-specific validated outcomes instrument. This case series provides Level IV prognostic evidence regarding the natural history of patients with lumbar stenosis.
Keller RB, Atlas SJ, Singer DE. The Maine Lumbar Spine Study, Part I. Background and concepts. *Spine.* 1996;21(15): 1769-1776.	See description	This is a mixed patient sample including both spinal stenosis and those with disc herniations. Data are not presented to allow for subgroup analysis of lumbar stenosis.	In critique, while these papers clearly document the natural history of a group of patients who did not receive surgical intervention for lumbar spinal stenosis, these patient samples contain both patients with stenosis and patients with disc herniation. As a result, these reports do not allow subgroup analysis and could not be used as evidence regarding the natural history of patients with lumbar spinal stenosis. The guideline work group con-

			cluded that the natural history of spinal stenosis cannot be objectively extrapolated from this study.
Mariconda M, Fava R, Gatto A, Long C. Milano C. Unilateral laminectomy for bilateral decompression of lumbar spinal stenosis: a prospective comparative study with conservatively treated patients. *J Spinal Disord Tech*. 2002;15(1): 39-46.	IV	This is an evaluation of the control group of 22 patients from prospective study with some design flaws. Minimal intervention. Thirty percent (7 of 22) of patients treated medically/interventionally were satisfied with treatment and results. Nine percent (2 of 22) crossed over to surgery.	In critique of this study, the medical/interventional group was a compilation of patients who refused surgical treatment during the randomization process and those who were randomized to medical/interventional treatment. Furthermore, the details of medical/interventional treatment were not provided. For these limitations, the study is considered a case series and provides Level IV prognostic evidence concerning the natural history of lumbar spinal stenosis.

Degenerative Lumbar Spinal Stenosis
Natural History

-Secondary Evidentiary Table-

(*Exclusions from Primary Evidentiary Table Due to Active Conservative Treatments*)

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusions
Simotas AC, Dorey FJ,. Hansraj KK, Cammisa F Jr. Nonoperative treatment for lumbar spinal stenosis. Clinical and outcome results and a 3-year survivorship analysis. *Spine.* 2000;25(2): 197-203; discussions 203-4.	See text	This study is a case series with non-standardized outcome measures looking at efficacy of multimodal medical/interventional treatment modalities. This does not truly address natural history, as all patients received aggressive medical/interventional treatment.	Forty-nine patients with clinical and radiographic evidence of stenosis treated with an aggressive program of medical/interventional therapy; nine went on to surgery, only 12 reported sustained improvement at 33 months.
Waikakul W, Waikakul S. Methylcobalamin as an adjuvant medication in conservative treatment of lumbar spinal stenosis." J Med Assoc	See text	This is an evaluation of the control group from a study looking at vitamin B12. Conservative group was treated with multimodality therapy, including medications, physical therapy and multivitamins. All patients with severe symptoms were	Before the trial 28% (23 of 82) patients could walk greater than 1000 meters. At two-year follow-up, 85% (68 of 80) patients could walk greater than 1000 meters.

Thai. 2000;83(8): 825-831.		excluded.	
Zucherman JF, Hsu KY, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine.* 2005;30(12): 1351-1358.	See text	Control group from study looking at surgical device. Conservative group was treated with epidural steroid injections, physical therapy and NSAIDS/analgesics. All patients with severe symptoms were excluded.	At two-year follow-up, the symptom severity score marginally improved and physical function score marginally deteriorated.

Degenerative Lumbar Spinal Stenosis
Diagnosis/Imaging:
HISTORY AND PHYSICAL FINDINGS

-Primary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusions
Adamova B. Vohanka S, Dusek L. Differential diagnostics in patients with mild lumbar spinal stenosis: the contributions and limits of various tests. *Eur Spine J.* 2003;12(2): 190-196.	IV	This is a case control study evaluating the contributions and the limitations of various tests used to diagnose patients with clinical evidence of mild lumbar spinal stenosis. Twenty-nine consecutive patients with mild lumbar spinal stenosis were compared to two control groups without spinal stenosis: healthy volunteers and patients with diabetic polyneuropathy. The control groups were age and height matched. The criteria for mild lumbar spinal stenosis were neurogenic claudication and/or low back pain, at least one level of central lumbar spinal stenosis documented on CT, no paresis, ability to walk without crutches, and no opiate use. All subjects underwent plain	In critique, the strength of the study is its comparison of the performance of lumbar spinal stenosis patients, as confirmed by clinical findings and CT with those patients who do not have stenosis on ETT. The ability of the ETT to distinguish spinal stenosis from other causes of leg pain was not tested. This study provides Level IV diagnostic evidence that the ETT is potentially useful in diagnosing spinal stenosis.

		radiographs, an exercise treadmill test (ETT), electrophysiologic examination, and a clinical evaluation. Lumbar spinal stenosis patients and diabetic neuropathy patients underwent CT also. The authors reported that the lumbar spinal stenosis group had significantly smaller spinal canals than diabetic controls and significantly greater time on ETT (ie, worse performance) than diabetics and normals. They found no difference in CT findings between those with neurogenic claudication and those without, but indicated that the lumbar spinal stenosis patients with neurogenic claudication had significantly worse performance on the ETT than the lumbar spinal stenosis patients without neurogenic claudication. Based on these findings, the authors concluded that the ETT is clinically useful in diagnosing patients with mild lumbar spinal stenosis. They stated that any premature termination should be carefully analyzed, avoiding false-positive results in older patients (dyspnea, vascular claudication, joint complaints, etc).	
Amundsen T, Weber H, Lilleas F, Nordal HJ, Abdelnoor M. Magnaes B.. Lumbar spinal stenosis. Clinical and radiologic features. *Spine.* 1995;20(10): 1178-86.	IV	This is a study of 100 consecutive patients hospitalized for symptomatic spinal stenosis, defined as sciatica with or without back pain, with compression on imaging studies not caused by a herniated disc. Patients were studied with a clinical exam, ETT, bicycle test, plain radiographs and CT/Myelo. The measures reported for ETT were walking distance and relief with forward bending; measures reported for the bicycle test included pain in the legs during cycling relieved by forward flexion as positive; all other results as negative.	In critique, this case series provided no control group for comparison. Furthermore, the relationship between ETT/bicycle test and radiologic parameters was not reported. This study provides Level IV diagnostic evidence that exercise and bicycle test are abnormal in patients with lumbar spinal stenosis.

		Of the 86 patients who were able to complete the ETT, 72 had claudication and 23 experienced relief bending forward. Of the 59 patients who were able to complete the bicycle test, 36 of those were positive. For most patients the diameter of canal increased in flexion; in 33 patients it decreased in the flexed position. The study found no relationship between clinical parameters and radiologic parameters. The authors concluded that the degree of narrowing did not correspond to symptoms or functional test results.	
Fritz JM, Erhard RE, et al. Preliminary results of the use of a two-stage treadmill test as a clinical diagnostic tool in the differential diagnosis of lumbar spinal stenosis. *J Spinal Disord.* 1997;10(5): 410-416.	III	This is a study reporting on the initial experience with the two-stage ETT in the differential diagnosis of patients with low back pain, lower extremity pain and self-reported deficits in walking tolerance. The authors hypothesized that the findings on ETT would discriminate between stenotic and nonstenotic patients. Forty-five patients with low back pain, lower extremity pain and self-reported limitations in walking tolerance were studied with MRI or CT, Oswestry Disability Index (ODI), Visual Analog Scale (VAS), three self-reported postural variables and two stage-ETT. Based on imaging, all patients were classified as stenotic or nonstenotic (HNP, etc). The authors reported that a linear discriminant analysis using time to onset of symptoms and recovery time resulted in a likelihood ratio of 14.5. Likelihood ratios on self-reported variables were much lower (<2.0). They found no significant differences in average postures during ETT. The authors concluded that a two stage treadmill test may be useful in the differential diagnosis of lumbar stenosis.	In critique, it was not clearly stated whether the patients were consecutively selected and there was no consistently applied and agreed upon gold standard. The use of validated outcomes measures is in the study's favor. This study provides Level III diagnostic evidence that a two-stage treadmill test may be useful in the differential diagnosis of lumbar stenosis.

Jonsson B, Annertz M, Sjoberg C, Stromqvist B. A prospective and consecutive study of surgically treated lumbar spinal stenosis. Part I: Clinical features related to radiographic findings. *Spine.* 1997;22(24): 2932-7.	II	This is a prospective study of clinical and radiographic characteristics of patients undergoing surgery for lumbar spinal stenosis. One hundred five consecutive patients scheduled for decompressive surgery for lumbar spinal stenosis were interviewed and examined prior to surgery. Duration of symptoms, age, sex, walking ability, night symptoms and neurologic findings were recorded. Imaging included myelography in 93% (98 of 105) of patients. The AP canal diameter was measured at all lumbar levels. Pain at rest and at night was reported in 15.4% (68 of 105) and 16.7% (60 of 105) of patients respectively. Walking ability was less than 0.5 km in 66% (69 of 105) and worsened with increased age. SLR was negative in 66% (70 of 105). Total spinal block on myelography was present in 11% (13 of 105) with a mean AP canal diameter of 6.8 mm in the other patients. Reflex abnormalities were found in 42-66%. Pain was more intense and positive Straight leg raise (SLR) was more common in younger patients; reflexes were abnormal more often in older patients. No correlation was found between symptoms and signs and spinal canal constriction. The authors concluded that the signs and symptoms of lumbar spinal stenosis are related to age but not radiographic data.	In critique, this descriptive study only included patients with lumbar spinal stenosis severe enough to require surgery. This study provides Level II diagnostic evidence that severity of radiographically-defined lumbar spinal stenosis does not correlate with clinical signs or symptoms. In this subset of patients with severe lumbar spinal stenosis, the patient's age correlated better than radiographic with symptoms and findings.
Katz JN, Dalgas M, Stucki G, et al. Degenerative lumbar spinal stenosis. Diagnostic value of the history and physical examination." Arthritis Rheum. 1995;38(9): 1236-	IV	This is a study assessing the value of historical and physical findings in the diagnosis of lumbar spinal stenosis. The study included 93 consecutive patients evaluated in a spine center. The diagnosis of lumbar spinal stenosis was made by expert physician assessment in 46% (43 of 93) of patients	In critique, this study relies on expert opinion as the "gold standard" for diagnosis of lumbar spinal stenosis with radiographic confirmation in 88% of patients. Thus the study lacks a consistently applied gold standard. Furthermore, the stenosis patients

1241.		with at least 80% confidence and confirmed by imaging in 88%. Patients with <20% confidence for lumbar spinal stenosis had diagnoses including nonspecific musculoskeletal pain, scoliosis, spondylolisthesis and fibromyalgia. All patients underwent a standardized history and physical exam including assessment of gait, Romberg, lumbar extension test and neuromuscular examination. Historical findings most strongly associated with lumbar spinal stenosis (LR>2) were greater age (LR 2.5), severe lower extremity pain (LR 2.0) and absence of pain when seated (LR 6.6). Physical findings most strongly associated with lumbar spinal stenosis were wide-based gait (LR 14.3), abnormal Romberg test (LR 4.3), thigh pain after 30 seconds of lumbar extension (LR 2.5), and neuromuscular deficits (LR 2.1). Independent correlates of lumbar spinal stenosis were advanced age, wide-based gait and thigh pain with lumbar extension. The authors concluded that the history and physical examination were useful in the diagnosis of lumbar spinal stenosis.	were compared to patients with other clinical diagnoses but without imaging. This patient population is not well described. This study provides Level IV evidence that the diagnosis of lumbar spinal stenosis is suggested by greater age, severe lower extremity pain, absence of extremity pain when seated and/or improvement of pain when seated as well as lower extremity pain with spinal extension greater than 30°, an abnormal Romberg test and wide-based gait.
Mann NH3rd, Brown MD, et al. Statistical diagnosis of lumbar spine disorders using computerized patient pain drawings. *Comput Biol Med*. 1991;21(6):383-97.	IV	This is a study using computerized discriminant analysis to assess the accuracy of low back patient pain drawings in classifying patients into one of five different diagnostic categories. The authors selected 250 patient records from the practice of an orthopedic spine surgeon. The diagnoses were verified by review of the record and course of treatment. Pain drawings were quantified and categorized into one of five groups: benign disorders (BD), herniated nucleus pulposus (HNP), spinal stenosis (SS), underlying disorders (UD) and psychogenic disorders (PSY). The pain diagram	In critique, the gold standard for diagnosis of spinal stenosis (and other spinal conditions) was clinical expert opinion and was thus lacking. The clinical features of the patients with lumbar spinal stenosis were not described. The sensitivity of the pain diagram for diagnosis of lumbar spinal stenosis was low and worse than all four other diagnostic groups. This study provides Level IV diagnostic evidence that the patient pain diagram is a poor

		correctly identified the diagnosis in 46.2% of analyses overall and 55.6% of BD, 51.7% of HNP, 56.3% of PSY, 32.2% SS, and 35.2% UD. The authors concluded that patient pain drawings are helpful in the diagnosis of spinal disorders.	screening tool for SS in populations of patients with spinal disorders.
Moon ES, Kim HS, Park JO, et al. Comparison of the predictive value of myelography, computed tomography and MRI on the treadmill test in lumbar spinal stenosis. *Yonsei Med J.* 2005;46(6): 806-11.	III	This is a study comparing radiographic parameters and walking capacity in patients with severe spinal stenosis. Thirty-five consecutive patients with lumbar stenosis undergoing surgery were included. All patients had MRI, CT myelography and dynamic myelography with measurement of the dural cross-sectional area (DCSA) at the pathologic level. Treadmill walking test (TT) was performed at two speeds on two occasions. Time to first symptom (TAF) and total ambulation time (TAT) were determined. Of the patients in the study, 91.6% (32 of 35) completed the TT. Three patients (8.6%) were unable to complete the TT because of deconditioning and knee arthritis. The mean TAT was 242.2 meters. The mean DCSA on MRI was 47.58 mm^2. There was no correlation between walking ability and severity of radiographic stenosis. The authors concluded that the TT is a reliable and reproducible measure for assessing the function of patients with lumbar spinal stenosis.	In critique, this was a small study of preoperative patients with severe stenosis. The clinical features of patients are not described or correlated with TT performance. The TT was not studied in control populations of other spinal or vascular disorders. The test was not performed postoperatively or correlated with surgical outcomes. This study provides Level III diagnostic evidence that the TT is a reliable and reproducible measure for assessing function of patients with lumbar spinal stenosis but that its findings cannot be correlated with those of imaging studies of spinal stenosis.

Degenerative Lumbar Spinal Stenosis
Diagnosis/Imaging:
HISTORY AND PHYSICAL FINDINGS

-Secondary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusions
Deen HG Jr, Zimmerman RS, et al. Test-retest reproducibility of the exercise treadmill examination in lumbar spinal stenosis. *Mayo Clin Proc.* 2000; 75(10):1002-1007.	III	This is a prospective study undertaken to provide further validation of the treadmill test by evaluating its reproducibility and assessing whether there is any learning phenomenon by which patients could improve their treadmill test performance simply by practicing the test procedure. The study involved 28 patients with clinical diagnosis of neurogenic claudication and severe spinal stenosis on imaging. All had ETT pre- and postlaminectomy, each ETT retested within two to four days. Time to first symptoms and time to severe symptoms on ETT were the outcome measures employed. The authors concluded that the ETT has good test-retest reproducibility.	In critique, the study employed no asymptomatic group, therefore, it holds little diagnostic value. This study provides Level III diagnostic evidence that the ETT has good test-retest reproducibility.
Katz JN, Stucki G, et al. Predictors of surgical outcome in degenerative lumbar spinal stenosis. *Spine.* 1999;24(21): 2229-2233.	IV	This study is a prospective case series of 272 consecutive patients with back, buttock and/or lower extremity pain and compression of the cauda equina or exiting nerve roots on CT or MRI. All underwent surgery. Complete data was available on 73% (199 of 272) of the patients completed. The proportion of patients with severe pain decreased from 81% before surgery to 31% after surgery. The most powerful predictor of a good outcome was the patient's report of good or excellent health before surgery. The physical and radiographic findings did not correlate with outcome. The authors concluded that traditional objective measures do not predict outcome.	In critique, there was a high drop-out rate among participants. There was no asymptomatic group, therefore, it holds little diagnostic value. This study provides Level IV prognostic evidence that symptoms and physical findings do not correlate well with surgical outcome.
Tadokoro K, Miyamoto H, et al. The prognosis of conservative	IV	This study is a case series of 263 patients, 70 years or older, with spinal stenosis. For approximately two weeks, each patient received in-bed pelvic traction, application of body cast, and epidural steroid	In critique, there was a high, although expected, drop-out rate. Because there was no asympto-

treatments for lumbar spinal stenosis: analysis of patients over 70 years of age. *Spine.* 2005;30(21): 2458-2563.		infiltration such as epidural block and selective nerve root blocks. 9 pts died and 25 were lost to follow-up leaving 89. Clinical evaluation included the Japanese Orthopaedic Association Score (JOA) and radiographs in all patients, as well as myelography in 84 patients. Of the 123 patients, 121 were improved at discharge, with improvement in the mean JOA score from 11.1 to 15.9. At follow-up >2yrs, JOA scores declined to 14.3. There was no association between radiographic evaluations and the disturbance level of ADL at the final follow-up. A complete block demonstrated a worse prognosis than the other two types, CDWOB and RD. The authors concluded that the prognosis of medical/interventional treatment for aged lumbar spinal stenosis was relatively good, particularly in patients with radicular pain. Patients with complete block in the myelogram may not respond favorably to medical/interventional treatment.	matic group, there is little diagnostic value. This study provides Level IV prognostic evidence that a total block on myelography is associated with poor outcome with medical/interventional treatment.

Degenerative Lumbar Spinal Stenosis
Diagnosis/Imaging:
SENSITIVITY/SPECIFICITY OF TESTS

-Primary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Adamova B. Vohanka S, Dusek L. Differential diagnostics in patients with mild lumbar spinal stenosis: the contributions and limits of various tests. *Eur Spine J.* 2003;12(2):190-196.	IV	This study is a case control study in which 29 consecutive patients with clinical and CT evidence of lumbar spinal stenosis were compared to a control group of normal subjects and another group with diabetes-related neuropathy. Groups were evaluated for exercise tolerance and by electrophysiological studies. Chronodispersion of the tibial F-wave distinguished lumbar spinal stenosis neurogenic claudication patients from the other groups.	In critique of the study, the authors did not describe in detail the specific radiographic and clinical criteria used to establish the diagnosis of lumbar spinal stenosis. This study provides Level III diagnostic evidence that the contribution of electrophysiological methods in the evaluation of lumbar spinal stenosis patients is limited, but can differentiate diabetic polyneuropathy from lumbar spinal stenosis.
Adamova B, Vohanka S, et al. Dynamic electrophysiological examination in patients with lumbar spinal stenosis: is it useful in clinical practice? *Eur Spine J.* 2005;14(3):269-276.	IV	This study is a case control study of 36 consecutive patients with lumbar spinal stenosis confirmed on CT compared with 28 patients having diabetic polyneuropathy and 32 healthy volunteers. Soleus H-reflex, tibial F-wave and MEPs were evaluated in each patient before and after exercise. Authors concluded that the use of these tests in the diagnosis of lumbar spinal stenosis was limited. Changes were statistically significant but minimal.	In critique of the study, the utilization of electrodiagnostic tests was limited by the absence of established cut-off values. The authors did not describe in detail the specific radiographic and clinical criteria used to establish the diagnosis of lumbar spinal stenosis. This study provides Level III diagnostic evidence that exercise-induced EMG changes are minimal and of limited clinical value in evaluating lumbar spinal stenosis.
Asztely M, Kadziolka R, Nachemson A. A comparison of sonography and	III	This study is a comparison study in nonconsecutive patients between ultrasonography and myelography as a gold standard using technology that	In critique, the study utilizes technology now considered outdated.

myelography in clinically suspected spinal stenosis. *Spine.* 1983; 8(8):885-890.		is now considered obsolete. AP measurements of the spinal canal on ultrasound were compared to measurements on myelography at 170 levels in 59 patients. The correlation between these measurements was low.	This study provides Level III diagnostic evidence that ultrasound using this methodology is not useful as a substitute for myelography.
Bell GR,. Rothman RH, Booth RE. A study of computer-assisted tomography. II. Comparison of metrizamide myelography and computed tomography in the diagnosis of herniated lumbar disc and spinal stenosis. *Spine.* 1984;9(6): 552-556.	II	This study is a prospective comparison of metrizamide myelography and noncontrasted (not postmyelo) CT to intraoperative findings. The authors developed a "correlation scale" to judge the degree of agreement between the imaging studies and surgical exploration. There were 122 patients with surgically-confirmed pathology. Masked readings of CT and myelographic images were compared with surgical findings. The strength of correlation was assessed. The details of the CT technique were not specified. Based on their data, the authors concluded that myelography was 93% accurate and CT was 89% accurate in the diagnosis of lumbar spinal stenosis. Authors concluded that myelography is more accurate than CT in the diagnosis of stenosis.	In critique, site specific findings showed no significant difference between CT and myelography (67% and 68% accurate, respectively) in diagnosing spinal stenosis. This study provides Level II diagnostic evidence that the accuracy of CT and myelography in the diagnosis of lumbar spinal stenosis are comparable.
Bischoff RJ, Rodriguez RP, Gupta K, et al. A comparison of computed tomography-myelography, magnetic resonance imaging, and myelography in the diagnosis of herniated nucleus pulposus and spinal stenosis. *J Spinal Disord.* 1993;6(4): 289-295.	III	This is a comparative study of the findings of MRI, myelography and CT myelography with intraoperative findings in 119 levels in 57 patients. They describe specificity and sensitivity values for these studies relative to operative findings. In making the diagnosis of lumbar spinal stenosis, CT myelography and MRI were equally accurate (85%), whereas myelography was the most specific (81%).	In critique of this study, the patient population was limited to the 12% (59 of 475) of the available patients, who had surgery and all three imaging studies preoperatively. This may present a selection bias toward patients with more difficult diagnoses. The interpretation of intraoperative findings was subjective. Also, Figure 1 demonstrates a very subtle degree of stenosis, interpreted as positive by the authors, raising questions about threshold.

			This study provides Level III diagnostic evidence, based on the use of nonconsecutive patient sample, that the accuracy of CT myelography and MRI are comparable in the diagnosis of lumbar spinal stenosis.
Bolender N.F, Schonstrom NS, Spengler DM. Role of computed tomography and myelography in the diagnosis of central spinal stenosis. *J Bone Joint Surg Am.* 1985;67(2): 240-246.	II	This study compared the intraoperative findings, as a gold standard, with myelography (with extension) and CT. The study population included 24 patients with lumbar spinal stenosis confirmed by surgical exploration and 30 patients with abdominal CT scans performed for other reasons. The AP diameter of the osseous canal on CT correlated with surgical findings in only 20% of cases. The AP diameter of the dural sac on myelography correlated with surgical findings in 83% of cases. The effectiveness of CT was improved by using the dural sac cross-sectional diameter. The authors proposed that a dural sac area (DSA) of 100 mm^2 was unequivocal evidence of stenosis. The authors concluded that myelography was more sensitive than CT and that CT assessment of the DSA was more accurate than measurement of bony diameter of the spinal canal.	In critique of the study, hard criteria for the intraoperative diagnosis of central stenosis were not detailed. CT technology has evolved significantly since this study was published. This study provides Level II diagnostic evidence that the dimensions of the bony canal may significantly underestimate the severity of canal narrowing caused by soft tissue. The AP diameter of the dural sac on myelography and the dural sac area on CT represent better measures of central canal stenosis.
Eberhardt KE, Hollenbach HP, Tomandl B, Huk WJ. Three-dimensional MRI myelography of the lumbar spine: comparative case study to X-ray myelography. *Eur Radiol.* 1997;7(5): 737-742.	III	This study assessed the value of magnetic resonance myelography (MRIM). Findings on MRIM and X-ray myelography were compared to surgical findings in 80 patients with radiculopathy. The sensitivity of MRIM for detecting nerve root compression secondary to lumbar spinal stenosis was 92.5% compared to 82.5% for X-ray myelography. The authors conclude that MRI myelography is as sensitive and may be more sensitive than contrast myelography for the detection of abnor-	In critique, criteria for surgical findings were not well-defined. Based on the lack of a well-defined gold standard, this study provides Level III diagnostic evidence that MRI myelography is an effective means of assessing nerve root compression in lateral or foraminal lumbar spinal stenosis, and may be a useful adjunct to routine MRI.

		malities affecting the lumbar nerve roots.	
Hamanishi C, Matukura N, Fujita M, Tomihara M, Tanaka S. Cross-sectional area of the stenotic lumbar dural tube measured from the transverse views of magnetic resonance imaging." *J Spinal Disord.* 1994;7 (5):388-393.	IV	This study evaluated the incidence of dural sac narrowing on MRI in four different groups of patients: asymptomatic controls, low back pain, lumbar radiculopathy, and neurogenic claudication. A geometric formula and a digitizer were used to calculate to the dural sac area. Findings of these calculations were applied across all four patient groups. Cross-sectional area of less than 100 mm^2 at more than two of three levels was significantly correlated with the presence of intermittent claudication.	In critique, there was no gold standard for comparison. There was no correlation between clinical symptoms and point of maximal narrowing. This study provides Level IV diagnostic evidence that a decrease in the dural sac area below 100 mm^2 may correlate with the presence of intermittent neurogenic claudication.
Herkowitz HN, Garfin SR, Bell GR, Bumphrey F, Rothman RH. The use of computerized tomography in evaluating non-visualized vertebral levels caudad to a complete block on a lumbar myelogram. A review of thirty-two cases. *J Bone Joint Surg Am.* 1987;69(2): 218-224.	II	This study described the use of CT in the evaluation of levels caudad to a complete, or near complete, myelographic block in 32 patients. They found that CT provided clinically useful information that was confirmed at the time of surgery. Sixty percent of the nonvisualized levels showed stenosis or a herniated disc that was confirmed at surgery.	In critique, this was an early study showing the value of CT in addition to myelogram in evaluating the spinal canal. This study provides Level II diagnostic evidence that CT can provide useful information about levels below a myelographic block.
Herkowitz HN, Wiesel SW, Booth RE, Rothman RH. Metrizamide myelography and epidural venography. Their role in the diagnosis of lumbar disc herniation and spinal stenosis. *Spine.* 1982;7(1): 55-64.	II	This study compared the efficacy of epidural venography and metrizamide myelography in 30 consecutive patients with suspected lumbar disc herniation or lumbar spinal stenosis on clinical exam. Readings of both tests were compared to surgical findings. The sensitivity and specificity of epidural venography and metrizimide myelography were 83%/88% and 97%/100%, respectively. At the time of publication, the authors felt that epidural venography was a useful adjunct to myelography in patients with a congenitally short	In critique, interpretations of the imaging studies do not appear to have been masked to the results of surgery. This early study provides Level II diagnostic evidence that metrizamide myelography is more accurate in the evaluation of lumbar disc herniations and lumbar spinal stenosis than epidural venography.

		dural sac.	
Jacobson R. E. Lumbar stenosis. An electromyographic evaluation. *Clin Orthop Relat Res.* 1976;(115): 68-71.	III	This study is a retrospective review of 97 patients investigated for "lumbar root pain." All patients underwent electromyography (EMG), plain radiographs, axial tomograms and myelography. The authors conclude that 77% (41of 53) of patients with radiographic evidence of spinal stenosis frequently have bilateral EMG findings in contrast to patients with disc herniation who had unilateral findings. One-third of patients with stenosis and unilateral symptoms had bilateral EMG findings. Of the 42 patients with disc herniation, only eight had multiradicular findings on EMG.	In critique, the imaging criteria for stenosis were not specifically defined. The severity of stenosis in relation to the EMG findings was not reported. Because of these methodological flaws, this potential Level II study is downgraded to a Level III study. This study provides Level III diagnostic evidence that lumbar spinal stenosis is associated with multiradicular or bilateral EMG findings.
Jia LS, Shi ZR. MRI and myelography in the diagnosis of lumbar canal stenosis and disc herniation. A comparative study. *Chin Med J (Engl).* 1991;104(4): 303-6.	III	This study is a prospective comparison of MRI to myelography in 78 nonconsecutive patients who had surgery. Findings on MRI and myelography were compared with operative findings as the gold standard. MRI provided an accurate diagnosis in 85.2% of cases and myelography in 90% of cases. The authors found that MRI was as good as myelography for the diagnosis of herniated discs. The authors recommend MRI because it is noninvasive and nonionizing.	In critique of this early study, details of the raw data were not provided. This study provides Level III diagnostic evidence that MRI is as good as myelography for the diagnosis of herniated discs or stenosis in the majority of patients.
Johansen JG. Computed tomography in assessment of myelographic nerve root compression in the lateral recess. Spine. 1986;11(5): 492-5.	III	This is a prospective study on X-ray myelography compared to noncontrast CT performed in 1986. A nonconsecutive series of 30 patients who presented with clinical symptoms of a mononeuropathy, in whom an isolated myelogram revealed a unilateral shortening of a nerve root sheath. An average of six days later, these patients were imaged by CT. In 18 of these patients, the isolated myelogram was interpreted to lateral recess spinal stenosis; eight of these 18 had the diagnosis changed to "lateral disc herniation" when the CT images were reviewed.	In critique, this early report describes a nonconsecutive series of patients. This early study presents Level III diagnostic evidence that X-ray myelography may allow some isolated root compression, actually due to a disc herniation, to be misinterpreted as lateral recess stenosis Noncontrast CT imaging may be more useful than X-ray myelography in the assess-

			ment of the etiology of nerve root compression in the lateral recess.
Kent DL, Haynor DR, Larson EB, Deyo RA. Diagnosis of lumbar spinal stenosis in adults: a metaanalysis of the accuracy of CT, MRI, and myelography. *AJR Am J Roentgenol.* 1992;158(5): 1135-1144.	II	This study is a systematic review assessing the accuracy of CT, MRI and myelography in diagnosing patients with lumbar spinal stenosis. This meta-analysis identified 14/116 relevant studies with reference standard other than another imaging test. All studies received a grade of C or D, because of failure to assemble a representative cohort, small sample size or failure to maintain independent readings. The sensitivity of MRI in the diagnosis of adult spinal stenosis was 81-97%, sensitivity of CT was 70-100% and sensitivity of myelography was 67-78%.	In critique, although the results from the cited studies were difficult to pool, this was a thorough meta-analysis of literature from 1986 to 1991. This study provides Level II diagnostic evidence suggesting that each of these diagnostic studies are useful, and that none of the three is unequivocally superior in the diagnosis of adult lumbar spinal stenosis.
Lohman CM, Tallroth K, Kettunen JA, Lindgren KA. Comparison of radiologic signs and clinical symptoms of spinal stenosis. *Spine.* 2006;31(16): 1834-1840.	II	This study is a prospective study of consecutive patients with clinical symptoms of lumbar spinal stenosis who were studied using noncontrast, static CT technique, and with CT images obtained while the patient was subjected to axial load. A prospective comparison was performed between these two imaging methods, and compared to clinical symptoms as assessed by the Oswestry Disability Index (ODI) questionnaire and a visual analog pain scale (VAS). Of 117 patients referred for imaging for clinically suspected spinal stenosis, all patients underwent CT scanning in the supine position, and were imaged again at the lower three lumbar disc levels while wearing a harness that applied an axial load of 40% of the patient's body weight. Forty-six percent of the axial loaded patients were found to have spinal canal narrowing of <99 mm^2 at one or more levels on static imaging. Under axial load, the number of levels with canal diameters of 99mm^2 or less increased from 132 to 172. Fur-	In critique, this is a well performed prospective study. The report provides Level II diagnostic evidence that patients with no canal narrowing as measured by CT can present with clinical complaints suggestive of lumbar spinal stenosis. CT images obtained under axial load can demonstrate narrowing of the spinal canal at levels where no stenosis was documented on static imaging. Axial load can also increase the observed degree of stenosis at levels with documented stenosis on static imaging. In neither static or axial load CT imaging, did the presence of canal narrowing or the degree of canal narrowing correlate with clinical symptoms as assessed by validated instruments.

		ther, the number of levels with cross-sectional areas less than 74 mm^2 increased from 73 to 108. Fifty of the 117 patients complained of pain during the axial loading process, but there was no correlation noted between the induced pain and the presence or degree of stenosis. No correlation could be found between the degree of canal narrowing and clinical symptoms on either the static or axial load images. Indeed, when patients with documented canal narrowing were compared to those with normal dural sac cross-sectional areas, the scores for the ODI and VAS were the same.	
Manaka M, Komagata M, Endo K, Imakiire A. Assessment of lumbar spinal canal stenosis by magnetic resonance phlebography. *J Orthop Sci.* 2003;8(1): 1-7.	IV	This study is a case control study of the findings on MRI phlebography in 53 patients with intermittent claudication compared to 16 patients with other lumbar diseases and 13 normal patients. The authors found significantly more filling defects on MRI phlebography in patients with lumbar stenosis compared to patients with other diagnoses and to the normal patients. The severity of abnormalities correlated with the time at which intermittent claudication appeared on a walking treadmill test and decreased with flexion. The abnormalities improved in six patients who underwent surgery.	In critique, the results of cross-sectional imaging if obtained were not presented for either the stenosis group nor for the group with other diagnoses. There was no gold standard. Whereas six patients underwent surgery, the findings at surgery were not reported. This study showed Level IV diagnostic evidence that abnormalities on MRI phlebography are more frequent in patients with intermittent claudication.
Modic MT, Masaryk T, Boumphrey F, Goormastice M, Bell G. Lumbar herniated disk disease and canal stenosis: prospective evaluation by surface coil MRI, CT, and myelography. *AJR Am J Roentgenol.*	III	This study is a comparative study of surface coil MRI, CT and X-ray myelography in 60 consecutive patients with a clinical suspicion of a lumbar disc herniation or stenosis who were being evaluated for surgery. MRI was performed in every patient with surface coil technique. Myelo-	In critique, testing of patients was not uniform in that subsets of patients underwent CT and myelography which introduces potential bias as the patients may have been referred for specific tests depending on the suspected pathology. Not every patient underwent surgery, and the

1986;147(4): 757-765.		graphy, CT or CT myelography were performed in subsets of patients. Forty-eight patients were operated on at 62 levels with surgical findings as the gold standard. Masked interpretations of the imaging procedures were compared to each other and to the results of surgery. There was 86.8% agreement between MRI and CT/CTM at 151 levels. With respect to surgical findings, the accuracy for MRI was 82%, CT/CTM was 83% and myelography was 71%. CT and myelography missed one metastatic lesion, and CT missed an ependymoma. Findings on CT and MRI were complementary, however, as the diagnostic accuracy increased when studies were used in combination.	criteria for a surgical diagnosis were not specified. This study provides Level III diagnostic evidence that the accuracy of MRI and CT is comparable in the diagnosis of lumbar disc herniation and stenosis in patients who undergo surgery.
Molitor H. Somatosensory evoked potentials in root lesions and stenosis of the spinal canal (their diagnostic significance in clinical decision making). *Neurosurg Rev.* 1993;16(1): 39-44.	IV	This study is a retrospective evaluation of the utility of somato-sensory evoked potential (SEP) in 92 patients with conflicting data from clinical, imaging and neurophysiological testing with respect to the diagnosis of various disorders affecting the nervous system. The "gold standard" was the eventual diagnosis reached by the clinicians after considering all tests. In 14 patients who were eventually determined to have lumbar stenosis, SEPs were found to be useful for excluding demyelinating disease but not for confirming the diagnosis. Except for the time-consuming segmental stimulation (DSEP), the results of electrodiagnostic testing were frequently disappointing.	In critique, the tests were interpreted in a nonmasked fashion, and the "gold standard" was expert consensus opinion. In summary, this study provides Level IV diagnostic evidence that SEP may be useful to exclude other neurologic disorders such as demyelinating disease in patients with suspected lumbar spinal stenosis.
Moon ES, Kim HS, Park JO, et al. Comparison of the predictive value of myelography, com-	II	This is a study of the predictive value of findings on MRI, myelography, postmyelographic CT and flexion/extension myelography on the results of a walking treadmill test. A	In critique, the authors did not state whether interpretations and performance of the treadmill tests were masked to the results of the other tests.

puted tomography and MRI on the treadmill test in lumbar spinal stenosis. *Yonsei Med J.* 2005;46(6): 806-811.		group of 35 consecutive patients undergoing lumbar decompression for spinal stenosis were studied and the degree of stenosis on imaging studies were compared with the results of the treadmill test.	This study provides Level II diagnostic evidence that there is no significant correlation between the severity of stenosis as measured on the imaging tests and the patient's walking tolerance.
Nardin RA, Pate MR, et al. Electromyography and magnetic resonance imaging in the evaluation of radiculopathy." *Muscle Nerve.* 1999;22(2): 151-155.	IV	This study is a retrospective study comparing the utility of EMG and MRI in the diagnosis of cervical and lumbosacral radiculopathy. This study evaluated a population that included 47 nonconsecutive patients with a clinical history compatible with radiculopathy who were examined with an EMG and MRI within two months of each other. Fifty-five percent had an EMG abnormality and 57% an MRI abnormality correlating with the clinical symptoms. The two studies agreed in 60% of patients. As only one study was positive in 40% of patients, the authors concluded that the studies were complementary.	In critique, the study group was selected from nonconsecutive patients who had been referred for EMG, which limits the general applicability of the results. The MRI technique was not specified and may not have been uniform. There was no gold standard. This study shows Level IV diagnostic evidence that EMG and MRI results may be complementary in the diagnosis of patients with suspected cervical or lumbosacral radiculopathy.
Postacchini F, Amatruda A, Morace GB, Perugia D. Magnetic resonance imaging in the diagnosis of lumbar spinal canal stenosis. *Ital J Orthop Traumatol.* 1991;17(3): 327-337.	III	This study evaluated the MRI findings of stenosis and compared the diagnostic accuracy of this method of imaging with that of water soluble myelography and CT scanning in patients with stenosis of the spinal canal. Twenty-two patients had myelography, CT and MRI. All had symptoms in lower limbs, two had undergone previous surgery. Fifteen had MRI first; seven had myelo and or CT first. Myelo and CT were performed on separate occasions (ie, no postmyelo CT done). MRI with 1.5T, CT 2-5 mm. All studies were interpreted by a single-masked neuroradiologist. Patients were divided into two groups according to myelography. Group 1 consisted of 19	In critique, the study had a small sample size, with only three patients diagnosed with scoliosis. The CTs and myelograms were performed on separate occasions. Thus it is downgraded to a Level III from a potential Level II study. This study provides Level III diagnostic evidence that MRI is as sensitive, but not as specific, as myelography in the diagnosis of lumbar spinal stenosis. Furthermore, in this study, MRI was shown to be more accurate than CT in diagnosis of stenosis.

		patients whose myelogram showed compression caused by stenosis; group 2 consisted of 3 patients with scoliosis with stenosis on MRI, negative myelogram. Stenosis was defined as a cross-sectional area of the dural tube less than 120 mm^2. Authors reported that both complete block on myelogram always corresponded to complete interruption of dural sac on MRI but a partial block on myelogram was often interpreted as a complete block on MRI findings. MRI gave no false negatives. The noncontrast CT was then compared to MRI but not to the myelogram. Of the 13 cases, five showed stenosis on MRI, but not CT. The authors concluded that spinal canal stenosis surgery may be planned on the basis of MRI findings alone, except in scoliotic patients.	
Risius B, Modic MD, Hardy RW, Duchesneau PM, Weinstein MA. Sector computed tomographic spine scanning in the diagnosis of lumbar nerve root entrapment. *Radiology.* 1982;143(1): 109-14.	IV	This study reports findings in 25 patients with negative myelography and abnormalities within the neural foramina on CT. The authors utilized a grading system assessing a decrease in the size of the neural foramen and the effacement of perineural fat in the neural foramina, and compared these findings to the results at surgery in a subset of patients. In 24 of the 25 patients, the CT abnormality corresponded to the side of the patient's symptoms. Fourteen patients underwent surgery and 11 had excellent results. The authors concluded that abnormalities within the neural foramen on CT should be operated on if they correlate with the patient's symp-	In critique, this case series had a small number of patients who were selected because of a discrepancy in the findings, and offers no mention of sensitivity or specificity. This study provides Level IV diagnostic evidence that CT can detect abnormalities in the neural foramen not seen on myelography.

		toms.	
Schnebel B, Kingston S, Watkins R, Dillin W. Comparison of MRI to contrast CT in the diagnosis of spinal stenosis. *Spine.* 1989;14(3): 332-337.	III	This study is a retrospective comparison imaging studies in patients with lumbar spinal stenosis. A single reader compared MRI and CT myelogram findings in 41 patients, eight who had surgically confirmed stenosis, six with neurogenic claudication. The ability of CTM and MRI to detect disc degeneration, stenosis and spondylolisthesis was assessed and compared. MRI and CTM correlated in 96.6% of lumbar spinal stenosis cases. MRI was superior to CTM in demonstrating disc degeneration. The authors concluded that MRI is the imaging method of choice in patients with suspected lumbar spinal stenosis.	In critique, this is a retrospective comparison of CTM and MRI in a small number of patients with lumbar spinal stenosis demonstrating excellent correlation between the two methods. This study provides Level III diagnostic evidence that MRI and CTM provide similar information in patients with lumbar spinal stenosis.
Snowden ML, Haselkorn JK, et al. Dermatomal somatosensory evoked potentials in the diagnosis of lumbosacral spinal stenosis: comparison with imaging studies. *Muscle Nerve.* 1992;15(9): 1036-1044.	III	This study is a retrospective analysis of the accuracy of an electrodiagnostic test in the evaluation of patients with imaging confirmed lumbar spinal stenosis. The authors retrospectively reviewed the results of dermatomal somatosensory evoked potentials (DSEP) in 58 of 155 patients referred for evaluation of possible lumbar spinal stenosis in whom CT and/or MRI imaging was available. Abnormal DSEP responses were graded as single or multiple root and compared with clinical and imaging results. DSEP with multiple root findings was 78% sensitive for lumbar spinal stenosis with a positive predictive value for an abnormal DSEP was 93%. The authors concluded that patients with lumbar spinal stenosis commonly have abnormal DSEP charac-	In critique, this is a retrospective study assessing the findings of DSEP in patients with lumbar spinal stenosis. No comparison with DSEP results in other radicular syndromes was made and, as noted by the authors, DSEP cannot distinguish between lumbar spinal stenosis, arachnoiditis or disc herniation with radiculopathy. There was no consistently applied gold standard. This study provides Level III diagnostic evidence that DSEP is frequently abnormal in patients with lumbar spinal stenosis.

		terized by multiple root abnormalities.	
Tervonen O, Koivukangas J. Transabdominal ultrasound measurement of the lumbar spinal canal. Its value for evaluation of lumbar spinal stenosis. *Spine.* 1989;14(2): 232-5.	II	This is a comparative study of diagnostic studies in the assessment of lumbar spinal canal dimensions. Transabdominal ultrasound through the disc spaces and myelography were performed in 76 consecutive patients with back disorders. CT imaging was available in 42/76 patients. Lumbar spinal stenosis was present in 10 patients. The lower three lumbar levels were adequately assessed by ultrasound in 66% (50/76) of patients. In 15 patients, no visualization was possible because of obesity, severe degenerative changes or spondylolisthesis. Using imaging criteria of canal AP diameter of <10 mm^2 or cross-sectional area of < 100 mm^2 for lumbar spinal stenosis, US was 90% sensitive and 96% specific for the diagnosis. The authors concluded that ultrasound was well-suited for screening purposes.	In critique, this study included only a small number of patients with lumbar spinal stenosis. Only two thirds of patients could be studied by ultrasound. This study provides Level II diagnostic evidence that transabdominal ultrasound may be useful as a screening test in some patients with lumbar spinal stenosis.
Tsuchiya K, Katase S, et al. Application of multi-detector row helical scanning to postmyelographic CT. *Eur Radiol.* 2003;13(6): 1438-43.	III	This study is a prospective comparison of imaging techniques in patients with cervical, thoracic and lumbar disorders. Forty-six consecutive patients (16 with lumbar spinal stenosis) referred for preoperative CT/myelography were imaged using multidetector row helical CT (HCT), conventional CT and MRI (34 patients). Diagnosis was confirmed by subsequent surgery. Assessment by three independent readers included dural sac abnormalities, nerve abnormalities, bone spurs, and ossified ligaments. HCT was superior to CT in evaluating the dural sac in 39/46 patients	In critique, this study evaluated HCT in a mixed population including 16 patients with lumbar spinal stenosis. Furthermore, the comparison of the two imaging studies was subjective. This study provides Level III diagnostic evidence that HCT is superior to conventional CT in preoperative imaging of patients with lumbar spinal stenosis.

		and comparable to MRI. HCT was superior to CT all 22 patients with bony spurs and in visualization of nerve root abnormalities in 24/46 patients. The authors concluded that post-myelo HCT was superior to other imaging techniques in assessing the dural sac, nerve roots and bony abnormalities.	
Willen J, Danielson B. The diagnostic effect from axial loading of the lumbar spine during computed tomography and magnetic resonance imaging in patients with degenerative disorders. Spine. 2001;26(23): 2607-2614.	III	This study is a descriptive study showing changes in imaging findings in 172 pts with axial loading on cross-sectional imaging (50 CTM and 122 with MRI). Significant changes were defined as a decrease in the cross-sectional dural sac area (DSA) (>15 mm^2) to less than 75 mm^2, as significant changes in the degree of lateral recess stenosis or foraminal stenosis or as a significant change in the size of a disc herniation or synovial cyst. "Additional valuable information" found with axial loading in 50/172 patients (29%): in 69% of patients with neurogenic intermittent claudication, in 14% of patients with sciatica and in 0% of patients with low back pain.	In critique of this study, the author does not specify whether these were consecutive patients. The study was down classified to Level III. In conclusion, this study provides Level III diagnostic evidence that axial loading shows additional findings in patients with neurogenic claudication and radiculopathy. The clinical significance of these findings was not demonstrated.
Zileli B, Ertekin C, Zileli M, Yunten N. Diagnostic value of electrical stimulation of lumbosacral roots in lumbar spinal stenosis. *Acta Neurol Scand.* 2002;105(3): 221-227.	III	This study is a comparative study of two methods of electrodiagnostic testing in patients with lumbar spinal stenosis. Twenty patients, mean age 53.1 years (38-69) with imaging confirmed lumbar spinal stenosis were studied. Eleven patients had neurogenic claudication (NIC) without neurologic findings; nine patients had NIC with reflex loss. Ten controls were also studied. All patients were examined by both conventional EMG and lumbosacral root stimulation (LRS) with recording of distal latencies. Abnormalities were found in 75% (15/20)	In critique, this is a small study which demonstrates electrodiagnostic abnormalities in 75-85% of patients with lumbar spinal stenosis. Patients with other spinal disorders were not studied. Patient selection criteria were not identified. This study provides Level III diagnostic evidence that electrodiagnostic testing is frequently abnormal in patients with symptomatic lumbar spinal stenosis.

		of patients on EMG and 85% (17/20) of patients on LRS. More severe abnormalities were seen in patients with neurologic findings. All patients with NIC without reflex loss had abnormal findings on one or both studies. Electrodiagnostic studies correlated with imaging findings in 60% (12 of 20) of patients. The authors concluded that both electrodiagnostic techniques were useful and complementary in evaluating patients with lumbar spinal stenosis.	

Degenerative Lumbar Spinal Stenosis
Diagnosis/Imaging:
SENSITIVITY/SPECIFICITY OF TESTS

-Secondary Evidentiary Table on Observer Reliability-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Cihangiroglu M, Yildirim, Bozgeyik Z, et al. Observer variability based on the strength of MR scanners in the assessment of lumbar degenerative disc disease. *Eur J Radiol.* 2004;51(3): 202-208.	See Text	In this study 95 nonconsecutive patients with acute back pain or radiculopathy were prospectively studied by MRI on either 0.3 (57 patients) or 1.5 Tesla (38 patients) scanners. The lower three lumbar disc levels only were evaluated. Two independent neuroradiologists read each study and re-read each study 15 days later.. Final diagnosis was by consensus reading a third time by the same radiologists. Inter- and intra-rater reliability was assessed by kappa coefficients. Inter-and intra-rater reliability was "almost perfect" (kappa=.81-1.00) for detecting disc pathology; "substantial" (kappa=.61-.80) for defining the disc pathology; but only "moderate" (kappa= .41-.60) for diagnosing root compression and stenosis. For the more difficult root compression and stenosis diagnoses, the higher Tesla MRIs yielded slightly higher scores. The authors concluded that higher field machines should be used for surgical decision making and that MRI findings alone should not be used to make surgical decisions when stenosis is the diagnosis.	In critique of this study, no patients were studied with both 0.3 and 1.5 Tesla machines to evaluate the impact of the high field strength on inter- and intra-rater reliability. This report provides Level I prognostic evidence supporting the conclusion that both inter- and intra-rater reliability is influenced by both the field strength of the MRI and the diagnosis being considered. The diagnosis of spinal stenosis by MRI remains subjective because of the lack of clear and consistent diagnostic criteria on MRI.
Coste J, Judet O, Barre O, Siaud JR, Cohen de Lara A, Paolaggi JB. Inter- and intraobserver variability in the interpretation of com-	See text	In this prospective study, 20 patients with sciatica were compared to 20 sex and age-matched asymptomatic volunteers. All subjects were scanned at the lower two lumbar disc levels with 4 mm cuts and 1 mm overlap. The 40 scans were independently	In critique, there was a good deal of heterogeneity of variance in the readings between inter-rater and intra-rater findings. This appears to arise from the differences in consistency of interpretations be-

puted tomography of the lumbar spine. *J Clin Epidemiol.* 1994;47(4): 375-381.		interpreted by two radiologists and two rheumatologists in a masked manner. All the scans were re-read four months later by the same individuals. Inter- and intra-rater reliability were assessed by kappa statistics. Substantial levels of inter- and intra-observer agree were obtained only in diagnosing HNP (kappa =.7 and =.9 respectively). The diagnosis of disc bulge, spinal stenosis and facet arthrosis proved much more unreliable. This proved especially true for spinal stenosis. (inter-rater kappa= .03 at L4-5, kappa = .20 at L5-S1/ intra-rater kappa=.08 at L 4-5 kappa=.38 at L5-S1). The authors conclude the unenhanced CT scan is reliable only for the diagnosis of lumbar HNP and not for the other conditions studied.	tween radiologists and the rheumatologists. The authors suggested that experience in reading MRIs in the radiologists may have been the reason suggesting that with increase experience in MRI reading, increased kappa levels might be expected. This study provides Level I prognostic data supporting good inter- and intra-rater reliability for the diagnosis of HNP on CT scan. It further provides Level I prognostic data on the lack of usefulness of the CT scan in diagnosing lumbar spinal stenosis and facet arthrosis because of incompletely articulated diagnostic criteria.
Drew R, Bhandari M, Kulkami AV, Louw D, Reddy K, Dunlop B. Reliability in grading the severity of lumbar spinal stenosis. *J Spinal Disord.* 2000;13(3): 253-258.	IV	In this study, thirty CT scans were selected by two neuroradiologists from a data base to represent normal to severally stenosed lumbar spines in patients not previously operated upon. The scans contained bony and soft-tissue windows, 3 mm cuts and sagittal reconstructions. These 30 scans were each reviewed by four spinal surgeons and the findings recorded. All scans were re-read by the same surgeon four weeks later. Analysis of inter-and intra-rater reliability was by kappa statistics. There was moderate inter-rater agreement (kappa=.58 +/- 0.06) and intra-rater agreement (kappa=.59 +/- 0.04) on the over-all presence or absence of stenosis. However, when asked to assess the degree of stenosis on a seven-point scale, inter-rater agreement was poor (kappa=.26 +/- .04). Furthermore, inter-rater reliability worsened with a progression	In critique of this study, the authors fail to indicate clearly how the scans in the database had been originally diagnosed. This study provides Level I prognostic data indicating that the diagnosis of lumbar spinal stenosis can be diagnosed in general by CT scans, but specific and clinically useful diagnostic conclusions cannot be derived from CT scans alone.

		of the stenosis from canal to foramen (Central Stenosis: kappa=.46 +/- .04; Lateral Recess Stenosis: kappa=.32 +/-.04 and Foraminal Stenosis: kappa=0.18 +/- .04). The authors conclude that the poor reliability of CT scans in diagnosing varying degrees of spinal stenosis brings into question the results of studies using this diagnostic test in these diagnoses.	
Speciale AC, Pietrobon R, Urban CW. Observer variability in assessing lumbar spinal stenosis severity on magnetic resonance imaging and its relation to cross-sectional spinal canal area. *Spine.* 2002;27(10): 1082-6.		In this study, 15 MRI scans of the lumbar spine from nonconsecutive patients known to have spinal stenosis clinically were shown to seven observers: two orthopedic spinal surgeons, two neurosurgeons and three neuroradiologists. All of the patients had radiculopathy or claudication and 60% had back pain. All underwent surgery after their scans. Inter- and intra-rater reliable was estimated with kappa statistics. The scans were re-read two to three months after initial reading in a masked fashion. Inter-rater reliability was fair by the Landis and Koch Scale (kappa=.26 +/-.26). Intra-rated reliability was poor overall (kappa=.11). These poor results were interpreted as stemming from the lack of clearly articulated criteria to support diagnostic categories.	In critique of this study, the authors had available to them information on confirmation of diagnosis by surgical treatment that was not utilized to substantiate the diagnosis of spinal stenosis that would have contributed to completeness of this study. This study provides Level I prognostic evidence that inter- and intra-rater reliability is only poor to fair in the diagnosis of spinal stenosis on MRI scans.

Degenerative Lumbar Spinal Stenosis

OUTCOME MEASURES

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Atlas SJ, Deyo RA, van den Ancker M, Singer DE, Keller RB, Patrick DL. The Maine-Seattle back questionnaire: a 12-item disability questionnaire for evaluating patients with lumbar sciatica or stenosis: results of a derivation and validation cohort analysis. *Spine.* 2003;8(16): 1869-1876.	II	This study is a prospective diagnostic case series looking at the use of the Maine-Seattle Back Questionnaire (MSBQ) as compared to the gold standard 23 item Roland Morris Disability Questionnaire (RMDQ). The study was of 507 HNP patients with sciatica and 148 lumbar spinal stenosis patients. To validate the MSBQ, this study looked at internal consistency, construct validity, reproducibility and responsiveness in detecting change over a three-month period. The comparative analysis demonstrated internal consistency was lower for the 12 item MSBQ than for the RMDQ. Reproducibility with the MSBQ was good over three months. There was a high degree of construct validity and responsiveness in comparison to the RMDQ.	In critique, this study documents a high level of internal consistency, construct validity and responsiveness for this questionnaire. This study provides Level II diagnostic evidence that the MSBQ is a valid measurement of disability in a population of patients with lumbar spinal stenosis.
McDonough CM, Grove MR, Tosteson TD, Lurie JD, Hilibrand AS, Tosteson AN. Comparison of EQ-5D, HUI, and SF-36-derived societal health state values among spine patient outcomes research trial (SPORT) participants. *Qual Life Res.* 2005;14(5): 1321-1332.	II	This study evaluated the performance of several health state classifications in the SPORT study including SF 6D, eQWB, EQ-5D, and HUI. The study involves more than 2000 patients from multiple centers with a primary diagnosis of HNP, with spinal stenosis and spondylolisthesis. The study is ongoing and does not specify a follow-up period at the time of this analysis. Authors compared the measures to each other and to the ODI and patient satisfaction scores, and thus do not have a specific gold standard comparison. All instruments seemed to respond appropriately, in general, although all responded differently, and it was unclear how sensitive they would be	In critique of this study, ODI is assumed to be a gold standard, though this cannot be verified. This study has large numbers, and implements a good methodology. These data offer Level II diagnostic evidence, due to the lack of an established gold standard, that these health related quality of life measures show adequate responsiveness when evaluating spinal stenosis.

		to more subtle change, in particular. For this data, no firm conclusions can be drawn other than to say that the instruments are different, they will provide different results, and thus are not interchangeable.	
Pratt RK, Fairbank JC, Virr A. The reliability of the Shuttle Walking Test, the Swiss Spinal Stenosis Questionnaire, the Oxford Spinal Stenosis Score, and the Oswestry Disability Index in the assessment of patients with lumbar spinal stenosis. *Spine.* 2002; 27(1): 84-91.	III	This study evaluated the reliability of four different outcome assessments for spinal stenosis, including shuttle walking test (SWT), ODI, Swiss Spinal Stenosis Questionnaire (SSS) and the Oxford Claudication Score (OCS),used to study 32 clinic patients with the diagnosis of spinal stenosis one week apart to test reliability. The outcome assessments were then applied to 17 patients who had undergone surgery for spinal stenosis and had preop evaluation scores as well as 18 month follow-up. All tests appeared to be appropriately responsive and reliable. Significant improvements in SWT were noted in 11 of 17 patients. ODI correlated most closely with patient satisfaction. SSS was most reproducible. Authors concluded that they successfully validated the reliability of the four assessment tools.	In critique, this study had a small sample size and large subgroup variance. An external reference standard of patient satisfaction was used for comparison purposes without a consistent gold standard. These findings offer Level III diagnostic evidence that three outcome questionnaires, one general (ODI) and two specific (SSS and OCS) are reliable and responsive measures of spinal stenosis, as is a functional exam (SWT). The ODI may allow comparison of outcomes across multiple "disabilities.".
Stucki G, Daltroy L, Liang MH, Lipson SJ, Fossel AH, Katz JN. Measurement properties of a self-administered outcome measure in lumbar spinal stenosis. *Spine.* 1996;21(7): 796-803.	II	This study is a prospective, multicenter case series of 193 consecutive patients with spinal stenosis. The purpose of this study was to develop a short self administered questionnaire on symptom severity, physical functional status and patient satisfaction. Follow-up at six months was selected as the point of maximal benefit. Scale characteristics and validity were assessed on data from 193 patients. Responsiveness was assessed on 130 of the 193 patients. Of the 193 patients, 29 did not return the questionnaire, eight had incomplete questionnaires at six months, and at the time of analysis, 25 study patients had not reached the six-month follow-up. The test/retest reliability was assessed on a random sample of 23 patients and ranged from 0.82 to 0.96. The internal consistency ranged from 0.64-	In critique, the reproducibility, internal consistency, validity and responsiveness of this test were determined by comparison with known validated outcome measurement instruments, although these instruments are not necessarily specific to lumbar spinal stenosis and do not represent a gold standard. This study provides Level II diagnostic evidence that the devised questionnaire scales of symptom severity, physical function, and satisfaction are reproducible, internally consistent, valid and responsive measures of outcome in patients with lumbar spinal stenosis. This instrument is currently re-

		0.92 and the responsiveness from 0.96-1.07. The questionnaire was compared to the following standardized outcome measures: visual analog scale (VAS), sickness impact profile (SIP), cumulative illness rating scale and neuromuscular impairment index.	ferred to as the Zurich Claudication Questionnaire (ZCQ) or Swiss Spinal Stenosis Questionnaire (SSS).
Tenhula J, Lenke LG, Bridwell KH, Gupta P, Riew D. Prospective functional evaluation of the surgical treatment of neurogenic claudication in patients with lumbar spinal stenosis. *J Spinal Disord.* 2000;13(4): 276-282.	II	This study is a prospective study of 32 patients undergoing surgery for spinal stenosis, assessing the functional evaluation of surgical treatment by comparing functional tests to known validated outcome measures. Of these 32 patients, 26 had fusions: 11 at one level, 21 at multiple levels. Results were assessed by treadmill and bicycle tests as well as ODI and VAS scores. There were significant improvements in ODI and VAS at 1 and 2 years. Performance on the treadmill test correlated well with these scores, however, bicycle test was less responsive.	In critique of this study, there were a small number of patients. These data provided Level II diagnostic evidence that treadmill testing for walking ability provides a satisfactory functional measure of outcomes for surgery for spinal stenosis.
Tuli S, Yerby S, Katz JN. Methodological approaches to developing criteria for improvement in lumbar spinal stenosis surgery. *Spine.* 2006;31(11): 1276-1280.	II	This study applied the Swiss Spinal Stenosis Questionnaire (SSS) to a group of patients surgically treated for spinal stenosis. The questionnaire has three domains, physical functioning, symptom, and severity. The threshold values for improvement had been validated for individual domains in a prior study. Patient satisfaction was utilized to determine appropriate responsiveness of the instrument. The study evaluated sensitivity and specificity of success based on achievement of one, two or all three domains. The authors concluded that achieving two domains provided the best balance of satisfactory sensitivity and specificity for minimally clinically important difference.	In critique of this study, although there is no consensus on how to determine a minimally clinically important difference, the authors were able to evaluate a large number of patients using domains with prior validated threshold measures. These data offer Level II diagnostic evidence that the SSS can be used as a validated questionnaire in assessing the success of surgery for spinal stenosis. Exceeding threshold values for two of three domains gave satisfactory balance of sensitivity and specificity.
Yamashita K, Hayashi J, Ohzono K Hiroshima K. Correlation of patient satisfaction with symptom severity and walking ability after surgical	IV	This study is a prospective evaluation of 77/83 patients undergoing surgical decompression for spinal stenosis, comparing patient satisfaction to measures of pain as well as self-reported walking ability (five-tiered scale, arbitrarily based on time). Follow-up from one to seven	In critique of this study, non-validated outcome measures were used. This study provided Level IV diagnostic evidence that patient satisfaction was more dependent

treatment for degenerative lumbar spinal stenosis. *Spine.* 2003;28(21): 2477-2481.		years. There were significant correlations, although functional ability (walking) was least correlated with satisfaction.	on degree of pain than loss of function. Care must be taken when deciding on the type of outcome measures to use. In particular, the degree of satisfaction may not reflect improvements in walking ability.

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
PHARMACOLOGICAL TREATMENT

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Eskola A, Alaranta H, Pohjolainen T, Soini J, Tallroth K, Slatis P. Calcitonin treatment in lumbar spinal stenosis: clinical observations. *Calcif Tissue Int.* 1989;45(6): 372-4.	IV	This study is described as an "open follow-up study" to test the efficacy of intramuscular calcitonin for the treatment of lumbar spinal stenosis. The methodology was not clearly stated as retrospective or prospective. The study followed fifteen patients with neurogenic claudication with lumbar spinal stenosis over a period of six months. Clinical inclusion criteria were bilateral leg pain, maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, symptom intensity (scored using a numerical system), and a performance test of power and swiftness of the lower extremities. At three-month follow-up, there was a statistically significant improvement in symptoms intensity score. At six-month follow-up, there were statistically significant improvements in lower extremity performance tests. There was an average improvement of 491 meters walking distance.	In critique of this study, the authors did not use a validated outcomes instrument, the study population was small, there was no control group, follow-up was short, and the methodology is unclear. This study provides Level IV therapeutic evidence for the effectiveness of intramuscular calcitonin treatment for neurogenic claudication associated with lumbar spinal stenosis.
Eskola A, Pohjolainen T, Alaranta H, Soini J. Tallroth K, Slatis P. Calcitonin treatment in lumbar spinal stenosis: a randomized, placebo-controlled, double-blind, cross-over	II	This study is a double-masked, randomized controlled crossover trial of thirty-nine patients with neurogenic claudication from lumbar spinal stenosis. With this design, every patient was treated with intramuscular calcitonin for a portion of the study period so that each patient could serve as his own control. Clinical inclusion	In critique of the study, the radiographic inclusion criteria are somewhat contradictory. While they stated that all patients had less than 10 mm sagittal canal diameter, the authors subsequently stated that only 19 of 39 patients had central stenosis.

study with one-year follow-up. *Calcif Tissue Int.* 1992;50(5): 400-3.		criteria were bilateral leg pain, maximum walking tolerance of 1500 m. Radiographic inclusion criterion was less than 10 mm spinal canal diameter on myelography. Outcome measures were walking distance, pain (Visual Analog Scale) and a performance test of power and swiftness of the lower extremities. At three- to six-month follow-up, walking distance and pain were improved during calcitonin treatment. After crossover, pain relief was better than walking distance improvement. Patients with mild pain or severe neurogenic claudication showed no improvement.	The two groups were not matched for severity of initial symptoms nor were their baseline characteristics statistically compared. The results are not stratified between patients with central or lateral recess stenosis. Notwithstanding the VAS pain score, the other outcome measures were not validated and no outcome measure was disease-specific. These data represent Level II therapeutic evidence of the short term effectiveness of calcitonin in the treatment of lumbar spinal stenosis.
Iwamoto J, Takeda T, Ichimura S . Effect of administration of lipoprostaglandin E(1) on physical activity and bone resorption in patients with neurogenic intermittent claudication. *J Orthop Sci.* 2001;6(3): 242-247.	IV	This study is a case series with a prospective evaluation of 20 elderly men (average age 67 years old) treated with intravenous lipoprostaglandin E(E (1) with neurogenic claudication from lumbar spinal stenosis. The study population included patients with burning sensation in the legs and perineal region while walking, with or without urinary disturbance (12 patients). In an additional eight patients, symptoms also included radiculopathy. There were no stated radiographic inclusion criteria. Outcome was measured using the Japanese Orthopaedic Association instrument. Total score was statistically improved from 14.3 to 16.8. The authors concluded that intravenous treatment with lipoprostaglandin E(1) can improve subjective symptoms in elderly male patients with lumbar stenosis.	In critique of this study, the patient population was small and there were no stated radiographic inclusion criteria. Follow-up was short at six months. This case series provides Level IV therapeutic evidence for the short term efficacy of lipoprostaglandin E(1) for the treatment of lumbar spinal stenosis in elderly males.
Murakami M, Takahashi K, Sekikawa T, Yasuhara K, Yamagata M, Moriya H. Effects of intravenous lipoprostaglandin E1 on neu-	IV	This study is a case series of 37 patients with neurogenic claudication with lumbar spinal stenosis treated with intravenous lipoprostaglandin E(1). The study population included patients with burning sensation in the legs and perineal region while walking	In critique of this study, the patient numbers were small; the follow-up was variable and incompletely documented. This case series provides

rogenic intermittent claudication. *J Spinal Disord.* 1997;10(6): 499-504.		with or without urinary disturbance (cauda equina group, eight patients), those with radicular symptoms only (11 patients) and those with mixed symptoms (21 patients). There are no stated radiographic criteria for inclusion in the study. Outcome was measured using the Japanese Orthopaedic Association instrument. In short-term follow-up (10 days), overall scores improved from 15.8 to 19.2. There were statistically significant improvements in all subcategories of the JOA score except for clinical signs. In subgroup analysis, the cauda equina and mixed group showed statistically significant improvements in overall JOA scores; however, the radicular group did not. According to the authors' categorization of JOA score changes, 22 were considered to have good to excellent results. In so-called long-term follow-up (two to 23 months) of 31 patients with fair, good or excellent initial results, only 10 showed sustained improvement while 21 returned to their baseline level.	Level IV therapeutic evidence that intravenous lipoprostaglandin E(1) may provide short-term (10 days) benefit in patients with lumbar spinal stenosis but little long-term relief.
Podichetty VK, Segal AM, et al. Effectiveness of salmon calcitonin nasal spray in the treatment of lumbar canal stenosis: a double-blind, randomized, placebo-controlled, parallel group trial. *Spine.* 2004;29(21): 2343-2349.	II	This study is a randomized, double-masked, controlled trial studying the effectiveness of intranasal salmon calcitonin for the treatment of lumbar spinal stenosis. Fifty-five patients were randomized, 36 to the treatment group and 19 to the control group. After an initial six-week period, the placebo group was given calcitonin as a crossover group; however, the treatment group continued receiving calcitonin. Inclusion criteria were pseudoclaudication, defined as discomfort, pain, numbness, weakness, heaviness or vague discomfort in one or both lower extremities made worse by standing, walking or extension and relieved by sitting, squatting or forward flexion. The investigators stated that stenosis was radiographically confirmed; however, criteria were not listed. Outcome measures included	In critique of this study, the patient numbers were low, there was a relatively short follow-up period and there was a fairly high drop out rate (22%). While the study design was potentially Level I, these shortcomings limit the evidence to Level II. This study provides Level II therapeutic evidence that intranasal salmon calcitonin is not effective for the treatment of lumbar spinal stenosis.

		the Modified Oswestry Low Back Pain questionnaire, walking time and distance, LCS-specific questionnaire, SF-36 and Visual Analog Scale for Pain. At final follow-up, eight patients withdrew from the calcitonin group and four from the placebo group. Baseline characteristics for the two groups were statistically comparable. There were no significant differences between the treatment and control groups in VAS pain, SF-36 or total walking time or distance.	
Waikakul W, Waikakul S. "Methylcobalamin as an adjuvant medication in conservative treatment of lumbar spinal stenosis. *J Med Assoc Thai.* 2000;83(8): 825-31.	II	This study is a randomized controlled trial to evaluate the effect of methylcobalamin as an adjunct to medical/interventional treatment in 152 patients with lumbar spinal stenosis. Treatment with methylcobalamin was continued for six months; follow-up was two years. Patients had moderate symptoms. Plain radiographs were obtained for all patients; MRI or CT was obtained in some case. There were no radiographic inclusion criteria. Conservative care was administered in both groups, which included patient education, activity modification, exercises/physical therapy, oral analgesics, muscle relaxants and epidural steroid injections. There were no standard or systematic outcome measurements. Outcomes were limited to physical examination findings and walking distance. Both groups showed improvement in physical examination findings but there were no significant differences between them. There was a trend for a greater number of patients who could walk more than 1000 m after treatment; however, this could not be statistically confirmed.	In critique of this study, the randomization process was not masked as it relied on medical record numbers. Furthermore, there were no validated or standardized outcome measures utilized. In addition, numerous cointerventions were applied. Lastly, this randomized study demonstrated no significant differences in outcomes but did not calculate or report confidence intervals. Because of these deficiencies, this potentially Level I study is downgraded to a Level II study. This study provides Level II therapeutic evidence that methylcobalamin is not effective for the treatment of lumbar spinal stenosis.

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
PHYSICAL THERAPY AND EXERCISE

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Onel D, Sari H, Donmez C. Lumbar spinal stenosis: clinical/radiologic therapeutic evaluation in 145 patients. Conservative treatment or surgical intervention? *Spine.* 1993;18(2): 291-298.	IV	This study is a prospective case series of 145 patients with neurogenic claudication diagnosed with CT with or without myelography as having lateral and/or central canal stenosis were prospectively evaluated. Treatment was one month of in-patient therapy that included ultrasound, infrared heating, active therapy (William's flexion and McKenzie extension) and cotreatment with subcutaneous salmon calcitonin. Tested parameters were pain on motion, lumbar range of motion, straight leg raise (SLR), neurologic exam and walking distance. Results demonstrated 91% became pain-free with range of motion (100% were painful prior to treatment). 55% (67 of 112) of patients with limited lumbar extension improved to "normal" range of motion. Flexion was limited in 30% (43 of 112) of patients prior to treatment. After treatment, 70% (20 of 43) gained normal movement with flexion. SLR was limited in 29% (33 of 112) of patients prior to treatment; of these, 70% (23 of 33) regained a "normal" SLR after treatment. All 145 patients had neurogenic claudication prior to treatment; after treatment 89% improved and 29% had unlimited walking capacity. Before treatment, 29% had motor impairment; after treatment 53% (23 of 43) had normal motor function.	In critique, this study was conducted during a one-month hospitalization and there was no subsequent follow-up. This was an uncontrolled study with multiple treatment modalities. No validated outcome measures were employed. This case series provides Level IV therapeutic evidence that multiple modalities of physical therapy in combination with subcutaneous salmon calcitonin can relieve symptoms of lumbar spinal stenosis for the duration of therapy. No conclusions regarding the management of lumbar spinal stenosis by physical therapy can be drawn based on the results of this study.

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
MANIPULATION

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Murphy DR, Hurwitz EL, Gregory AA, Clary R. A non-surgical approach to the management of lumbar spinal stenosis: a prospective observational cohort study. BMC Musculoskelet Disord. 2006;23(7): 16.	IV	This study is a prospective observational case series of 57 consecutive patients with clinically and radiographically defined lumbar spinal stenosis. Mean age of patients was 65 years, 2/3 female, treated with distraction manipulation by standard technique of Cox and neural mobilization. Patients were also treated with designated exercises. Some patients also were treated with other physical therapy (spinal mobilization and stabilization). Patients were treated two to three times weekly for a mean number of 13.3 (range two-50) treatments. Mean follow-up was 16.5 months (range three-48 months). Forty-four patients were available for long-term follow-up. Outcome measures included the Roland Morris Disability Questionnaire (RMDQ) score, patient self –assessment of percent improvement, average pain intensity rating. The authors reported mean improvement in the RMDQ score at long-term follow-up was 5.2, and 66.7% of patients achieved a clinically significant improvement of >3 points in the RMDQ score. Current pain decreased by a mean of 38.4% at long-term follow-up, average pain 51.7% and worst pain 44.7%. Self-rated improvement was 75.6% overall. The authors concluded that the combination of DM and NM may be a useful therapy for patients with lumbar spinal	In critique, the results of this case series are compromised by the inclusion of additional physical therapies and treatments. In addition, the wide range in ages of the study population (32-80 years), the wide range in the number of treatments (two-50) and the range in long-term follow-up (three-48 months) further degrade the value of this study. Finally, there were no validated outcomes measures in this study. This case series provides Level IV therapeutic data suggesting that distraction manipulation and neural mobilization may be beneficial in the treatment of lumbar spinal stenosis.

		stenosis.	

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
INJECTION OUTCOMES

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Botwin KP, Gruber RD, Bouchlas CG, et al. Fluoroscopically guided lumbar transformational epidural steroid injections in degenerative lumbar stenosis: an outcome study. *Am J Phys Med Rehabil.* 2002;81(12): 898-905.	IV	This study is a prospective case series of 34 consecutive patients with unilateral radicular leg pain from spinal stenosis who had failed six weeks of noninvasive medical/interventional treatment that included NSAIDs and/or physical therapy. All patients underwent a multiple-injection protocol of transforaminal fluoroscopically-guided contrast-enhanced epidural steroid injection (betamethasone/lidocaine). MRI was obtained in all patients. Radiographic inclusion criteria were mild, moderate or severe central stenosis with lateral recess or foraminal stenosis. Outcome measures were Visual Analog Scale for pain, Roland five-point pain scale, a five-tiered standing and walking tolerance measure and a five-tiered patient satisfaction scale. Follow-up at 12 months was assessed by mailed-questionnaire. Six patients underwent surgery. Of the 28 who did not have surgery, 64% had improved walking tolerance, 75% reported greater than 50% reduction in pain and 57% had improved standing tolerance. Patients had an average of 1.9 injections.	In critique of this study, the patient numbers were small. Notwithstanding the VAS pain score, the other outcome measures were not validated instruments. This study represents Level IV therapeutic evidence that transforaminal fluoroscopically-guided contrast-enhanced epidural steroid injections can provide long-term (12 months) relief in about two thirds of patients with unilateral radiculopathy from lumbar spinal stenosis.
Ciocon JO, Galindo-Ciocon D, Amaranth L, Galindo D. Caudal epidural blocks for elderly patients with lumbar canal stenosis. *J Am Geriatric Soc.*	IV	This study is a prospective case series of thirty patients with lumbar spinal stenosis who underwent a series of three caudal epidural steroid injections without fluoroscopic guidance. The agent used was depomedrol and xylocaine. Patients had complaints of leg pain and neuro-	In critique of this study, patient numbers in this case series were low. These data offer Level IV therapeutic evidence that a series of three nonfluoroscopi-

1994;42(6): 593-596.		genic intermittent claudication with or without back pain. All had confirmation of stenosis by MRI that was graded as mild in seven patients (23%), moderate in 20 patients (67%), and severe in three patients (10%). Outcome measure included a Roland five-point pain scale and patients were followed for four to 10 months. Pain scores decreased from an average 3.4 to 1.5 after treatment. Notably, the investigators found that the degree of pretreatment pain correlated with the degree of radiographic central stenosis; however, the response to injection was not correlative.	cally-guided caudal epidural blocks can decrease pain from lumbar spinal stenosis at four to 10 months' follow-up.
Cuckler JM, Bernini PA, Wiesel SW, Booth RE, Rothman RH, Pickens GT. The use of epidural steroids in the treatment of lumbar radicular pain: A prospective, randomized, double-blind study. *J Bone Joint Surg Am.* 1985;67(1): 63-6.	III	This study is a prospective, randomized, double-masked trial comparing non-fluoroscopically-guided single injections of epidural steroid to placebo injections in 73 patients with radicular pain, 37 of whom had neurogenic claudication from lumbar spinal stenosis. There were 20 stenotic patients in the steroid group and 17 in the placebo group. Outcome measure was physician assessment of pain improvement. A so-called successful outcome was deemed greater than 75% pain decrease. At an average follow-up of 21.5 months, there was no significant difference in the number of successes in the treatment and control groups.	In critique of this study, the number of stenotic patients included was small and the definition of success was subjective and not based on a standardized outcome measure. Furthermore, a group of 15 patients who underwent a second injection with steroid in a non-masked fashion were not analyzed separately. The attrition rate was not reported. While potentially a Level I study, the lack of complete masking would downgrade this study to Level II. The further shortcomings, noted above made the work group classify the results of this study as Level III evidence. This study provides Level III therapeutic evidence that a single, nonfluoroscopically-guided interlaminar injection does not produce long-term (average 21.5 months) relief.
Delport EG,. Cucuzzella AR, Marley JK, Pruitt CM, Fisher JR. Treatment of lumbar spinal stenosis with epidural steroid injections: a retrospective	IV	This study is a retrospective case study of 140 consecutive patients with lumbar spinal stenosis treated with a multiple injection protocol of fluoroscopically-guided transforaminal or caudal epidural steroid injections. Radiographic inclusion criterion was MRI-confirmed cen-	In critique, the results were not stratified for the caudal injection versus the transforaminal injections, limiting conclusions of the results of these two techniques. As the investigators stated that they employed cau-

outcome study. *Arch Phys Med Rehabil.* 2004;85(3): 479-484.		tral, lateral recess or foraminal stenosis at one or more levels. Clinical inclusion criteria included leg pain or neurogenic claudication with or without back pain. The investigators stated they directed injections to the site of neural compression noted on imaging. They employed caudal blocks for multilevel central canal stenosis and presumably transforaminal injection for single-level disease. Follow-up was conducted by telephone interview between 6 to 36 months. Outcome measures were pain rated by a three-tiered system, duration of pain relief, and the impact on daily activities. Thirty-two percent had more than two months of pain relief, 38% had less than two months, 29% had no pain relief, 21% had improvement in daily activities, and 20% eventually underwent surgery after an average of 2.23 injections were administered.	dal injections for multilevel disease, a stratification of results according to the extent of disease would also have been useful. This case series provides Level IV therapeutic evidence that multiple fluoroscopically-guided transforaminal or caudal epidural injections can reduce pain and improve daily function for at least two months in about one third of patients with leg pain or neurogenic claudication from spinal stenosis.
Fukusaki M, Kobayashi I, Hara T, sumikawa K. Symptoms of spinal stenosis do not improve after epidural steroid injection. *Clin J Pain.* 1998;14(2): 148-151.	II	This study is a prospective, randomized, double-masked trial evaluating the efficacy of a single interlaminar nonfluoroscopically-guided epidural steroid injection in 53 patients with lumbar spinal stenosis. Patients were randomized to three groups: epidural saline injection (16 patients), epidural local anesthetic (18 patients), and epidural anesthetic plus steroid (19 patients). The clinical inclusion criteria were neurogenic claudication with leg pain and a walking tolerance less than 20 m. Radiographic inclusion criteria were central stenosis with less than 15 mm sagittal canal diameter on CT and/or MRI, lateral recess stenosis or mixed central and lateral recess stenosis. The only outcome measure was walking distance rated as excellent (greater than 100 m), good (20 to 100 m) and poor (less than 20 m). At one month, 6.3% of the saline patients experienced good or excellent results while 16.7% and 15.8% of the anesthetic and anesthetic-steroid group experienced good or excellent results. This difference was significant. However, at	In critique of this study, the only measured outcome was walking distance. No validated outcome measures were used. Supporting the study, there were no study drop-outs and the three groups were homogenous in baseline characteristics. This study provides Level II therapeutic evidence that a single nonfluoroscopically-guided interlaminar ESI for spinal stenosis can improve short-term (one month) walking distance, but not at three months.

		three months, there were no significant differences between the groups.	
Hoogmartens M, Morelle P. Epidural injection in the treatment of spinal stenosis. *Acta Orthop Belg.* 1987;53(3):409-411..	IV	This study is a retrospective case series of 49 patients with lumbar spinal stenosis with neurogenic claudication undergoing a multiple injection protocol of caudal epidural steroid blocks with radiographic guidance. The clinical inclusion criterion was walking distance of 100 m or less. Injections were a combination of local anesthetic and steroid. Imaging was not standardized and not obtained in all patients. There was a 22% drop-out rate from the study. The outcome measure was a mailed-questionnaire that judged outcome as excellent, good, fair and poor. At an average 23-month follow-up, 32% experienced good or excellent results, 16% had fair results and 52% had poor results.	In critique of this study, the details of the outcome questionnaire were not provided, limiting the generalizability of the data. This case series provides Level IV therapeutic evidence that a nonfluoroscopically-guided multiple caudal injection protocol produces good or excellent results in about one third of patients at 23 month follow-up.
Ng L, Chaudhary N, Sell P. The efficacy of corticosteroids in periradicular infiltration for chronic radicular pain: a randomized, double-blind, controlled trial. *Spine.* 2005;30(8):857-862.	II	This study is a prospective, randomized controlled trial evaluating the efficacy of a single transforaminal fluoroscopically-guided contrast-enhanced injection. Thirty-two of the patients had spinal stenosis. The inclusion criterion was unilateral leg pain from foraminal stenosis confirmed by MRI. All patients had failed six weeks of medical/interventional treatment that included physical therapy and NSAIDs. Fifteen patients received an injection with local anesthetic alone and seventeen received anesthetic and steroid. Outcome measures were ODI, VAS and walking distance. At all time periods during a maximum follow-up of 12 weeks, there were no significant differences between the two groups.	In critique of the study, the absolute values of the stenotic group were not presented. More importantly, the control group received an anesthetic injection, which may have had a therapeutic effect on its own. There were no confidence intervals reported for this study that showed no significant differences. This study provides Level II therapeutic evidence that the addition of steroid to a transforaminal anesthetic injection offers little clinical benefit.
Ng LC, Sell P. Outcomes of a prospective cohort study on peri-radicular infiltra-	IV	This study is a prospective case series study examining the results of a single transforaminal injection with steroid in 117 patients with chronic radicular pain	In critique of this study, there was no statistical comparison of the treatment effect in the spinal stenosis group alone. Without

tion for radicular pain in patients with lumbar disc herniation and spinal stenosis. *Eur Spine J.* 2004;13(4):325-329.		from herniated disc or spinal stenosis. Sixty-two patients had spinal stenosis diagnosed by MRI. Outcome measures were ODI, VAS, modified Zung depression score, and the Low Back Outcome Score. Follow-up was a maximum of three months. The ODI improved by six points, the VAS improved by 12 points, and the LBOS improved by 26 points. Sixteen percent (10 of 62) of patients dropped out to undergo surgery.	this, the clinical effect is difficult to discern. These case series provide Level IV therapeutic evidence that a single transforaminal ESI can provide a small long-term (three-month) effect on chronic, unilateral radicular pain from spinal stenosis.
Papagelopoulos PJ, Petrou HG, Triantafyllidis PG, et al. Treatment of lumbosacral radicular pain with epidural steroid injections. *Orthopedics.* 2001;24(2):145-149.	IV	This study is a prospective case series of 50 patients, 13 of whom had radicular pain from spinal stenosis, who underwent a single nonfluoroscopically-guided interlaminar injection with anesthetic and steroid. Four patients had central stenosis; nine patients had lateral recess stenosis. They all had CT or MRI performed; however, the authors did not list specific radiographic inclusion criteria. Follow-up was at a mean of 24 months. The outcome measure was unclear but was presented as excellent, good, fair or poor. Four patients with central stenosis completely improved, two had some improvement, and one patient underwent surgery after six months. In the lateral recess group, seven completely improved and two had some improvement.	In critique of this study, the outcome measure was not described and therefore its clinical relevance is unclear. Patient numbers were low. This case series provides Level IV therapeutic evidence that a single nonfluoroscopically-guided interlaminar injection can provide some long-term improvement in patients with radicular pain from spinal stenosis.
Riew KD, Yin Y, Gilula L, et al. The effect of nerve-root injections on the need for operative treatment of lumbar radicular pain. A prospective, randomized, controlled, double-blind study. *J Bone Joint Surg Am.* 2000;82-A(11):1589-1593.	II	This study is a prospective, randomized, double-masked trial of 55 patients with radicular pain from herniated disc or spinal stenosis who underwent a multiple injection transforaminal fluoroscopically-guided protocol. The clinical inclusion criterion was radicular leg pain. The radiographic inclusion criterion was nerve root compression diagnosed by MRI or CT. While the authors stated that there were no significant differences in the number of patients with herniated disc or spinal stenosis in the two groups, the actual patient numbers were not reported. Follow-up was 13 to 28 months. Outcome measures included the North	In critique of this study, the number of patients with stenosis is not reported. Thus, it is not possible to determine the power of the study. In addition, the absolute improvements of the primary outcome score (NASS Outcome Instrument) were not reported, though the authors stated that these values improved in the stenotic patients who received steroid and anesthetic. The authors do not separately report the results of anesthetic injection alone in the stenotic patients. Because of

		American Spine Society Outcome Instrument and the avoidance of undergoing a subsequent surgery. In the stenosis patients who did not undergo surgery, there was a significant decrease in neurologic symptoms and low back pain; however, it is unclear if these patients received the steroid or nonsteroid injection. Stenotic patients who received steroid and anesthetic had a significant decrease in low back pain and significant improvement in treatment expectation scores. In total, 47% (26 of 55) of patients eventually underwent surgery, but it is not clear how many were stenosis versus herniated disc patients.	these limitation, this potentially Level I study was downgraded to a Level II study. This study provides Level II therapeutic evidence that transforaminal ESI can decrease the likelihood that a patient with radicular leg pain and spinal stenosis will undergo an operation.
Zennaro H, Dousset V, Viaud B, et al. Periganglionic foraminal steroid injections performed under CT control. *AJNR Am J Neuroradiol.* 1998;19(2):349-352.	IV	This study is a case series of 41 patients, 21 of whom had foraminal stenosis, who underwent a single CT-guided transforaminal epidural steroid injection. Clinical inclusion criterion was radicular pain. Imaging studies included CT; some also had an MRI. The average follow-up was nine months. The outcome measure was a pain questionnaire, the details of which were not described. Ninety-five percent of patients with lumbar stenosis had pain relief at final follow-up. Three patients had recurrence of pain during the follow-up period.	In critique of this study, the pain score was not detailed and no validated outcome measure was used. The absolute reduction of pain scores was not reported, limiting evaluation of the magnitude of clinical effect. This case series provides Level IV therapeutic evidence that CT-directed transforaminal ESI can have a high success rate for radicular pain from foraminal stenosis.

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
INJECTION ACCURACY

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Mehta M, Salmon N. Extradural block: Confirmation of the injection site by x-ray monitoring. *Anaesthesia.* 1985;40(10):1009-1012.	I	This study assessed the ability to accurately access the spinal canal using a nonfluoroscopically-guided interlaminar epidural injection technique in 100 patients with a variety of lumbar spinal conditions. In 17% of cases, the injection was completely or partially outside of the spinal canal.	In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind interlaminar injection is correct in 83% of cases.
Renfrew DL, Moore TE, Kathol MH, el-Khoury GY, Lemke JH, Walker CW. Correct placement of epidural steroid injections: Flouroscopic guidance and contrast administration. *AJNR Am J Neuroradiol.* 1991;12(5):1003-1007.	I	This study examined the accuracy of needle placement during nonfluoroscopically-guided caudal epidural steroid injection in 328 patients, some of which had lumbar spinal stenosis. Results were categorized according to technician experience. Injections by physicians who had performed less than 10 procedures were in the epidural space in 47% of cases. Injections by those who had performed 10 to 50 procedures were in the epidural space in 53% of cases. Injections by those who had performed more than 50 procedures were correctly placed in 62% of cases.	In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal injection is correct in 47 to 62% of cases.
Stitz M, Sommer H. Accuracy of blind versus fluoroscopically guided caudal epidural injections. *Spine.* 1999;24(13):1371-1376.	I	This study assessed the accuracy of nonfluoroscopically-guided caudal epidural injections in the lumbar spine of 54 patients. Needles were first placed in a masked manner by palpation of landmarks only. Fluoroscopic evaluation with contrast demonstrated that the needle was in the epidural space in 74.1% of cases.	In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis. This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 74% of cases.
White AH, Derby R, Wynne G. Epidural injections for the di-	I	This study report a series of 300 consecutive injections. The authors found that caudal injection using palpable landmarks alone was incorrectly placed	In critique, the population had a variety of lumbar diagnoses, not limited to spinal stenosis.

agnosis and treatment of low back pain. *Spine.* 1980;5(1):78-86.		25% of the time, as confirmed by contrast-enhanced fluoroscopy. Needle placement was incorrect in 30% of cases during interlaminar injection by landmark palpation alone.	This study provides Level I diagnostic evidence that blind caudal epidural injection is accurately placed in 75% of cases and that blind interlaminar epidural injection is accurately placed in 70% of cases.

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
BRACING-TRACTION-ELECTRICAL STIMULATION-TENS

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Prateepavanich P, Thanapipatsiri S, Santisatisakul P, Somshevita P, Charoensak T. The effectiveness of lumbosacral corset in symptomatic degenerative lumbar spinal stenosis. *J Med Assoc Thai.* 2001;84(4):572-576.	III	This study is a self-controlled comparative study of 21 patients with a mean age of 62.5 using a lumbosacral corset for the treatment of symptomatic degenerative lumbar spinal stenosis and neurogenic claudication. Patients over age 50, with reproducible neurogenic claudication, degenerative changes on radiographs, and no contraindications to using a treadmill or corset were included in the study. Outcome measures were VAS in daily activities and walking distance. Patients served as their own control. Each patient was walked on a treadmill with and without the use of a corset, one week apart and claudication distances were determined. Patients also reported VAS during daily activities. There was a statistically significant increase in walking distance (from 314 to 393 feet) and a decrease in pain (VAS from 5.9 to 4.7) with the use of the corset.	In critique, the sample size of patients is small. The study is otherwise well designed for the authors' goal. This study provides Level III therapeutic evidence that the use of lumbosacral corset can increase walking distance before claudication and reduce pain in patients with lumbar spinal stenosis. There is no evidence that use of a brace has any lasting results once discontinued.
Willner S. Effect of a rigid brace on back pain. *Acta Orthop Scand.* 1985(56):40-42.	IV	This study is a prospective case series of 48 patients with a mean age of 45 years. Of these patients, 15 had spondylolisthesis, seven had lumbar spinal stenosis confirmed by myelography with symptoms of claudication, and the remaining 26 patients had long-term low back pain of unknown etiology. All patients were placed in a Flexaform (rigid LSO)	In critique, the sample size of patients in this study with spinal stenosis is extremely small and no validated outcome measures were used. There is no mention of compliance with brace use or pain reduction when out of the brace. This study provides Level IV therapeutic evidence that rigid

		brace for an average of one year. In the group with spinal stenosis, two cases were totally free from pain, four patients reported an obvious improvement with increased walking capacity and in one case, the pain was unchanged.	bracing can reduce pain in spinal stenosis.

Degenerative Lumbar Spinal Stenosis
Medical/Interventional Treatment:
LONG TERM OUTCOMES

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleas F. Lumbar spinal stenosis: conservative or surgical management?: a prospective 10-year study. *Spine.* 2000;25(11):1424-1435; discussion 1435-1426.	IV	This study is a case control, comparative study of 100 patients with symptomatic spinal stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management, and 31 patients were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent). To review long-term outcomes, we reviewed 50 patients who were selected for medical/interventional treatment because of moderate symptoms and 18 medical/interventional patients who were randomly assigned, for a total of 68 patients treated medically/interventionally in this study. At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in	For evaluation of this article, the reviewers chose to include only the patients in the medical/interventional treatment groups, limiting this study to a case series, or Level IV evidence. In critique of this study, there are no standardized outcomes utilized, and there was a substantial number of patient deaths and patients crossing over to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment, but this program appears reasonably effective. It is unclear that the results of initial treatment rendered differ from the natural history of spinal stenosis. The study provides Level II prognostic data that after 10 years, 70% of patients who received minimal medical/interventional treatment experienced good results based on self-assessed pain.

		this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.	
Simotas AC, Dorey FJ, Hansraj KK, Cammisa F, Jr. Nonoperative treatment for lumbar spinal stenosis. Clinical and outcome results and a 3-year survivorship analysis. *Spine.* 2000;25(2):197-203; discussions 203-194.	IV	This study is a case series of 49 people, with a mean age of 69, meeting radiologic and clinical criteria of spinal stenosis. Patients were treated medically/interventionally with exercises, analgesics and epidural steroid injections. Patients were followed an average of 33 months. Outcome measures were VAS, Roland Morris Disability Questionnaire score, an overall rating of depression and anxiety levels, an outcome measure of lumbar stenosis by Stucki and a motor examination. At three years, nine of these patients needed surgical decompression. Of the remaining 40 patients, 12 had none or only mild pain, 11 reported mild improvement, 12 reported no change and the remaining five were probably or definitely worse. Two of these patients had significant motor deterioration.	In critique, this study used validated outcome measures and a defined medical/interventional treatment method. This study provides Level IV therapeutic evidence that that with medical treatment, 71% (35 out of 49) of patients with stenosis will remain the same or improve with medical/interventional treatment over three years. The remaining 18% (14 out of 49) will worsen to the point that they require surgery.
Waikakul W, Waikakul S. Methylcobalamin as an adjuvant medication in conservative treatment of lumbar spinal stenosis. *J Med Assoc Thai.* 2000;83(8):825-831.	IV	This study is a prospective cohort study on the treatment of lumbar spinal stenosis using methylcobalamin as an adjunct to medical/interventional care. Conservative care consisted of patient education, activity modification, exercises to strengthen the trunk and abdominal muscles, physical therapy, NSAIDs, analgesics, muscle relaxants and epidural steroid injections. The patients were followed for two years. Outcome measures were physical examination and neurogenic claudication distance (1000 m). In the group that received medical/interventional care only, initially 59 out of 82 patients were unable to walk 1000 m. At two years, only 12 out of 80	In critique, we have opted to judge this study as two separate case series when evaluating long-term outcomes. This study is limited by lack of standardized medical/interventional treatment or outcome measures and limit to two-year follow-up. This study provides Level IV therapeutic evidence that medical/interventional care can improve walking distance in patients with lumbar spinal stenosis.

		were unable to walk 1000 m. Two patients went to surgery. In the group that was treated with methylcobalamin and medical/interventional care, initially 50 out of 70 could not walk 1000 m. At two years, the 69 patients remaining could walk >1000 m. One single patient required surgical intervention.	
Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine.* 2005;30(12):1351-1358.	IV	This study is a randomized controlled trial in which patients were randomized into two groups: one treated with X-Stop and one treated medically/interventionally. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years. The primary outcome measure was the Zurich Claudication Questionnaire. Secondary outcomes included the SF-36 and range of motion. Of the 91 medical/interventional patients, 81 were available for follow-up. Forty-four percent of medical/interventional patients experienced at least some improvement in their pain and 43% of patients experienced at least some improvement in their physical function.	In critique, medical/interventional treatment was not controlled and secondary outcome measure results were not available. Data on two-year outcomes of the medical/interventional group show poorer results than other medical/interventional studies. This study provides Level IV prognostic evidence that approximately 40% of patients will show improvements in pain and physical function.

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
SURGICAL MGT VS. NATURAL HISTORY

-Primary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleas F. Lumbar spinal stenosis: conservative or surgical management?: A prospective 10-year study. *Spine.* 2000;25(11):1424-1435; discussion 1435-1426.	II and IV	This study is a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management, and 31 with moderate to severe symptoms were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis and response to treatment (worse, unchanged, fair, excellent). The study reported a good result in the medically/interventionally treated group of 70% (35 of 50) patients at six months, 64% (32 of 50) at one year, and 57% (28 of 49) at four years. The study reported a good result in the surgically treated group of 79% (15 of 19) at six months, 89% (17 of 19) at one year, and 84% (16 of 19) at four years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (seven of 18) at six months, 33% (six of 18) at ine year, and 47%	In critique, no standardized outcome measures were utilized, a substantial number of patients died and /or crossed over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment rendered differed from the natural history of spinal stenosis. Also the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc). The surgically treated group improved more than the medically/interventionally treated group, although of the group with medical/interventional treatment, a large number of patients did quite well. This study provides Level II therapeutic evidence that patients with moderate to severe

		(8 of 17) at four years. Of these patients 56 % (10 of 18) reported being worse at six months. Of the patients randomly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (nine of 13) at one year, and 92% (11 of 12) at four years. At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.	symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result only about 40% of the time. This study also provides Level IV evidence that a cohort of patients with severe symptoms at presentation will have a good outcome with decompression 80-90% of the time and a cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.
Herno A, Airaksinen O, Saari T, Luukkonen M. Lumbar spinal stenosis: a matched-pair study of operated and non-operated patients. *Br J Neurosurg.* Oct 1996;10(5):461-465.	IV	This study is a retrospective cohort study using a matched pair design of operated and nonoperated patients with spinal stenosis. Operative indications included disabling leg pain, progressively limited walking distance and presence of major or progressive neural deficits. Fifty-four of the 57 medically/interventionally treated patients were matched with 54 of the 496 treated surgically. Twenty-five percent of the patients had previous back surgery and were excluded. ODI and functional status were evaluated only at follow-up. The average follow-up was 4.3 years. Men fared slightly better with operative intervention than without it ($p<0.05$). There was no difference in outcome between the matched pair groups. They concluded that medical/interventional treatment is a reasonable option in patients with moderate spinal stenosis.	In critique, the study suffered from diagnostic variability in the patient population and a wide variation of surgical techniques. Only 10 of the 54 medically/interventionally treated patients were offered and refused surgical treatment. The medical/interventional group had less severe symptoms than the operative group (37/57). Of the 54 surgically treated patients, 10 had unclear reasons for surgery. The initial clinical status of these patients at the time of the index myelogram was unknown. Because of these deficiencies, this potentially Level III retrospective cohort study was downgraded to a Level IV therapeutic study. This study provided Level IV therapeutic evidence that patients with mild or moderate stenosis and severe comorbidities may be managed medically/interventionally. For stenosis with a complete block on imaging and severe symptoms, surgical decompression is

			the method of choice. No definitive conclusions regarding surgical management versus natural history of lumbar stenosis can be drawn from this study.
Hurri H, Slatis P, Soini J, et al. Lumbar spinal stenosis: assessment of long-term outcome 12 years after operative and conservative treatment. *J Spinal Disord.* 1998;11(2):110-115.	IV	This study is a retrospective case series of 75 patients with lumbar stenosis diagnosed with myelography and CT. The patients were treated and followed for 12 years. Baseline symptoms include: 98% LBP, 80% leg pain, 21% leg fatigue and 41% leg numbness. 57 patients were treated operatively by various techniques and 18 patients were treated medically/interventionally. The authors did not detail the medical/interventional treatment. The authors reported at least slight improvement in 63% of surgically treated and in 44% (eight of 18) of medically/interventionally treated patients. They reported worsening in 18% of operatively treated and 11% (two of 18) of medically/interventionally treated patients over time. Using the Oswestry Disability Index (ODI) they showed no differences between these groups at final follow-up.	In critique, this case series is limited by the nonstandardized medical/interventional treatment and failure to stratify outcomes such as claudication, neurologic function and pain. The only reported outcome that allowed subgroup analysis of the medical/interventional group was ODI. The strengths of this study include its long follow-up and use of the ODI as an outcome measure. This study provides Level IV therapeutic evidence that a poorly defined surgical treatment group can expect the same functional outcomes, as measured by the ODI, as a group of medically/interventionally treated patients.
Johnsson KE, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis. A comparison of surgically treated and untreated patients. *Spine.* 1991;16(6):615-619.	IV	This study is a comparative study of 63 patients with moderate or severe lumbar stenosis as diagnosed by myelography (partial block was diagnostic of moderate stenosis, a total block of severe stenosis) and symptoms of neurogenic claudication, radiculopathy or mixed symptoms. All patients were offered surgery. Patients who were too ill to have surgery as determined by anesthesia or declined surgery were placed in the no-care group (19 patients); the remaining 44 patients had decompressive surgery without fusion. Outcomes included a four-level pain scale, a 100 mm visual analog scale for degree of improvement or deterioration, a measure of walking capacity and electrodiagnostic studies. The duration of follow-up is not clearly stated in the study. However, at follow-up , 42% (8 of 19) of the patients not operated upon, 33% (10 of 30) of the surgical patients with moderate stenosis, and 57%	In critique, the authors used nonvalidated outcome measures since their VAS for pain was divided into only 4 strata. Length of follow-up is not clearly listed and some data are ambiguous. In this study, no-surgery apparently is the same as no treatment other than pain medication, although treatment for this group is not clearly defined. This study demonstrates Level IV therapeutic evidence that decompression provides improvement in pain 50-60% of the time, however 20-36% of patients are likely to worsen. Nonsurgical management will provide pain relief about 33%

		(8 of 14) of the surgical patients with severe stenosis were symptom free. With regard to patient pain rating at follow-up, in the nontreatment group, 32% (six of 19) noted improvement in pain, compared with 57% (17 of 30) in the surgical group with moderate stenosis and 64% (9 of 14) in the surgical group with severe stenosis. Patients who felt their pain was worse at follow-up included 10% (2 of 19) in the nontreated group compared with 20% (six of 30) in the surgical group with moderate stenosis and 36% (5 of 14) in the surgical group with severe stenosis. *Severe deterioration was not found in untreated patients*. Electrophysiological parameters seemed to worsen equally in both groups.	of the time, while about 10% of the time pain is likely to worsen in medically/interventionally treated patients.
Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine.* 2005;30(12):1351-1358.	I	This study is a prospective, randomized, controlled trial of 191 patients with mild to moderate symptoms of lumbar stenosis. Diagnostic criteria were an age of at least 50 years, the presence of leg, buttock or groin pain with or without back pain that was relieved during flexion, the ability to sit for 50 minutes without pain, the ability to walk at least 50 feet, and stenosis at one or two levels as seen on CT or MRI. The surgery group included 100 patients, who had placement of the X-Stop. The control group had 91 patients who were medically/interventionally managed. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years. The primary outcome measure was the Zurich Claudication Questionnaire, a validated and disease specific questionnaire. Secondary outcomes included the SF-36 and range of motion. At two years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X STOP group and by 7.4% in the control group. At the same point, the mean Physical Function scores improved by 44.3% in the X STOP group and by -0.4% in the control group.	In critique, medical/interventional treatment was not controlled and secondary outcome measures were not available. Data on two-year outcomes of the medical/interventional group showed poorer results than other medical/interventional studies reviewed. This study provided Level I therapeutic evidence that placement of the X-Stop in patients with mild to moderate symptoms of stenosis was more effective in this patient population than a medical/interventional treatment regimen.

		At the two-year evaluation, 60% (56 of 93) of surgical patients reported a clinically significant improvement in the Symptom Severity domain compared with 19% (15 of 81) patients in the control group, 57% (53 of 93) of patients reported clinically significant improvement in the Physical Function compared with 15% (12 of 81) of patients in the control group, and 73% (68 of 93) of patients were at least somewhat satisfied compared with 36% (28 of 78) of patients in the control group.	

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
SURGICAL MGT VS. NATURAL HISTORY

- Secondary Evidentiary Table -

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III. 1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis. *Spine.* 1996;21(15):1787-1794; discussion 1794-1785.	III	This study is a prospective cohort study of 148 patients with lumbar stenosis including patients with herniated discs. Eighty-one of the patients were treated surgically and 67 were treated medically/interventionally. On average, patients in the surgical group had more severe imaging findings and symptoms, and worse functional status than patients in the medical/interventional group at entry. Patients with moderate symptoms were divided between the two groups. Outcomes included patient-reported symptoms of leg and back pain, functional status (Medical Outcomes Study SF-36), disability (modified Roland Morris Disability Questionnaire score) and satisfaction with care. One year after study entry, 28% of medically/interventionally and 55% of surgically treated patients reported definite improvement in their predominant symptoms. Information describing either surgical or medical/interventional treatments was not evident in the study.	In critique, the authors included a mixed diagnostic group of patients with degenerative stenosis and disc herniations. This limited the ability of the work group to analyze the data available as it pertained to lumbar stenosis as a single diagnostic entity. The data available indicated that for moderate symptoms, surgical treatment was more effective than medical/interventional treatment.
Chang Y, Singer DE, Wu YA, Keller RB, Atlas SJ. The effect of surgical and nonsurgical treatment on longitudinal outcomes of lumbar spinal stenosis over 10 years. *J Am Geriatr*	II	This study is a prospective comparative study of 144 patients; 77 surgical, 67 medical/interventional patients. The 10-year rate for additional surgery after the initial period of treatment was 23% for the surgical group (18 of 77) and 38% (25 of 67) for the medical/interventional group. The 10-year survival rate was 69%. The surgery	Surgery had better outcomes controlling for covariants. Subsequent surgery had worse outcomes independent of whether the initial treatment was surgical or medical/interventional treated.

Soc. 2005;53(5):785-792.		group suffered worse baseline symptoms and functional status but reported greater improvements in symptoms and function at final follow-up. Benefits of surgery, however, did diminish over time.	
Gibson JN, Waddell G. Surgery for degenerative lumbar spondylosis. *Cochrane Database Syst Rev.* 2005(4):CD001352.	III	This is a lengthy systematic review from the Cochrane database on surgery for lumbar *spondylosis*.	In critique, the review discussed the broader topic of lumbar spondylosis, which includes a wider variety of diagnoses than this work group is addressing. When discussing surgical management for lumbar stenosis, it indicates that results are typically favorable. However, this article does not compare surgical to medical/interventional management or medical/interventional care.
Turner JA, Ersek M, Herron L, Deyo R. Surgery for lumbar spinal stenosis. Attempted meta-analysis of the literature. *Spine.* 1992;17(1):1-8.	III	This study is a meta-analysis of articles for surgery for lumbar spinal stenosis, including Level IV data. There is no discussion of medical/interventional management. Of surgical patients, good outcomes are reported 64% of the time using the authors more stringent criteria and 72% using the author's divergent criteria. Of studies looking at degenerative spondylolisthesis, 83%-85% of the time patients experienced good outcomes.	In critique, this analysis included low quality studies published before 1992. The outcome data is problematic due to retrospective mixes of back and leg pain, functional disability and vocational functioning not clearly defined.

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
DECOMPRESSION/LAMINECTOMY

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Airaksinen O, Herno A, Turunen V, Saari T, Suomlainen O. Surgical outcome of 438 patients treated surgically for lumbar spinal stenosis. *Spine.* 1997;22(19):2278-2282.	IV	This study is a retrospective case series of 438 patients with a 4.3 year average follow-up who underwent lumbar decompression for spinal stenosis. The study attempted to determine the preoperative variables associated with outcome. The investigators found that good to excellent outcome was seen in 62% of patients, and was found to be correlated with ability to work before surgery and no prior back surgery. Poor outcome was associated with diabetes, co-existing hip pathology and preoperative fracture of the spine. Men had a higher incidence of good to excellent outcome compared with women (65% compared with 57% respectively). The Oswestry Disability Index (ODI) was used at the postoperative visit only. The results suggest that clear myelographic stenosis and no prior surgical intervention, no comorbidities of diabetes, no hip joint arthrosis and no preoperative fracture of the lumbar spine are factors associated with a good outcome in surgical management of lumbar spinal stenosis.	In critique of this study, it was a heterogeneous patient population, with stenosis ranging from a complete myelographic block to minimal or no stenosis. There were no data to support their conclusions that myelographic stenosis correlated with outcome. Although ODI was used as an outcome measure, the investigators grouped numerical results into broad categories of good to excellent (ODI < 40) versus poor to very poor (ODI > 40). There was an 11% complication rate . This paper offers Level IV therapeutic evidence that good to excellent outcomes are seen in 62% of patients with surgical intervention in a patient population with lumbar spinal stenosis of widely varying degrees of severity.
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleas F. Lumbar spinal stenosis: conservative or surgical management?: a prospective 10-year	II and IV	This study is a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. Patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management, and 31 with moderate to severe symptoms were ran-	In critique, no standardized outcome measures were utilized, and a substantial number of patient died or crossed over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no di-

study. *Spine.* 2000;25(11):1424-1435; discussion 1435-1426.		domly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis, and response to treatment (worse, unchanged, fair, excellent). With medical/interventional treatment, a good result was reported by 70% (35 of 50) patients at six months, 64% (32 of 50) at one year, and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year, and 84% (16 of 19) at four years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (seven of 18) at six months, 33% (six of 18) at one year, and 47% (eight of 17) at four years. Of these patients 56 % (10 of 18) reported being worse at six months. Of the patients randomly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (nine of 13) at one year, and 92% (11 of 12) at four years. At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.	rect statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment rendered differed from the natural history of spinal stenosis. Also the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc). The surgically treated group improved more than the medically/interventionally treated group, although of the group with medical/interventional treatment, a large number of patients did quite well. This study provides Level II therapeutic evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result only about 40% of the time. This study also provides Level IV evidence that a cohort of patients with severe symptoms at presentation will have a good outcome with decompression 80-90% of the time and a cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.
Arinzon Z, Adunsky A, Fidelman Z,	III	This study is a prognostic case control study investigating the effect of decompression surgery for lumbar spinal stenosis in	In critique of this study, it highlights the clinical results of lumbar decompression in diabetic patients. Conclu-

Gepstein R. Outcomes of decompression surgery for lumbar spinal stenosis in elderly diabetic patients. *Eur Spine J.* 2004;13(1):32-37.		elderly diabetic patients. The study included 62 diabetic patients and 62 sex and age matched nondiabetic controls. The mean follow-up was 40.3 months. Comorbidities were assessed and outcomes were measured using the Visual Analog Scale (VAS), basic activities of daily living (BADL) and walking distance. The authors concluded that decompression surgery for symptomatic spinal stenosis is beneficial in elderly diabetic patients. However, the results are related to successful pain reduction, physical and mental health status, severity of clinical presentation, insulin treatment and duration of diabetes. The benefits in diabetic patients are low as compared with nondiabetic patients with regard to symptom relief, satisfaction, BADL function and rate of complications.	sions regarding mental health status were not supported with appropriate outcome tools to assess mental health. They failed to address the degree of stenosis in both the diabetic group and control group. This study provides Level III prognostic evidence to support decompressive surgery for lumbar spinal stenosis in elderly diabetic patients. It also highlights the higher complication rate ($p<0.0001$) and less successful pain relief compared with nondiabetic patients ($p=0.0067$).
Arinzon ZH, Fredman B, Zohar E, et al. Surgical management of spinal stenosis: a comparison of immediate and long term outcome in two geriatric patient populations. *Arch Gerontol Geriatr.* 2003;36(3):273-279.	III	This study is a retrospective, prognostic study of the effects of age on decompressive surgery for lumbar spinal stenosis. A total of 283 patients were grouped according to age. One group was aged 65-74 years old and the second group was > 75 years old. Follow-up was up to 42 months with a minimum of nine-month follow-up. Within both treatment groups, there was a significant ($p<0.0001$) subjective improvement in low back and radicular pain as well as the ability to perform daily activities. When compared to preoperative levels, the oral scores for pain while performing daily activities were significantly improved ($p<0.001$) in both treatment groups. The authors concluded that the overall postoperative complication rate was similar between the groups and that age is not a contraindication for decompressive lumbar spinal stenosis. Both groups are equally likely to suffer minor perioperative complications.	In critique of this study, it lacked validated outcome tools and standardized surgical procedures. This paper provides Level III prognostic evidence that age > 75 is not a contraindication for lumbar decompression compared with patients 65-74 years old.
Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III. 1-year outcomes of surgical and	II	This study is a prospective cohort study involving 148 patients, of which 81 underwent surgery and 67 had medical/interventional management. Outcomes were assessed using the modified Roland Morris Disability Questionnaire and the SF-36. On average, patients in the surgical	In critique, the study was nonrandomized. On average, patients in the surgical group had more severe imaging findings and symptoms and worse functional status than patients in the medical/interventional group at entry. Few patients with mild symptoms were

nonsurgical management of lumbar spinal stenosis. *Spine.* 1996;21(15):1787-1794; discussion 1794-1785.		group had more severe imaging findings and symptoms and worse functional status than patients in the medical/interventional group at entry. Few patients with mild symptoms were treated surgically, and few patients with severe symptoms were treated medically/interventionally. However, of the patients with moderate symptoms, a similar percentage was treated surgically or medically/interventionally. One year after study entry, 28% of medically/interventionally and 55% of surgically treated patients reported definite improvement in their predominant symptoms ($P = 0.003$). For patients with moderate symptoms, outcomes for surgically treated patients were also improved compared with those of medically/interventionally treated patients. Surgical treatment remained a significant determinant of one-year outcome, even after adjustment for differences between treatment groups at entry ($P = 0.05$). The maximal benefit of surgery was observed by the time of the first follow-up evaluation, which was at three months. Although few medically/interventionally treated patients experienced a worsening of their condition, there was little improvement in symptoms and functional status compared with study entry. The authors concluded that when evaluating one-year patient-reported outcomes, patients with severe lumbar spinal stenosis who were treated surgically had greater improvement than patients treated medically/interventionally.	treated surgically, and few patients with severe symptoms were treated medically/interventionally. There was short follow-up of only one year. Two groups of patients were included in this study. One group presented with neurogenic claudication and radiographic findings of lumbar spinal stenosis. The second group presented with radiculopathy (sciatica) and radiographic findings of lumbar spinal stenosis and concomitant HNP. No attempt was made to separate these two groups for data analysis. This paper provides Level II therapeutic evidence that surgical treatment provides greater improvement in patients with spinal stenosis compared with medical/interventional treatment at one-year follow-up. Of the surgical group, 80% reported improvement at one year.
Atlas SJ, Keller RB, Robson D, Deyo RA, Singer DE. Surgical and nonsurgical management of lumbar spinal stenosis: four-year outcomes from the Maine lumbar spine study. *Spine.*	II	This study is a prospective comparative study involving 148 patients: 81 underwent surgery and 67 had medical/interventional management. Eighty-three percent of patients treated surgically and 78% of patients in the medical/interventional group were available for four-year follow-up, respectively. Outcome was assessed using the modified Roland Morris Disability Questionnaire and the SF-36. After 4 years, 70% of the surgically treated and 52% of the medically/interventionally	In critique, the study was nonrandomized. On average, patients in the surgical group had more severe imaging findings and symptoms and worse functional status than patients in the medical/interventional group at entry. Few patients with mild symptoms were treated surgically, and few patients with severe symptoms were treated medically/interventionally. Follow-up was moderate at four years and longer follow-up may show further deterioration of results. There was a 22.1%

2000;25(5):556-562.		treated patients reported that their predominant symptom, either leg or back pain, was better ($P < 0.05$). Satisfaction of patients with their current state at four years was reported by 63% of the surgically treated and 42% of the medically/interventionally treated patients ($P < 0.04$). Surgical treatment remained a significant determinant of four-year satisfaction, even after adjustment for other independent predictors ($P < 0.001$). The medically/interventionally treated patients had no significant change in outcomes over four years, whereas the initial improvement seen in the surgically treated patients modestly decreased over the subsequent four years. The relative benefit of surgery declined with time whereas the medical/interventional group remained stable with time.	crossover to surgery group. There were two groups of patients included in this study. One group presented with neurogenic claudication and radiographic findings of lumbar spinal stenosis. The second group presented with radiculopathy (sciatica) and radiographic findings of lumbar spinal stenosis and concomitant HNP. No attempt was made to separate these two groups for data analysis. This paper provides Level II therapeutic evidence that surgical treatment provides greater improvement in patients with spinal stenosis compared with medical/interventional treatment at four-year follow-up. Of the surgical group, 70% reported improvement of their predominant complaint at four years. This study showed deterioration from one-year results presented in the author's previous study.[17]
Atlas SJ, Keller RB, Wu YA, Deyo RA, Singer DE. Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the Maine lumbar spine study. *Spine.* 2005;30(8):936-943.	II	This study is a prospective comparative study of 148 patients treated surgically or medically/interventionally for lumbar spinal stenosis. They had long-term follow-up between eight and 10 years for 97 of 123 (79%) patients (including 11 patients who died before the 10-year follow-up but completed a eight- or nine-year survey); 56 of 63 (89%) initially treated surgically and 41 of 60 (68%) initially treated medically/interventionally. Patients undergoing surgery had worse baseline symptoms and functional status than those initially treated medically/interventionally. Outcomes using the modified Roland Morris Disability Questionnaire and the SF-36 at one and four years favored initial surgical treatment. After eight to 10 years, a similar percentage of surgical and medical/interventional patients reported that their low back pain was improved (53% vs. 50%, $P < 0.8$), their predominant symptom (either back or leg pain) was improved (54% *vs.* 42%, $P <$	In critique of this study, it was nonrandomized. There was a high reoperation rate in the surgical group at 10 years, with 23% of the surgical patients undergoing at least one additional spine operation. There was also a high crossover rate in the medical/interventional group with 39% of medical/interventional patients having at least one lumbar spine operation. Two groups of patients were included in this study: one group presented with neurogenic claudication and radiographic findings of lumbar spinal stenosis; the second group presented with radiculopathy (sciatica) and radiographic findings of lumbar spinal stenosis and concomitant HNP. No attempt was made to separate these two groups for data analysis. This study provides Level II therapeutic evidence that at eight- to 10-year follow-up, surgical treatment was similar to medical/interventional treatment with regard to low back pain relief,

		0.3), and they were satisfied with their current status (55% *vs.* 49%, $P < 0.5$). These treatment group findings persisted after adjustment for other determinants of outcome in multivariate models. However, patients initially treated surgically reported less severe leg pain symptoms and greater improvement in back-specific functional status after 8 to 10 years than medically/interventionally treated patients. By 10 years, 23% of surgical patients had undergone at least one additional lumbar spine operation, and 39% of medical/interventional patients had at least one lumbar spine operation. Patients undergoing subsequent surgical procedures had worse outcomes than those continuing with their initial treatment. Outcomes according to actual treatment received at 10 years did not differ because individuals undergoing additional surgical procedures had worse outcomes than those continuing with their initial treatment. They concluded that among patients with lumbar spinal stenosis completing eight- to 10-year follow-up, low back pain relief, predominant symptom improvement and satisfaction with the current state were similar in patients initially treated surgically or medically/interventionally. However, leg pain relief and greater back-related functional status continued to favor those initially receiving surgical treatment.	predominant symptom improvement and satisfaction with the current state. The surgically treated patients reported greater improvement in leg pain symptoms and greater improvement in back-specific functional status.
Fox MW, Onofrio BM, Hanssen AD. Clinical outcomes and radiological instability following decompressive lumbar laminectomy for degenerative spinal stenosis: a comparison of patients undergo-	IV	This study is a retrospective cohort study comparing 124 patients undergoing decompression with arthrodesis (32) versus decompression alone (92). The mean follow-up was 5.8 years (4.6-6.8). Outcomes were patient-reported outcomes in back and leg pain, numbness, weakness, ability to perform activities of daily living and walking abilities. Radiographic analysis was performed and showed progressive postoperative slip occurred in 31% of patients without preoperative slip and in 73% with preoperative subluxation in whom fusion was not attained. Slip progression correlated	In critique of this study, there were no validated outcome tools and surgical techniques were variable including occasional discectomies and different fusion techniques. Although this was a cohort study, the statistical analysis of arthrodesis versus nonarthrodesis groups was not performed. Data were not included to support their conclusions regarding the decompression across a minimally degenerated L4 or markedly degenerated L3 disc. There was a 22% complication rate, late deterioration of 10%, a weak follow-up of

ing concomitant arthrodesis versus decompression alone. *J Neurosurg.* 1996;85(5):793-802.		poorly with clinical outcome. Overall, 48% experienced good results, 31% fair results and 21% poor results. The complication rate was 22% complication and 10% had late deterioration. In conclusion, the majority of patients responded well to surgery. Radiographic instability was common after decompression for degenerative lumbar spinal stenosis, but did not predict clinical outcome. There are no definitive clinical or radiographic factors that predict patients at risk for a poor outcome. Postoperative radiographic instability is more likely to occur when preoperative spondylolisthesis, abnormal motion on dynamic imaging, decompression across a minimally degenerated L4 or markedly degenerated L3 disc and when a radical and extensive decompression at more than one level is planned. The group at greatest risk for poor outcome consists of those patients with normal preoperative alignment who do not have slip progression following surgery.	only 70%, and no radiographic assessment of fusion. In conclusion, this paper provides Level IV therapeutic evidence that 79% of patients experienced good to fair results following surgery with or without arthrodesis for lumbar spinal stenosis.
Mariconda M, Fava R, Gatto A, Longo C, Milano C. Unilateral laminectomy for bilateral decompression of lumbar spinal stenosis: a prospective comparative study with conservatively treated patients. *J Spinal Disord Tech.* 2002;15(1):39-46.	III	This study described an incompletely randomized, prospective study of 44 patients comparing single or multilevel laminectomy in patients with mild to moderate leg pain to patients treated with medical/interventional therapy. Outcomes were assessed using the Beaujon Scoring System. Twenty-two patients were assigned into each group. Only 32 of 44 patients were randomly assigned into each group. The mean functional status at one year was improved in both groups. Conservative treatment consisted of bed rest, use of a semirigid orthosis, physical therapy and appropriate exercise program. At four years, the good results were 68% in the surgical group and 33% in the medical/interventional group. Only 2.6% of patients had an increase in their spondylolisthesis. Reoperation rate was 9% crossover rate was 9%.	In critique of this study patients were relatively young with a mean age of 61 years and an inclusion criterion of only 40 years of age. Validated outcome measures were not used. The patient sample size was small. There was a mixed surgical technique with occasional undercutting of the contralateral lamina. There was partial randomization in the study with only 73% of the patients randomized. It is not known how long medical/interventional management was continued. Because of all of these deficiencies, the paper was classified as a Level III study. This study provides Level III therapeutic evidence to support good outcome in 68% of patients undergoing decompression for lumbar spinal stenosis compared with medical/interventional management.
Niggemeyer O, Strauss JM,	IV	This study is a meta-analysis of spinal stenosis analyzing 30 articles from 1975 to	In critique of this study, it was a meta-analysis of dated articles and most of

Schulitz KP. Comparison of surgical procedures for degenerative lumbar spinal stenosis: a meta-analysis of the literature from 1975 to 1995. *Eur Spine J.* 1997;6(6):423-429.		1995 with a total of 1668 cases. They compared three groups: decompression, decompression and fusion, and decompression and fusion with instrumentation. They concluded that in the first eight years, decompression is the best procedure. If symptoms had been present for 15 years or more, decompression and fusion was better. However, fusion is plagued with more complications.	the articles were Level IV studies. The investigator's decision to draw lines at seven years of symptoms and 15 years of symptoms seems arbitrary and there are small numbers of patients to support their conclusions that decompression and fusion is better than decompression alone. Good results ranged from 57- 72% with regard to leg and back pain and 62-78% with regard to neurologic symptoms. Because of these flaws in the design of the study, it was downgraded from a potential Level III study to a Level IV study. This study provides Level IV therapeutic evidence that surgical results from decompression with fusion in spinal stenosis patients are better than the results from decompression alone if symptoms have been present for 15 or more years whereas if symptoms have been present for less than eight years, decompression alone is superior.
Postacchini F, Cinotti G, Perugia D, Gumina S. The surgical treatment of central lumbar stenosis. Multiple laminotomy compared with total laminectomy. *J Bone Joint Surg Br.* 1993;75(3):386-392.	IV	This study compared the outcomes of multiple laminotomies with laminectomies in 67 patients with central spinal stenosis. The study separated the patients into three groups: Group I (26) had multiple laminotomies, Group II (9) had attempted laminotomies but had to be converted to laminectomies because of intraoperative decision and Group III (32) had total laminectomies. The average follow-up was 3.7 years. Outcome was assessed independently and clinically objective results were masked and graded as excellent, good fair and poor. Clinical outcome was excellent or good in 81% of Group I patients and 78% in groups II and III patients. There were three neurologic complications in Group I and one in Group III. With regards to degenerative instability, there was higher postoperative instability in Groups II and III (8/13) compared with Group I (4/8). Mean blood loss and clinical results did not differ between the three groups. The au-	In critique of this study, there are small numbers and there was a high intraoperative crossover if laminotomy was deemed inappropriate at time of surgery. There was an 11.5% neurologic complication rate with laminotomy. There was no conformity in surgical technique including occasional discectomies and fusions. This article provides Level IV therapeutic evidence for excellent or good outcomes in 78-81% of patients treated by laminectomy for central lumbar stenosis.

		thors concluded that multiple laminotomy is recommended for all patients with developmental stenosis and for those with mild to moderate degenerative spondylolisthesis. Total laminectomy is preferred for patients with severe degeneration.	
Thome C, Zevgaridis D, Leheta O, et al. Outcome after less-invasive decompression of lumbar spinal stenosis: a randomized comparison of unilateral laminotomy, bilateral laminotomy, and laminectomy. *J Neurosurg Spine.* 2005;3(2):129-141.	II and IV	This is a randomized control trial comparing surgical techniques for lumbar spinal stenosis. There were three separate groups. Group 1 had bilateral laminotomies, Group 2 had unilateral laminotomy and Group 3 had laminectomies performed. At one-year follow-up, 94% of patients were assessed with VAS, RMDQ and SF-36. Residual pain was lower in patients undergoing bilateral laminotomies or unilateral laminotomy compared to laminectomy ($p < 0.05$). The Roland Morris Disability Questionnaire scores significantly improved in all groups ($p<0.001$) corresponding to a dramatic increase in walking distance. SF-36 scores demonstrated marked improvement most pronounced in bilateral laminotomies. The number of repeated operations did not differ among groups. Patient satisfaction was significantly superior in patients treated with bilateral laminotomy, with 3%, 27% and 26% of patients unsatisfied in groups 1, 2 and 3 respectively ($p < 0.01$). In conclusion, bilateral laminotomy had the best outcomes. Overall complication rate was lowest with bilateral laminotomy and highest with laminectomies.	In critique, this study had very good follow-up of 94%. Bilateral and unilateral laminotomies allowed adequate and safe decompression of lumbar stenosis and resulted in a highly significant reduction of symptoms and disability, and improved health related quality of life. There was an improvement in the SF-36, VAS score and RDI but the standard deviations were high for the VAS and RDI. The study thus appears underpowered and was therefore downgraded from a potential Level I study to a Level II. By comparing three different groups, this study provides Level II therapeutic evidence that bilateral laminotomies or unilateral laminotomies provide better outcomes than laminectomies. However, when evaluating the evidence that decompression provides relief in patients with spinal stenosis, the evidence is only Level IV.
Trouillier H, Birkenmaier C, Kluzik J, Kauschke T, Refior HJ. Operative treatment for degenerative lumbar spinal canal stenosis. *Acta Orthop Belg.* 2004;70(4):337-343.	IV	This study is a retrospective observational cohort study of 85 patients with an average follow-up of 79 months. Of the 85 patients, 20 underwent fenestration and undercutting, 16 had hemilaminectomy or laminectomy and 43 underwent decompression and instrumented fusion. Patients were grouped preoperatively according to the degree of stenosis and segmental instability. Clinical evaluation included subjective self assessment, VAS, ODI and SF-36. Overall subjective improvement (VAS) of patients in groups 1 and 2 did not differ greatly and was more than 35% on average. The average improvement in ODI was 29% with limited decompression, 22% with extensive	In critique, this small study has heterogeneous patient groups and heterogeneous surgical techniques. Seventy-five percent of the laminectomy group had postoperative instability. Conclusions in this paper are difficult to evaluate because of the differing patient populations and differing surgical techniques. Across all groups, the Back VAS improved by 28-45%, leg VAS improved by 15-50%, SF36 improved by 2-18 points and the ODI improved by 10-28%. This study provides Level IV therapeutic data to support decompression in

		decompression and 15% with instrumented fusion. Results in group 3 were generally worse with an average improvement of 10%. The authors concluded that limited decompression is the ideal operative method, provided the indication is correct. Fusion cannot be avoided if segmental instability is present. Satisfactory long-term results can be achieved in lumbar stenosis with surgery adapted to the degree of instability and the degree of stenosis.	the treatment of lumbar spinal stenosis.
Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine.* 2005;30(12):1351-1358.	I	This study is a prospective, randomized, controlled trial of 191 patients with mild to moderate symptoms of lumbar stenosis. Diagnostic criteria were an age of at least 50 years, the presence of leg, buttock or groin pain with or without back pain that was relieved during flexion, the ability to sit for 50 minutes without pain, the ability to walk at least 50 feet, and stenosis at one or two levels as seen on CT or MRI. The surgery group included 100 patients which had placement of the X-Stop. The control group had 91 patients who were medically/interventionally managed. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years. The primary outcome measure was the Zurich Claudication Questionnaire. Secondary outcomes included the SF-36 and range of motion. At two years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X-Stop group and by 7.4% in the control group. At the same point, the mean Physical Function scores improved by 44.3% in the X-Stop group and by -0.4% in the control group. At the two-year evaluation, 60% (56 of 93) of surgical patients reported a clinically significant improvement in the Symptom Severity domain compared with 19% (15 of	In critique, medical/interventional treatment was not controlled and secondary outcome measures were not available. Data on two-year outcomes of the medical/interventional group showed poorer results than other medical/interventional studies. This study provided Level I therapeutic evidence that placement of the X-Stop in patients with mild to moderate symptoms of stenosis was more effective in this patient population than a medical/interventional treatment regimen.

		81) patients in the control group, 57% (53 of 93) of patients reported clinically significant improvement in the Physical Function compared with 15% (12 of 81) of patients in the control group, and 73% (68 of 93) of patients were at least somewhat satisfied compared with 36% (28 of 78) of patients in the control group.	

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
DECOMPRESSION v NATURAL HX or MED MGMT

-Primary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleas F. Lumbar spinal stenosis: conservative or surgical management?: a prospective 10-year study. *Spine.* 2000;25(11):1424-1435; discussion 1435-1426.	II and IV	This is a case control, comparative study of 100 patients with symptomatic spinal stenosis. Inclusion criteria were sciatic pain in the leg(s) with or without back pain and radiographic evidence of stenosis. These patients were divided into three groups: 19 patients with severe symptoms received surgical treatment, 50 patients with moderate symptoms received medical/interventional management and 31 with moderate to severe symptoms were randomly assigned. The surgical group received decompression without fusion, inpatient rehabilitation with a brace, back school and physical therapy when out of the brace. The medical/interventional group was admitted to inpatient rehabilitation for one month, braced for up to three months, back school and physical therapy when out of brace. Patients were seen at regular intervals for 10 years. Authors assessed patients based on pain (no or light pain, moderate pain, severe pain), degree of stenosis, and response to treatment (worse, unchanged, fair, excellent). With medical/interventional treatment, a good result was reported by 70% (35 of 50) patients at six months, 64% (32 of 50) at one year, and 57% (28 of 49) at four years. With surgery, a good result was reported by 79% (15 of 19) at six months, 89% (17 of 19) at one year, and 84% (16 of 19) at four	In critique, standardized outcome measures were not used, was and a substantial number of patients died or crossed over from medical/interventional to surgical treatment. Further, medical/interventional treatment consisted initially of a one-month stay on an inpatient rehabilitation unit for "back school" which is unlikely to apply in today's medical cost environment. In the randomized group, there is no direct statistical analysis comparing the surgical to the medical/interventional group. It is unclear that the results of initial treatment rendered differed from the natural history of spinal stenosis. Also, the medical/interventional group received minimal care (no injections, no indication of continued exercise program, etc). The surgically treated group improved more than the medically/interventionally treated group, although of the group with medical/interventional treatment, a large number of patients did quite well.

		years. Of the patients randomly assigned to the medical/interventional group, good results were reported for 39% (7 of 18) at six months, 33% (6 of 18) at one year, and 47% (8 of 17) at four years. Of these patients 56 % (10 of 18) reported being worse at six months. Of the patients randomly assigned to the surgical group, good results were reported for 92% (12 of 13) at six months, 69% (9 of 13) at one year, and 92% (11 of 12) at four years. At the conclusion of 10 years, 10 patients in the medical/interventional group had died, 19 patients crossed over to surgery, and 39 patients remained in this group. Of the patients remaining in the medical/interventional group, 70% experienced good results based upon the assessment of pain.	This study provides Level II therapeutic evidence that patients with moderate to severe symptoms at presentation will receive a good result about 90% of the time compared with medical/interventional patients who will receive a good result only about 40% of the time. This study also provides Level IV evidence that a cohort of patients with severe symptoms at presentation will have a good outcome with decompression 80-90% of the time and a cohort of patients with moderate symptoms will have a good result with medical/interventional treatment about 70% of the time.
Johnsson KE, Uden A, Rosen I. The effect of decompression on the natural course of spinal stenosis. A comparison of surgically treated and untreated patients. *Spine.* 1991;16(6):615-619.	IV	This study is a comparative study of 63 patients with moderate or severe lumbar stenosis as diagnosed by myelography (partial block was diagnostic of moderate stenosis, a total block of severe stenosis) and symptoms of neurogenic claudication, radiculopathy or mixed symptoms. All patients were offered surgery. Patients who were too ill to have surgery as determined by anesthesia or who declined surgery were placed in the no-care group (19 patients). The remaining 44 patients had decompressive surgery without fusion. Outcomes included a 4-level pain scale, a 100 mm visual analog scale for degree of improvement or deterioration, another for walking capacity and electrodiagnostic studies. At follow-up, the duration of which is	In critique, the authors used nonvalidated outcome measures since their VAS for pain was divided into only four strata. Length of follow-up is not clearly listed and some data are ambiguous. In this study, no-surgery apparently is the same as no treatment other than pain medication, although treatment for this group is not clearly defined. This study provides Level IV therapeutic evidence that decompression provides improvement in pain 50-60% of the time, however, 20-36% of patients are likely to worsen. This study also demonstrates Level IV evidence that medical/interventional management will provide pain relief

		not clearly defined, 42% (8 of 19) of the patients not operated on, 33% (10 of 30) of the surgical patients with moderate stenosis, and 57% (8 of 14) of the surgical patients with severe stenosis were symptom free. With regard to patient pain rating at follow-up, in the medical/interventional group, 32% (6 of 19) noted improvement in pain, compared with 57% (17 of 30) in the surgical group with moderate stenosis and 64% (9 of 14) in the surgical group with severe stenosis. Patients who felt their pain was worse at follow-up included 10% (2 of 19) in the nontreated group compared with 20% (6 of 30) in the surgical group with moderate stenosis and 36% (5 of 14) in the surgical group with severe stenosis. Severe deterioration was not found in untreated patients. Electrophysiologic parameters seemed to worsen equally in both groups.	about 1/3rd of the time, while about 10% of the time pain is likely to worsen.
Zucherman JF, Hsu KY, Hartjen CA, et al. A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. *Spine.* 2005;30(12):1351-1358.	I	This study is a prospective, randomized, controlled trial of 191 patients with mild to moderate symptoms of lumbar stenosis. Diagnostic criteria were an age of at least 50 years, the presence of leg, buttock or groin pain with or without back pain that was relieved during flexion, the ability to sit for 50 minutes without pain, the ability to walk at least 50 feet, and stenosis at one or two levels as seen on CT or MRI. The surgery group included 100 patients which had placement of the X-Stop. The control group had 91 patients that were medically/interventionally managed. Medical/interventional treatment included at least one epidural steroid injection, NSAIDs, analgesics and physical therapy. Physical therapy included back school, modalities, massage, stabilization and exercises. Patients were followed for two years. The primary outcome measure was the Zurich Claudication Questionnaire.	This study presents a recently developed approach to decompression that is indirect when compared to more traditional surgical treatments of laminectomy and laminotomy. The device described distracts two spinous processes and keeps them distracted on extension of the lumbar spine effectively increasing the canal diameter and affecting an "indirect" decompression. The work group thus felt analysis of this paper was appropriate for this section of the guideline. In critique, medical/interventional treatment was not controlled and secondary outcome measures were not available. Data on two-year outcomes of the medical/interventional group showed poorer results than

		Secondary outcomes included the SF-36, and range of motion. At two years, the mean Symptom Severity scores improved by 45.4% from the baseline scores in the X STOP group and by 7.4% in the control group. At the same point, the mean Physical Function scores improved by 44.3% in the X STOP group and by -0.4% in the control group. At the two-year evaluation, 60% (56 of 93) of surgical patients reported a clinically significant improvement in the Symptom Severity domain compared with 19% (15 of 81) patients in the control group, 57% (53 of 93) of patients reported clinically significant improvement in the physical function compared with 15% (12 of 81) of patients in the control group, and 73% (68 of 93) of patients were at least somewhat satisfied compared with 36% (28 of 78) of patients in the control group.	other medical/interventional studies. However, the ZCQ is a validated and disease-specific outcome measure and may represent a more sensitive instrument than those used in most comparable studies of outcomes. This study provided Level I therapeutic evidence that placement of the X-Stop in patients with mild to moderate symptoms of stenosis was more effective than this medical/interventional treatment regimen.

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
DECOMPRESSION v NATURAL HX or MED MGMT

-Secondary Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Atlas SJ, Deyo RA, Keller RB, et al. The Maine Lumbar Spine Study, Part III. 1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis. *Spine.* 1996;21(15):1787-1794; discussion 1794-1785.	III	This study is a prospective cohort study of 148 patients with lumbar stenosis including patients with herniated discs. Eighty-one of the patients were treated surgically and 67 were treated medically/interventionally. On average, patients in the surgical group had more severe imaging findings and symptoms and worse functional status than patients in the medical/interventional group at entry. Patients with moderate symptoms were divided between the two groups. Outcomes included patient-reported symptoms of leg and back pain, functional status (Medical Outcomes Study SF-36), disability (modified Roland Morris Disability Questionnaire) and satisfaction with care. One year after study entry, 28% of medically/interventionally and 55% of surgically treated patients reported definite improvement in their predominant symptoms.	In critique, the authors included a mixed diagnostic group of patients with degenerative stenosis and herniated discs. This limited the ability of the work group to analyze the data available as it pertained to lumbar stenosis as a single diagnostic entity. The study indicates that, for moderate symptoms, surgical treatment is more effective than medical/interventional treatment.
Gibson JN, Waddell G. Surgery for degenerative lumbar spondylosis. *Cochrane Database Syst Rev.* 2005(4):CD001352.	III	This is a lengthy systematic review from the Cochrane database on surgery for lumbar spondylosis.	In critique, the review discussed the broader topic of lumbar spondylosis which includes a wider variety of diagnoses than this work group is addressing. When discussing surgical management for lumbar stenosis, it indicates that results are typically favorable. However, this article does not compare surgical to medical/interventional management or medical/interventional care.

Turner JA, Ersek M, Herron L, Deyo R. Surgery for lumbar spinal stenosis. Attempted meta-analysis of the literature. *Spine.* 1992;17(1):1-8.	III	This study is a meta analysis of articles for surgery for lumbar spinal stenosis, including Level IV data. There is no discussion of medical/interventional management. Of surgical patients, good outcomes are reported 64% of the time using the authors' more stringent criteria and 72% using the author's divergent criteria. Of studies included looking at degenerative spondylolisthesis 83%-85% of the time patients experienced good outcomes.	In critique, this analysis included low quality studies published before 1992. The outcome data is problematic, eg, retrospective mixes of back and leg pain, and functional disability and vocational functioning not clearly defined.

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
DECOMPRESSION AND FUSION

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Bednar DA. Surgical management of lumbar degenerative spinal stenosis with spondylolisthesis via posterior reduction with minimal laminectomy. *J Spinal Disord Tech.* 2002;15(2):105-109.	IV	This study is a nonmasked, retrospective case series of 56 patients with back pain, claudication or both, with stenosis and spondylolisthesis who underwent a reduction of spondylolisthesis and a fusion. Outcome measures were VAS for pain and ODI. There was a 7% (4 of 56) rate of major complications. Of 50 patients with leg pain, 41 (82%) had pain relief. Of 40 patients with back pain, 30 (75%) had relief. At an average of 33 months after surgery, 23% (9 of 42) of patients reported that they still had severe pain (pain decreased from 9 to 8; Oswestry averaged decreased from 56% to 52%), while the remaining patients had an average reduction in their pain of 75% and an ODI improvement from 56% to 18%.	In critique, this was a case series yielding Level IV evidence. This study provides Level IV therapeutic evidence that indirect decompression via reduction and fusion of degenerative spondylolisthesis is effective 75% of the time.
Bridwell KH, Sedgewick TA, O'Brien MF, Lenke LG, Baldus C. The role of fusion and instrumentation in the treatment of degenerative spondylolisthesis with spinal stenosis. *J Spinal Disord.* 1993;6(6):461-472.	III	This study is a nonmasked, incompletely-randomized trial of 44 patients with spinal stenosis and spondylolisthesis. Patients were randomized to three groups: (1) decompression alone (9 patients), (2) decompression with in situ fusion (11 patients), and (3) decompression with instrumented fusion groups (24 patients). Patients with >10° or 3 mm of motion on preoperative flexion/extension radiographs were assigned to Group 3, accounting for larger numbers in this group. Outcome measures were patient assessment of ability to walk, patient assessment of surgical benefit, and progression to further spondylolisthesis. Patients were followed for greater than two years. Fusion	In critique, the sample size was small, randomization was poor, and no validated outcome measures were used. Fusion was assessed by routine X-ray studies with flexion and extension films. For these reasons this study provides Level III therapeutic evidence that instrumented fusion in the treatment of degenerative spondylolisthesis with lumbar spinal stenosis decreases progression of spondylolisthesis and patient symptoms as compared with decompression alone or decompression with in situ

		was evaluated by plain radiographs. Progression of spondylolisthesis was seen in 44% (4 of 9) of the group with decompression alone, 70% (7 of 10) of the group with in situ fusion, and 4% (1 of 24) of the group with decompression with instrumented fusion. Patient symptoms were associated with progression of slip. Thus the group with instrumentation had significantly less slip progression and significantly better fusion rate and outcome.	fusion.
Fischgrund JS, Mackay M, Herkowitz HN, Brower R, Montgomery DM, Kurz LT. 1997 Volvo Award winner in clinical studies. Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective, randomized study comparing decompressive laminectomy and arthrodesis with and without spinal instrumentation. *Spine.* 1997;22(24):2807-2812.	II	This study is a nonmasked, prospective, randomized, controlled trial comparing instrumented to noninstrumented fusion in patients with symptomatic spinal stenosis and associated spondylolisthesis. Inclusion criteria were a clinical diagnosis of stenosis (leg pain, claudication), failure of at least three months of medical/interventional care, plain radiographs showing single-level spondylolisthesis, and MRI or CT confirmed spinal stenosis at the level of listhesis. Outcome measures were a five-point VAS for back and leg pain and an operative result rating (excellent, good, fair or poor) based on examiner assessment of pain and functional level. Seventy-six patients underwent posterior decompression with concomitant posterolateral intertransverse process arthrodesis. The patients were randomized to a segmental transpedicular instrumented or noninstrumented group. Sixty-seven (88%) patients were available for a two-year follow-up. Clinical outcome was excellent or good in 76% of the patients in whom instrumentation was placed and in 85% of those in whom no instrumentation was placed. Successful arthrodesis occurred in 82% of the instrumented cases *versus* 45% of the noninstrumented cases. Overall, successful fusion did not influence patient outcome.	In critique, there was no masking in the evaluations of the outcomes, standardized outcome measures were not used and follow-up may not be long enough to see the effects of pseudoarthrosis. This study provides Level II therapeutic evidence that instrumented fusion increases the likelihood of obtaining a solid arthrodesis; however, this did not correlate with improved outcomes at two years.
Fox MW, Onofrio	IV	This study is a retrospective case series	In critique, no validated out-

BM, Hanssen AD. Clinical outcomes and radiological instability following decompressive lumbar laminectomy for degenerative spinal stenosis: a comparison of patients undergoing concomitant arthrodesis versus decompression alone. *J Neurosurg.* 1996;85(5):793-802.		of 124 patients surgically treated for lumbar stenosis. Included patients had spinal stenosis on myelography and postmyelography CT scan, although exact criteria were not defined. Outcome measures were patient-reported improvements in pain, walking ability and activity level. All patients underwent a wide decompressive laminectomy with or without medial facetectomy or laminotomy (depending on the stenosis present on imaging). Fusion was added if patients had: (1) preoperative spondylolisthesis with motion on imaging, (2) preserved preoperative disc height and who underwent a wide laminectomy and bilateral facetectomy across that space or (3) instability determined intraoperatively following decompression. Patients were followed between 4.6 and 6.8 years. Patients were graded good, fair or poor based on responses to a questionnaire. Stability was evaluated based on flexion/extension radiographs looking for > 3 mm slip or >2 mm of progression of existing slip. Surgical decompression varied from one to five levels, and 32 of 124 (26%) had fusion. Of all patients, 48% (60 of 124) had a "good" result, 31% (38 of 124) had a "fair" result and 21% (26 of 124) had a poor result. Fusions had 9% "poor" results compared with 25% for the nonfusion group. There was no correlation between radiographic "instability" and outcome. The biggest risk factor for increased anterior translation was initial presence of spondylolisthesis; other factors included minimal degeneration of the L4-5 disc, extreme degeneration at L3-4, more sagittal facet orientation, and females.	come measures were used and 30% of patients were lost to follow-up. This study provides Level IV therapeutic evidence that in patients with lumbar spinal stenosis with or without spondylolisthesis, 75% will have a good or fair result with decompression alone and 94% will have a good or fair result with decompression and fusion with instrumentation.
Ghogawala Z, Benzel EC, Amin-Hanjani S, et al. Prospective outcomes evaluation after decompression with or without instrumented fusion for	III	This study is a prospective cohort study of 34 patients with stenosis and grade I spondylolisthesis without gross instability (<3 mm translation on flexion/extension radiographs). Patients were divided, based on surgeon discretion, into a group who received laminec-	In critique, the sample size of this study is small and group assignment was open to bias. Both groups showed improvement. In its favor, the study employed validated outcome measures. Because of the small

lumbar stenosis and degenerative Grade I spondylolisthesis. *J Neurosurg Spine.* 2004;1(3):267-272.		tomy (20 patients) versus laminectomy and fusion with pedicle screw fixation (14 patients). Outcome measures were the ODI and SF-36. At one year, ODI improved 13.6 points with the decompression group versus 27.5 points for the decompression and fusion group. SF-36 scores improved 6.5 in the decompression group versus 15.9 in the decompression and fusion group. While improvement in both groups was statistically significant, the decompression and fusion group improved significantly more than decompression alone (P<0.002 on PCS and P<0.003 on ODI).	sample size and technique of group allocation, this potentially Level II study is downgraded to a Level III study. This study provides Level III therapeutic evidence that decompression with fusion is more effective than decompression alone in patients with grade I spondylolisthesis without instability.
Grob D, Humke T, Dvorak J. Degenerative lumbar spinal stenosis. Decompression with and without arthrodesis. *J Bone Joint Surg Am.* 1995;77(7):1036-1041.	II	This study is a randomized, controlled trial of 45 patients with symptomatic lumbar stenosis with less than 5 mm of intervertebral translation who were randomly assigned to 3 groups: (1) decompression with laminotomy and medial facetectomy, (2) decompression with arthrodesis of the most stenotic segment, and (3) decompression with arthrodesis of all the affected segments. Inclusion criteria included a clinical diagnosis of stenosis and confirmation with CT, myelogram or MRI scan to have a midsagittal diameter of less than 11 mm. Outcome measure was a result classification (very good, good, fair or poor) based on percentage of subjective pain relief, use of analgesics and reported impairment of daily activities. Average follow-up duration was 28 months. At this point in follow-up all groups showed an increase in walking ability and a decrease in pain. There was no difference between the groups noted.	In critique, the sample size of patients is small and no validated outcome measures were used. Because of these design flaws, this potentially Level I study was downgraded to a Level II study. This study provides Level II therapeutic evidence that there is no difference in nonvalidated outcomes between decompression and decompression with fusion in patients with stenosis and less than 5 mm of intervertebral translation.
Herkowitz HN, Kurz LT. Degenerative lumbar spondylolisthesis with spinal stenosis. A prospective study comparing decompression with decompression and intertransverse process arthrodesis. *J Bone*	II	This study is a randomized, controlled trial of a homogenous group of 50 patients with symptoms of degenerative stenosis and spondylolisthesis. Patients were randomized by alternating selection into two groups, one group (25 patients) underwent decompression alone and a second group (25 patients) had decompression and intertransverse process arthrodesis. Patients were followed	In critique, this study utilized nonvalidated outcome measures and the sample size was small, However, the results were statistically significant. This study provides Level II therapeutic evidence that decompression and intertransverse process arthrodesis provides

Joint Surg Am. 1991;73(6):802-808.		between 2.4 and four years. Outcome measures were a five-point pain scale and assessment of operative result (excellent, good, fair, poor). The decompression and arthrodesis group had a significantly higher number of excellent and good results (96%, 24 of 25) compared with the group who had decompression alone (44%, 11 of 25) (P=0.001). Pseudo-arthrosis occurred in 36% (9 of 25) of patients who underwent arthrodesis, but this presence did not alter outcomes. Progression of slip was noted in 96% (24 of 25) of patients with decompression alone compared with 28% (7 of 25) in the decompression and arthrodesis group.	better outcomes than decompression alone in the treatment of symptomatic degenerative stenosis with spondylolisthesis at three-year follow-up.
Katz JN, Lipson SJ, Lew RA, et al. Lumbar laminectomy alone or with instrumented or noninstrumented arthrodesis in degenerative lumbar spinal stenosis. Patient selection, costs, and surgical outcomes. *Spine.* 1997;22(10):1123-1131.	III	This is a prospective, observational study of 310 consecutive patients with spinal stenosis. Inclusion criteria included age ≥ 50 years, the presence of back, buttock and/or lower extremity pain; radiographic evidence of stenosis and the surgeon's judgment that patients had clinically significant degenerative lumbar spinal stenosis. A total of 279 patients participated and 199 were available at follow-up (71%). Outcome measures were health status (including SIP and Zung Depression Questionnaire), walking capacity, back and leg pain, and satisfaction with surgery. At follow-up, no radiographs were obtained. Of patients in the study, 71% underwent decompression, 14% had decompression with fusion, and 15% had decompression with fusion and instrumentation. The minimum follow-up was two years. Noninstrumented arthrodesis was associated with superior relief of low back pain at six months ($P = 0.004$) and 24 months ($P = 0.01$). There were no significant differences in the other outcomes across treatment groups.	In critique, the groups of patients were not homogeneous, a large number of patients were lost to follow-up (29%) and the numbers of patients in the fusion groups were very small. This study provides Level III therapeutic evidence that noninstrumented decompression and fusion provides better relief of low back pain at two-year follow-up than decompression alone or decompression and fusion with instrumentation.
Katz JN, Lipson SJ, Chang LC, Levine SA, Fossel AH, Liang MH. Seven- to 10-year outcome of de-	IV	This study is a retrospective review and prospective follow-up of 88 patients who had decompressive laminectomy with or without fusion from 1983 to 1986. Patients completed nonvalidated question-	In critique, nonvalidated outcome measures were used, only 63% of patients were available for follow-up, and there was heterogeneity in the operative

compressive surgery for degenerative lumbar spinal stenosis. *Spine.* 1996;21(1):92-98.		naires in 1993 (average duration of follow-up was 8.1 years) that included items about reoperations, back pain, leg pain, walking capacity and satisfaction with surgery. Of the 88 patients in the original cohort, 20 patients (23%) died and 20 (23%) had another surgical procedure. Of the 55 patients who answered questionnaires, 33% of the patients had severe pain and 53% of the patients were unable to walk two blocks. Only eight patients in this review had fusions; the evaluation showed no difference between them and the other patients. Seventy-five percent of patients undergoing surgery for spinal stenosis were satisfied.	number of levels decompressed. This study provides Level IV therapeutic evidence that there is no significant difference in outcomes between decompression alone or decompression and fusion with instrumentation in the treatment of lumbar spinal stenosis.
Kornblum MB, Fischgrund JS, Herkowitz HN, Abraham DA, Berkower DL, Ditkoff JS. Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective long-term study comparing fusion and pseudarthrosis. *Spine.* 2004;29(7):726-733; discussion 733-724.	III	This case control study described 58 patients with symptomatic lumbar stenosis and spondylolisthesis that had been studied prospectively in two prior studies. Patients were treated with a posterior decompression and bilateral posterior arthrodesis with bone graft. Radiographic evaluation was used to determine if fusion or pseudoarthrosis was present. Forty-seven patients were available for follow-up for a range of five to 14 years. Outcome measures were VAS for leg and back pain and a questionnaire about surgical outcome. Patients were divided into two cohorts based on presence or absence of pseudoarthrosis. The success was good in 86% of patients with solid fusion and good in only 56% of patients with pseudoarthrosis.	In critique, the sample size is small, only patients with noninstrumented fusions were included, 19% of patients were lost to follow-up, and although initial data was collected prospectively, it was obtained from data in two prior studies. This study provides Level III prognostic evidence that pseudoarthrosis is a poor prognostic indicator postoperatively in patients undergoing decompression and noninstrumented fusion for stenosis with spondylolisthesis at long-term follow-up.
Mardjetko SM, Connolly PJ, Shott S. Degenerative lumbar spondylolisthesis. A meta-analysis of literature 1970-1993. *Spine.* 1994;19(20 Suppl):2256S-2265S.	III	This study is a meta-analysis of literature to 1993 regarding degenerative spondylolisthesis with radicular symptoms. Most of the included studies are Level IV data. There is a high degree of heterogeneity in analysis because of the variety of reporting methods for results and outcomes data. Overall, surgical groups appeared to do better than no treatment at all, and decompression with fusion did better than decompression alone. There is no clear advantage clinically to instrumentation, although fusion rates are higher with instrumentation.	In critique, the data analyzed in this meta-analysis is mainly Level IV data and because of the heterogeneity of outcome measures used in the study, it is more difficult to draw conclusions. This study provides Level III therapeutic data that in patients with degenerative spondylolisthesis, decompression and fusion is more effective than decompression alone. The use of

			instrumentation increases the likelihood of fusion, though does not appear to influence clinical outcomes.
Matsudaira K, Yamazaki T, Seichi A, et al. Spinal stenosis in grade I degenerative lumbar spondylolisthesis: a comparative study of outcomes following laminoplasty and laminectomy with instrumented spinal fusion. *J Orthop Sci.* 2005;10(3):270-276	III	This study is a retrospective comparative study of 53 patients with single-level grade I spondylolisthesis and spinal stenosis at L4-5. These patients were divided (not randomized) into three groups. One group of 19 patients underwent decompressive laminectomy with fusion and instrumentation (19 patients). A second group of 19 patients underwent decompression of the canal using a laminoplasty technique to preserve the integrity of the midline structure. The last group (16 patients) refused surgery and was treated with an undefined medical/interventional program. Clinical outcomes were measured using the Japanese Orthopedic Association (JOA) score. Subjective LBP as well as the JOA score was significantly higher in the control group than in either surgical group. There were no significant differences in percent of slip or demographics. At two-year follow-up, the JOA scores showed no improvement in the control group, but significant improvement in the surgical groups ($p < 0.0001$). Alleviation of all symptoms including back pain was significantly better in the two surgical groups compared with the control group. There was no significant difference between the two surgical groups. Back pain improved in all three groups with greater improvement in the surgical groups. Degree of satisfaction was slightly higher in the decompression alone group. The fusion group had a higher complication rate. Slip progression was higher in the medical/interventional group and the decompression alone group compared with the fusion group.	In critique, the sample size was small, medical/interventional treatment was not defined, and the reasons for surgical refusal were not explained. This study provides Level III therapeutic evidence that in patients with single level stenosis at L4-5 and grade I spondylolisthesis, there is no difference in outcomes between laminoplasty and decompression with fusion at two-year follow-up. Progression of slip is more likely to occur in patients undergoing laminoplasty or no treatment as compared with patients undergoing fusion, although this does not influence outcomes at two years. Both of these surgical treatments offer better outcomes than medical/interventional treatment.
Niggemeyer O,	IV	This study is a meta-analysis of literature	In critique, low quality articles

Strauss JM, Schulitz KP. Comparison of surgical procedures for degenerative lumbar spinal stenosis: a meta-analysis of the literature from 1975 to 1995. *Eur Spine J.* 1997;6(6):423-429.		from 1975 to 1995 of patients with degenerative spinal stenosis. This analysis compared decompression to decompression and fusion to decompression and fusion with instrumentation. The main determinant was radiographic diagnosis as a fair number of studies evaluated did not specify symptoms. Over 30 studies were included for analysis for total of 1668 patients. Most of the patients (1476) underwent decompression only, and only 49 patients included underwent fusion without instrumentation. Studies with mixed diagnoses were included if data for patients with degenerative lumbar spinal stenosis could be extracted. Outcomes were classified as good, fair or poor. Results were arbitrarily divided into outcomes at less than seven years, seven to 15 years, and greater than 15-year follow-up. Their findings suggested better outcomes with decompression if symptoms were present for less than seven years, and with decompression and fusion with instrumentation if symptoms were present for greater than 15 years. Outcomes at eight to 15-year follow-up showed no significant differences between the three groups. Follow-up varied from one to 32 years and didn't specify follow-up periods of each cohort.	were included in this analysis to increase patient numbers and no validated outcome measures were available. In some articles, conclusions were not based on outcomes at all. This study provides Level IV therapeutic evidence to suggest that patients with spinal stenosis treated surgically have better results with decompression in the presence of symptoms for less than seven years, while those who are symptomatic for greater than 15 years obtain best results with decompression and fusion with instrumentation.
Postacchini F, Cinotti G, Perugia D. Degenerative lumbar spondylolisthesis. II. Surgical treatment. *Ital J Orthop Traumatol.* 1991;17(4):467-477.	IV	This study is a retrospective cohort study of 32 patients treated surgically for spinal stenosis. Fifteen patients underwent decompression only and 17 had decompression and fusion, including two with interspinous wiring. The types of stenosis and the surgical techniques were heterogeneous in both groups. All patients had neurogenic claudication or radicular pain. Patients were evaluated with a nonvalidated four scale instrument. Twenty-six patients had follow-up X-ray studies. Clinical follow-up ranged from 11 months to seven years. Thirty-three percent of the nonfusion patients who had postoperative imaging had pro-	In critique, this study was limited by a very small sample size and further compromised by heterogeneity of the types of stenosis as well as the surgical procedures. Non validated outcomes measures were used and follow-up was as short as 11 months. This study provides Level IV therapeutic evidence that surgical treatment for spinal stenosis results in good and excellent outcomes in the majority of cases. The quality of the study

		gression of translation. None of the fusion patients had progression and there were no nonunions. All fusion patients experienced good and excellent results and 66% of the decompression-only patients experienced good and excellent results.	limits comparison of treatment groups.
Rompe JD, Eysel P, Zollner J, Nafe B, Heine J. Degenerative lumbar spinal stenosis. Long-term results after undercutting decompression compared with decompressive laminectomy alone or with instrumented fusion. *Neurosurg Rev.* 1999;22(2-3):102-106.	IV	This study is a retrospective comparative study of 117 patients surgically treated for lumbar spinal stenosis. Of these patients, 39 underwent lateral canal undercutting as decompression for partial stenosis, 51 underwent complete laminectomy and foraminotomy for severe stenosis and 27 patients who had instability with spondylolisthesis or scoliosis in addition to stenosis underwent laminectomy and fusion. Patients were followed for five-10 years (mean eight). Of the initial patients, only 61% were available at follow-up. Outcome measures were the Low Back Pain Outcome Scale, Turner Score and questions about walking capacity, residual pain, necessity of treatment and satisfaction. Analysis was done on 25 of the patients who underwent undercutting decompression, 26 of the patients who underwent complete laminectomy and foraminotomy, and 21 of the patients who underwent laminectomy and fusion. Good or excellent results were reported in 36%, 31% and 24% of these patients respectively. These results had deteriorated compared with the 68-72% good and excellent results reported by the same patients at two-year follow-up. Despite poor outcomes, 60-70% of patients were still satisfied with their results.	In critique, a large number of patients were lost to follow-up, and nonvalidated outcome measures were used. This study provides Level IV treatment evidence that similar results are obtained with undercutting decompression for partial stenosis, complete laminectomy and foraminotomy for severe stenosis, and laminectomy and fusion for spondylolisthesis or scoliosis in addition to stenosis. In addition, this provides evidence that long-term results of decompression for stenosis generally deteriorate with time.
Yone K, Sakou T. Usefulness of Posner's definition of spinal instability for selection of surgical treatment for lumbar spinal stenosis. *J Spinal Disord.*	II	This study is a prospective comparative study of 60 patients with lumbar stenosis. Inclusion criteria were the presence of back pain, leg pain or claudication which failed to improve with medical/interventional care and stenosis on imaging though criteria were not clearly defined. Patients were assessed as to	In critique, the sample size of patients undergoing fusion in this study was small. This study provides Level II therapeutic evidence that in patients with lumbar spinal stenosis meeting Posner's criteria of

1999;12(1):40-44.		whether they had instability based on Posner's definition. Of these 60 patients, 33 met the criteria for instability. Of these 33 patients with instability, all were offered decompression and fusion. Decompression and fusion was performed in 19 patients while the remaining 14 refused fusion and underwent decompression alone. The 27 patients without instability also underwent decompression without fusion. The primary outcome measure was the JOA score. Of the patients who underwent instrumented fusion and the group who had no instability with decompression, 80% of the patients experienced good outcomes. Only 43% of the patients in the group with instability and decompression without fusion experienced good outcomes.	instability, decompression and fusion is more effective than decompression alone.
Zdeblick TA. A prospective, randomized study of lumbar fusion. Preliminary results. *Spine.* 1993;18(8):983-991.	II	This study is a prospective, randomized controlled trial of 124 patients with multiple diagnoses, including degenerative spondylolisthesis or degenerative scoliosis with stenosis. These patients were treated with decompression plus fusion, fusion with semirigid instrumentation or fusion with rigid instrumentation. Outcome measures were a four-grade clinical scale (excellent, good, fair, poor). Patients were followed for a minimum of two years and only one patient was lost to follow-up. Because of poor bone quality, nine patients crossed from implant to nonimplant group at the time of surgery. Several diagnoses and outcomes data were not presented in detail. Overall fusion rates were better with instrumentation, and better with rigid than semirigid instrumentation. This held true for the subset of patients with degenerative spondylolisthesis. Overall outcomes were better for groups with instrumented fusion but this was not detailed by diagnoses. Good or excellent clinical results were reported in 95% of the group with rigid instrumentation and in 89% of the group with semirigid instru-	In critique, this study included a heterogeneous group of patient diagnoses, nonvalidated outcome measures, and incomplete reporting of outcome data. Fusion was assessed by routine lumbar spine X-ray imaging but did include flexion and extension films. This study provides Level II therapeutic evidence that at two-year follow-up clinical and fusion results are better for rigidly instrumented fusion than for semirigid instrumentation which in turn was better than no instrumentation in this patient population.

		mentation.	

Degenerative Lumbar Spinal Stenosis
Surgical Treatment Work Group:
LONG TERM OUTCOMES

-Evidentiary Table-

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Airaksinen O, Herno A, Turunen V, Saari T, Suomlainen O. Surgical outcome of 438 patients treated surgically for lumbar spinal stenosis. *Spine.* 1997;22(19):2278-2282.	IV	This study is a retrospective case series of surgical outcomes for lumbar spinal stenosis. Of the 497 patients, 438 were available for follow-up, at a mean of 4.3 years. The ODI was used as an outcome measure and a masked review was performed. Overall, there were good or excellent results in 62 % of patients.	This study provides Level IV therapeutic evidence that surgery offers a 62% good or excellent result at four-year follow-up.
Amundsen T, Weber H, Nordal HJ, Magnaes B, Abdelnoor M, Lilleas F. Lumbar spinal stenosis: conservative or surgical management?: A prospective 10-year study. *Spine.* 2000;25(11):1424-1435; discussion 1435-1426.	IV	This study is a prospective comparative study of 100 patients with lumbar spinal stenosis. Patients were assigned to four groups. Those with severe symptoms had decompression (surgical group, S, n=19). Those with mild symptoms were treated medically/interventionally (conservative group, C, n=52). Those with moderate symptoms were randomized to medical/interventional (randomized conservative, RC, n=18) or operative care (randomized surgical, n=13). Follow-up was assessed at four and 10 years. All follow-up assessments were performed by the lead author who also determined the overall treatment result. An intent-to-treat analysis was performed on the randomized groups at four years (ie, crossovers from medical/interventional to operative care were treated as failures). For the 10-year analysis all surgical patients and all medically/interventionally treated patients were grouped together. At the four-year follow-up, the nonrandomized surgical group had 84% good results, the nonrandomized medi-	In critique, the method used for assigning patients to treatment groups was biased. Thus, although they characterize one of the arms of their study as randomized, the bias limits the ability to draw conclusions from the data on these patients. Furthermore, the numbers assigned to the randomized groups were small and unequal (suggesting bias in the randomization process) and no statistical tests for significance were applied. Outcome assessment by the treating physician using nonvalidated outcome measures introduces further bias. This study offers Level IV therapeutic evidence that surgery for severe spinal stenosis provides good or excellent results in approximately 80% of patients at four-year follow-up and the results were relatively stable at 70% good or excellent

		cal/interventional group had 57% good results, the randomized medical/interventional group had 47% good results, and the randomized surgical group had 92% good results. The operative group tended to deteriorate somewhat over time while the medical/interventional group tended to improve, such that at final follow-up there were good outcomes in 70-75% of both groups. Those operated on a delayed basis (crossovers) did not have worse results that than those operated on early.	results at 10 years. It also offers Level IV evidence that patients who have medical/interventional therapy first but then cross over to surgery will not harm their chances of success with surgery.
Atlas SJ, Keller RB, Wu YA, Deyo RA, Singer DE. Long-term outcomes of surgical and nonsurgical management of lumbar spinal stenosis: 8 to 10 year results from the Maine lumbar spine study. *Spine.* 2005;30(8):936-943.	IV	This study is a prospective outcome study comparing the results between patients treated surgically for spinal stenosis and those treated medically/interventionally. One hundred forty-eight patients initially enrolled. The dropout rate was 33%, primarily because of death. The surgical group had worse symptoms initially. There was a 39% cross over to the surgical group. Validated outcome measures were used. At four-year follow-up, the results favored surgery. Over time, the surgical results deteriorated, with the two groups converging at final follow-up. At 8- to 10-year follow-up, 50% of surgical patients had improved back pain, 67% had improved leg pain, 54% had improvement in their predominant symptom, 55% were satisfied with their current state and 82% would choose the same treatment.	In critique, there was a high dropout rate. This is expected in this age group, but nonetheless complicates data interpretation. This study provides Level IV therapeutic evidence that 50-67% of patients undergoing surgical treatment will show improvements in pain and satisfaction. Surgical results tend to deteriorate with time.
Caputy AJ, Luessenhop AJ. Long-term evaluation of decompressive surgery for degenerative lumbar stenosis. *J Neurosurg.* 1992;77(5):669-676.	IV	This is a retrospective review of 88 patients, out of an initial group of 100, who had decompressive surgery for lumbar spinal stenosis. There was a 5- to 10-year follow-up. There was no masking and nonvalidated outcome measures were used. Initial results were "good" in all patients, but deterioration was seen over time, with a 26% failure rate at five years.	In critique, there was no masked outcome assessment and non-validated outcome measures were used. This provides Level IV therapeutic evidence that at 5-10 years, 74% of patients treated surgically for spinal stenosis will have a good outcome.
Cornefjord M, Byrod G, Brisby H, Rydevik B. A long-term (4- to	IV	This study is a retrospective case series of 124 patients having surgery for lumbar spinal stenosis, with a four- to 12-year	In critique, validated outcome measures were not used in this case series.

12-year) follow-up study of surgical treatment of lumbar spinal stenosis. *Eur Spine J.* 2000;9(6):563-570.		follow-up. Ninety-six patients (77%) were available for follow-up. A masked observer assessed nonvalidated measures of lower extremity pain, low back pain, and walking distance. There were significant improvements (all $P < 0.001$) in all three outcome measures and patient satisfaction was 65%.	This provides Level IV therapeutic evidence that 65% of patients treated surgically for spinal stenosis will have a satisfactory outcome at four- to 12-year follow-up.
Hee HT, Wong HK. The long-term results of surgical treatment for spinal stenosis in the elderly. *Singapore Med J.* 2003;44(4):175-180.	IV	This study is a retrospective case series of 84 patients undergoing surgery for lumbar spinal stenosis. Of the 84 patients, 68 were available for follow-up at a mean of eight years (seven to nine years). Nonvalidated outcome measures were used. 68% experienced good or excellent results.	In critique, nonvalidated outcome measures were used in this case series and there was a 19% drop-out rate. This case series provides Level IV therapeutic evidence that surgical treatment for spinal stenosis can lead to 68% good or excellent results in the patients 60 years or older.
Herno A, Airaksinen O, Saari T. Long-term results of surgical treatment of lumbar spinal stenosis. *Spine.* 1993;18(11):1471-1474.	IV	This study is a retrospective case series of patients who had a surgical decompression for lumbar spinal stenosis. Of the 146 patients studied, 119 were available for follow-up at a mean of 6.8 years, and 108 were available at a mean of 12.8 years. The ODI and other outcome measures were used. At six years, the average ODI was 34.5 and overall good and excellent results were 67%. At 12 years, these results were 30.2 and 69% respectively.	In critique, there was no masked outcome measurement. There was a 26% drop-out rate. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis will have 67% good or excellent results at seven years and that the results will be maintained at 13 years.
Hurri H, Slatis P, Soini J, et al. Lumbar spinal stenosis: assessment of long-term outcome 12 years after operative and conservative treatment. *J Spinal Disord.* 1998;11(2):110-115.	IV	This study is a retrospective review of the long-term outcomes of 134 patients diagnosed with lumbar spinal stenosis. At 12-year follow-up, 48 had died, and of the remaining 86 patients 75 were available. Of the remaining 75 patients, 57 were treated surgically and 18 medically/interventionally. Patients were evaluated by telephone with nonvalidated outcome measures as well as the ODI. Sixty-three percent of the operative group improved, while 18% actually worsened. The final ODI was 29.	In critique, there was a high drop out rate, even for studies in this population. Furthermore, a validated outcome measure was only done at follow-up. This study provides Level IV therapeutic evidence that 63% of patients treated surgically for spinal stenosis will improve at long-term follow-up.
Javid MJ, Hadar EJ. Long-term follow-up review of patients who underwent laminectomy for lum-	IV	This study is a prospective case series of 170 patients with lumbar spinal stenosis who underwent surgery. Eighty-three had central stenosis, 61 had stenosis and HNP, and 23 had lateral recess stenosis.	In critique, there was no masked outcome measurement, nonvalidated measures were used, and there was large variability in the length of outcome.

bar stenosis: a prospective study. *J Neurosurg.* 1998;89(1):1-7.		Follow-up was performed anywhere from one to 11 years, with a mean of five years. Twenty-four patients were lost to follow-up. Among the spinal stenosis patients, 64-70% experienced good results.	This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 64-70% good or excellent results.
Jolles BM, Porchet F, Theumann N. Surgical treatment of lumbar spinal stenosis. Five-year follow-up. *J Bone Joint Surg Br.* 2001;83(7):949-953.	IV	This study is a retrospective case series of 155 patients treated surgically for lumbar spinal stenosis, with five- to eight-year follow-up. Of the 155 patients, 77 were available for follow-up. Validated outcome measures were used. Seventy-nine percent experienced good or excellent results.	In critique, there was a high drop-out rate, even for studies in this population. This study provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 79% good or excellent results at a five-year follow-up.
Jonsson B, Annertz M, Sjoberg C, Stromqvist B. A prospective and consecutive study of surgically treated lumbar spinal stenosis. Part II: Five-year follow-up by an independent observer. *Spine.* 1997;22(24):2938-2944.	IV	This study is a prospective case series of 105 patients with lumbar spinal stenosis treated surgically. Of the 105 patients, 88 were available for five-year follow-up. The reviewer was masked, outcomes were measured with a nonvalidated four-point scale (excellent, fair, no change, poor). Sixty-four percent experienced good or excellent results.	In critique, a nonvalidated outcome measure was used. This case series provides Level IV therapeutic evidence that patients treated surgically for spinal stenosis can expect 64% good or excellent results at a five-year follow-up.
Katz JN, Lipson SJ, Chang LC, Levine SA, Fossel AH, Liang MH. Seven- to 10-year outcome of decompressive surgery for degenerative lumbar spinal stenosis. *Spine.* 1996;21(1):92-98.	IV	This study is a retrospective case series of 88 patients who underwent surgery for lumbar spinal stenosis. Follow-up data was available in 55 patients. Of these patients, 85% had some initial improvement. Thirty-three percent had severe low back pain at final follow-up and 20% had severe lower extremity pain. Overall, 75% of patients were satisfied at final follow-up.	In critique, a nonvalidated outcome measure was used. Thirty-seven percent were lost to follow-up, most because of death. This case series provides Level IV therapeutic evidence that 75% of patients treated surgically for spinal stenosis will be satisfied at 7- to 10-year follow-up, although 33% had severe low back pain.
Nakai O, Ookawa A, Yamaura I. Long-term roentgenographic and functional changes in patients who were treated with wide fenestration for central lumbar	IV	This study is a retrospective case series of 41 patients treated with wide fenestration for lumbar spinal stenosis. Follow-up data was available in 34 patients, at 4.5 – eight years with a mean of 5.5 years.Seventy-one percent had a good or excellent result at final follow-up.	In critique, a nonvalidated outcome measure was used and sample size was small. This study provided Level IV therapeutic evidence that patients treated with surgery for spinal stenosis can expect satis-

stenosis. *J Bone Joint Surg Am.* 1991;73(8):1184-1191.			factory results 71% of the time.
Postacchini F, Cinotti G, Gumina S, Perugia D. Long-term results of surgery in lumbar stenosis. 8-year review of 64 patients. *Acta Orthop Scand Suppl.* 1993;251:78-80.	IV	This study is a retrospective case series of 64 patients treated surgically for lumbar spinal stenosis. There was a four- to 21-year follow-up, with a mean of eight years. Eighty-four percent experienced good or excellent short-term results and 67% experienced good long-term results.	In critique, a nonmasked assessment of nonvalidated outcome measures was used. This study provides Level IV therapeutic evidence that 76% of patients treated surgically for spinal stenosis will have a satisfactory result at long-term follow-up.
Rompe JD, Eysel P, Zollner J, Nafe B, Heine J. Degenerative lumbar spinal stenosis. Long-term results after undercutting decompression compared with decompressive laminectomy alone or with instrumented fusion. *Neurosurg Rev.* 1999;22(2-3):102-106.	IV	This study is a retrospective study of patients treated for spinal stenosis with a variety of surgical methods, all including some method of decompression. Five to 10-year follow-up data were available on 61% of patients. A validated questionnaire was used and the results collected by mail. At two-year follow-up, 60-70% experienced good or excellent results. At final follow-up, between 24-36% of patients experienced good or excellent results, with the results varying somewhat according to the type of surgery.	In critique, there was a 39% drop out rate and a variety of surgical treatments were used. This study provides Level IV therapeutic evidence that surgery for spinal stenosis provides 60-70% good or excellent results at two years, which declines to 24-36% good or excellent at five- to 10-year follow-up.
Sanderson PL, Getty CJ. Long-term results of partial undercutting facetectomy for lumbar lateral recess stenosis. *Spine.* 1996;21(11):1352-1356.	IV	This study is a retrospective case series of surgical treatment for lumbar spinal stenosis. Follow-up data were available on 57 out of 66 patients. Final follow-up was at a minimum of five years with a mean of eight years. Preoperatively all had lower extremity pain and 7% could walk > 30 minutes. At one year, 79% had complete resolution of their lower extremity pain, and 93% could walk > 30 minutes. There was minimal change in these results at final follow-up.	In critique, a nonmasked assessment of nonvalidated outcome measures was used. This study provides Level IV therapeutic evidence that 79% of patients treated surgically for spinal stenosis will have a good result at long-term follow-up.
Scholz M, Firsching R, Lanksch WR. Long-term follow up in lumbar spinal stenosis. *Spinal Cord.* 1998;36(3):200-204.	IV	This study is a retrospective case series of results of 72 patients treated surgically for lumbar spinal stenosis. Follow-up data were collected at two years and eight years. Eight-year data were available on 43 patients. Seventy-three percent had satisfactory results at two years and 62% at eight years.	In critique, a nonmasked assessment of nonvalidated outcome measures was used, and a very small subgroup was followed out to eight years. This study provides Level IV therapeutic evidence that 73% of

			patients treated surgically for spinal stenosis will have a good result at two years, declining to 62% at eight years.
Tuite GF, Stern JD, Doran SE, et al. Outcome after laminectomy for lumbar spinal stenosis. Part I: Clinical correlations. *J Neurosurg.* 1994;81(5):699-706.	IV	This study is a retrospective case series of 119 patients undergoing decompression surgery for lumbar spinal stenosis with a mean follow-up of 4.6 years. Seventy-nine percent had improvement at one year and 66% at final follow-up.	In critique, nonvalidated outcome measures were used, and were only collected at follow-up. This case series provides Level IV therapeutic evidence that 79% of patients treated surgically for spinal stenosis will have a good result at one year, declining to 66% at mean 4.6-year follow-up.

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