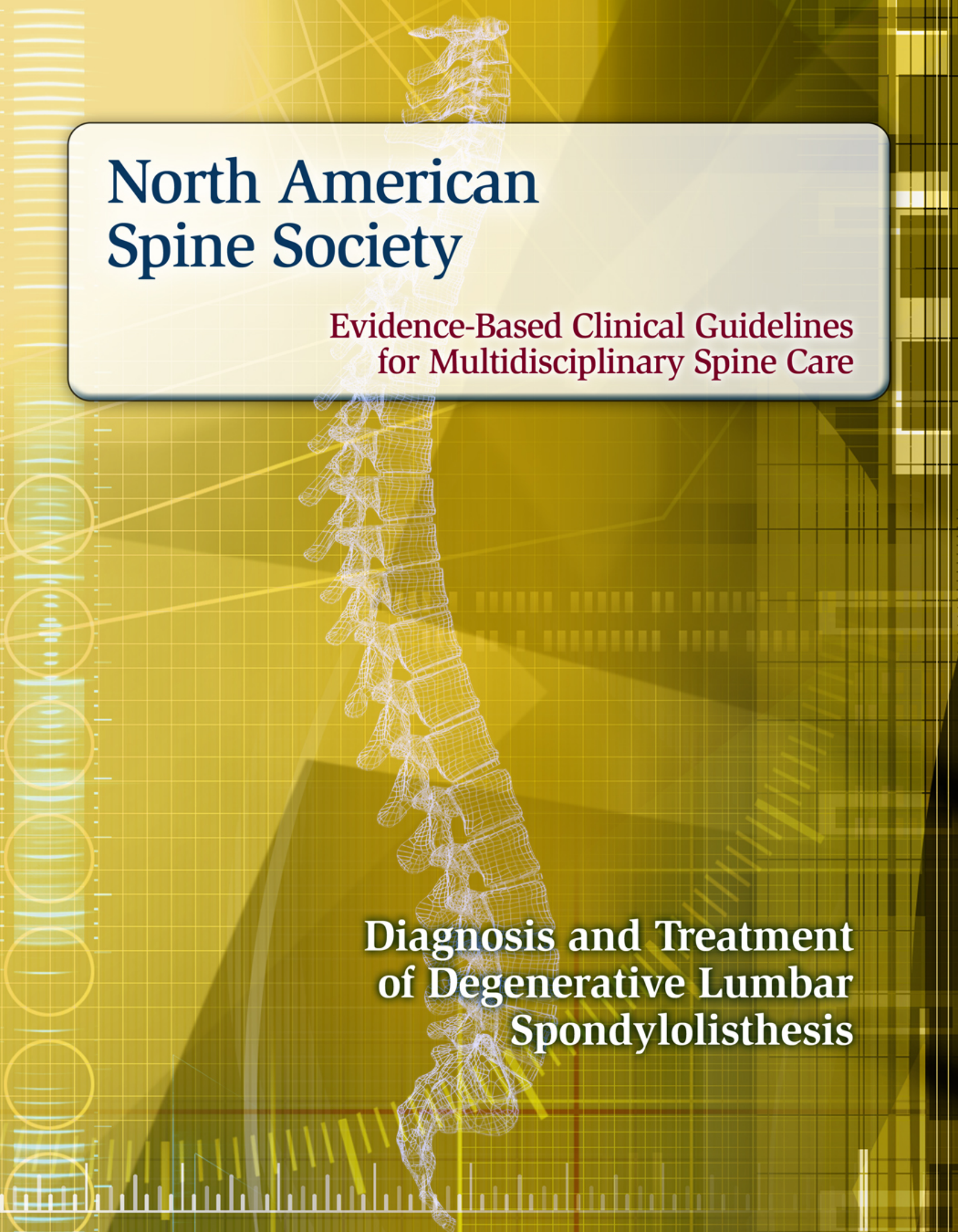
North American Spine Society

Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care



Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis

North American Spine Society

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for Multidisciplinary Spine Care

Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis

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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 Spondylolisthesis

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This clinical guideline should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution.

I. Introduction

Objective

The objective of the North American Spine Society (NASS) Clinical Guideline for the Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis is to provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of degenerative lumbar spondylolisthesis. The guideline is intended to reflect contemporary treatment concepts for symptomatic degenerative lumbar spondylolisthesis as reflected in the highest quality clinical literature available on this subject as of June 2007. 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 Evidence-Based Guideline Development Committee as an educational tool to assist practitioners who treat patients with degenerative lumbar spondylolisthesis. The goal is to provide a tool that assists practitioners in improving the quality and efficiency of care delivered to patients with degenerative lumbar spondylolisthesis. The NASS *Clinical Guideline for the Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis* provides a definition and explanation of the natural history of degenerative lumbar spondylolisthesis, outlines a reasonable evaluation of patients suspected to have degenerative lumbar spondylolisthesis and outlines treatment options for adult patients with a diagnosis of degenerative lumbar spondylolisthesis.

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 physician'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 low back pain and/or lower extremity symptoms related to spinal stenosis. In general, the nature of the pain and associated patient characteristics (eg, age) are more typical of a diagnosis of spinal stenosis than discogenic low back pain, lumbar sprain/strain, or mechanical low back pain.

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 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.

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 short comings 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 evaluated 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 compre-

hensive 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**
Once 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 will review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members have 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 have 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 have 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 have 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 Evidence-Based Guideline Development 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**
Once 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 have been 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 Spondylolisthesis

What is the best working definition of degenerative lumbar spondylolisthesis?

An acquired anterior displacement of one vertebra over the subjacent vertebra, associated with degenerative changes, without an associated disruption or defect in the vertebral ring.

Work Group Consensus Statement

The literature search has revealed several reports that describe variants of degenerative spondylolisthesis in which the degree of anterior displacement is measurably affected by the posture and position of the patient. These observations on position dependent deformities may have significant implications for the pathophysiology and natural history of degenerative spondylolisthesis; however, no longitudinal studies have yet addressed this issue. The position dependent variants of spondylolisthesis are therefore not included in this guideline.

Degenerative spondylolisthesis is an anatomic finding. The clinical symptoms of degenerative spondylolisthesis, however, are varied. Patients with degenerative lumbar spondylolisthesis can be asymptomatic. They can also present with axial back pain, or with neurogenic claudication and/or radicular pain, with or without axial back pain. Therefore, the work group agreed upon this anatomic definition but also evaluated the relevant literature inclusive of the variations of clinical presentation.

What is the natural history of degenerative lumbar spondylolisthesis?

The majority of patients with symptomatic degenerative lumbar spondylolisthesis and an absence of neurologic deficits will do well with conservative care. Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery. Progression of slip correlates with jobs that require repetitive anterior flexion of the spine. Slip progression is less likely to occur when the disc has lost over 80% of its native height and intervertebral osteophytes have formed. Progression of clinical symptoms does not correlate with progression of the slip.

In order to perform a systematic review of the literature regarding the natural history of patients with degenerative lumbar spondylolisthesis, a definition of degenerative lumbar spondylolisthesis 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 degenerative lumbar spondylolisthesis 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 degenerative lumbar spondylolisthesis was examined for its utility as a prognostic factor. The central question asked was: What happens to patients with degenerative lumbar spondylolisthesis who do not receive treatment?

Matsunaga et al[12] reported a retrospective review of 40 patients with spondylolisthesis. Inclusion criteria were a slippage rate of at least 5% by Morgan and King's compass method and at least five year follow-up of medical/interventional care. Outcome measures utilized included progression of slippage and Japanese Orthopaedic Association (JOA) score. Joint laxity was evaluated using Carter's test of knee, elbow and wrist hypermobility. General joint laxity using Carter's criteria was noted in 65% of these patients as compared with 8% of normal individuals.

Progression of slippage, defined as a slippage rate of 5% or more during the observation period, was observed in 12 (30%) of the 40 patients. The authors defined this to be the *progressive group*, and the other 28 patients to be the *nonprogressive group*. Comparison of these two groups showed no difference in age at presentation, duration of illness or duration of follow-up. Further, whereas the lumbosacral angle, lamina angle and facet inclination angle were greater in both groups, there were no significant differences between these groups.

In critique, this was a relatively small study, but did use a validated outcome measure. This potentially Level II retrospective, comparative study was downgraded to Level III evidence because of the small sample size and incomplete documentation of patient information. This study provides Level III evidence that slip is more likely to progress in laborers whose jobs require repetitive anterior flexion of the spine. Progression of slip is less likely in the presence of a relative intervertebral height of 20% or less, intervertebral osteophyte formation, subcartilagenous sclerosis or ligamentous ossification, suggesting that mechanisms of restabilization prevent progression of the slip. Progression of the slip does not correlate with clinical symptoms. The authors also observed that general joint laxity using Carter's criteria correlates with the presence of degenerative spondylolisthesis.

Matsunaga et al[11] reported a prospective, comparative, cohort study of 145 patients with degenerative anterolisthesis who were either determined not to need surgery (110 patients) or refused surgery (35 patients). The patients were followed from 10-18 years, although only 46 were followed up longer than 10 years. Outcome measures utilized included progression of spondylolisthesis (5% or more on radiographs), frequency of transitory radicular pain, improvement or worsening of symptoms and ability to walk without help.

Progression of slip was observed in 49 (34%) patients. Of the patients who were initially felt not to need surgery, 85 (77%) experienced improvement during follow-up and 25 remained the same. Of these patients, 84 (76%) continued to show no neurologic deficits on examination. Of the patients who refused surgery, 29 (83%) had worsened neurologic deficit on examination, and this was noted not to correlate with the progression of slippage. Fifteen of these patients were followed over 10 years and all of them required an assistive device to ambulate.

In critique of this study, no validated outcome measures were used. The initial sample of patients was not the group initially assigned to medical/interventional treatment, rather it consisted of patients who remained medically/interventionally treated at 10 years. This study provides Level II evidence that in patients who initially do not have neurologic deficits, the majority will do well with conservative care. Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery. Progression of the slip does not correlate with progression of clinical symptoms. Radicular pain, accompanied by neurologic deficits, forebodes a poor outcome. This study provides Level III evidence that low back pain can be expected to improve in patients with narrowed intervertebral disc spaces.

Vogt et al[17] described a cross sectional study of 788 white south central Pennsylvanian women over 65 years of age who were enrolled in a study intended to address osteoporotic fractures. Spine radiographs were digitized to retrospectively assess prevalence of anterolisthesis. Subluxation of 3 mm or more at any level (L3-4, L4-5, or L5-S1) was defined as a degenerative slip. Anterolisthesis was noted in 29% of this very specific population of white women over the age of 65. Of these patients, only a single level was involved in 90% of women with anterolisthesis. The incidence of slip was not affected by smoking, diabetes mellitus or oophorectomy.

Anterolisthesis was not associated with presence of back symptoms; however no validated outcome measure was used. This study provides Level II evidence that degenerative spondylolisthesis is found in 29% of this very specific population of white women over the age of 65. Slip is most likely to occur at a single level and does not necessarily correlate with back pain.

Kauppila et al[8] detailed a population-based, retrospective, cohort study of 217 men and 400 women. Radiographs were taken at a mean age of 54 years and again at 79 years. Degenerative spondylolisthesis was defined as >3 mm of forward or backward slip. Twenty-three men (12%) and 100 women (25%) developed some form of "slippage" either forward or backward. Forward slip occurred in eight men and 75 women, and backward slip occurred in 16 men and 35 women. Forward slip was 18% +/- 5.5 and backward slip magnitude was 15% +/- 4.0. Olisthesis did predict back pain or stiffness on most days (32% [39/123] in the degenerative spondylolisthesis group compared with 19% [90/484] in controls). Controlling for sclerosis still accounted for pain. Patients with acquired slips reported more daily back symptoms, but did not report more disability than controls.

In critique of the study, unlike most other studies in this area, a degenerative slip was defined as either a forward or backward slip. This paper offers Level III prognostic evidence that in an elderly population, back pain is correlated with the olisthesis; however, only one third with olistheses is symptomatic. Thus degenerative spondylolisthesis can be acquired in an asymptomatic population, with a higher incidence in females (4:1).

Mardjetko et al[10] reported a meta-analysis of degenerative lumbar spondylolisthesis literature from 1970-1993, primarily designed to study posterior fusion with and without instrumentation. However, three studies included addressed natural history with a total of 278 patients. Inclusion criteria were limited only to degenerative spondylolisthesis with radicular leg pain or neurogenic claudication. Of the three studies, only the Matsunaga paper addressed slippage and was considered by the work group to be a true natural history paper. Because of the limitations of this meta-analysis relative to the question of natural history, the reviewers chose to base recommendations on the Matsunaga paper directly and not include this article as a basis for the recommendations.

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 spondylolisthesis.

Recommendation #1:

A prospective study of untreated patients, all with degenerative lumbar spondylolisthesis without neurologic compromise, would provide Level I evidence regarding the natural history of the disease. This study could include stratification as to type of spondylolisthesis and evaluate progression of radiographic severity and clinical severity over time.

Recommendation #2:

Any systematic study of patients with untreated spondylolisthesis who presented with varying degrees of neurologic deficit would provide evidence regarding the natural history of the disease in this patient population. For example, defining and following a group of patients with lumbar spondylolisthesis and sensory deficits as compared with those who present with motor deficits that have not been treated would yield Level I evidence.

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IV. Recommendations for Diagnosis and Treatment of Degenerative Lumbar Spondylolisthesis

A. Diagnosis and Imaging

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

Obtaining an accurate history and physical examination is essential to the formulation of the appropriate clinical questions to guide the physician in developing a plan for the treatment of patients with degenerative lumbar spondylolisthesis.

Work Group Consensus Statement

Traditionally, the evaluation of a patient begins with the physician obtaining a history and performing a focused physical examination related to the patient's presenting complaints. This forms the basis upon which the physician formulates an initial list of diagnoses to explain the patient's symptoms and signs. Additional testing subsequently enables the physician to identify the most probable diagnosis and formulate a treatment plan.

When evaluating the Levels of Evidence in support of appropriate history and physical exam findings, the evidence is generally of a low level, as little contemporary research has been applied to the prognostic value of the history and physical exam in clinical decision-making. Nonetheless, the history and physical exam remain central to the practice of evidence-based medicine. An accurate history and physical examination forms the informational basis for the initiation of the evidence-based medicine process, namely asking meaningful, answerable questions.

When assessing studies related to historical and physical examination findings consistent with the diagnosis of degenerative lumbar spondylolisthesis, the work group evaluated this literature as prognostic in nature. Studies on the history and physical examination should identify signs or symptoms which increase the likelihood that a given disease process is present in the tested population. Selection of patients with these specific signs and symptoms should increase the incidence of a specific disease in the patient population. This increases the positive predictive value of subsequent diagnostic testing, and increases the likelihood that patients will respond to disease-specific therapies. Prognostic studies investigate the effect of a patient characteristic on the outcome of a disease.

Degenerative lumbar spondylolisthesis represents an anatomic entity. There are no clinical symptoms that are specific to degenerative lumbar spondylolisthesis. Patients with symptomatic degenerative lumbar spondylolisthesis complain primarily of radiculopathy or neurogenic intermittent claudication with or without concomitant back pain. However, there is a variable rate of back pain in patients with degenerative spondylolisthesis. The association between back pain and degenerative lumbar spondylolisthesis is inconsistent, as many patients with spondylolisthesis have no back pain.

The signs and symptoms of mechanical instability associated with degenerative lumbar spondylolisthesis without neurological symptoms have not been well characterized and are not addressed in this guideline.

In older patients presenting with radiculopathy and neurogenic intermittent claudication, with or without back pain, a diagnosis of degenerative lumbar spondylolisthesis should be considered.

Grade of Recommendation: B

Cauchioux et al[5] described a study in which the diagnostic evaluation of 26 patients with degenerative spondylolisthesis included plain radiographs and myelography. Specifically, the authors stated that they made the diagnosis based on the "presence of a slip of one vertebra on the vertebra below in the absence of a defect of the pars interarticularis." The study included 26 patients with nerve root compression secondary to degenerative slip, with 80% reporting back pain, 46% reporting primary chronic sciatica and 54% reporting primary neurogenic claudication. Sciatica tended to occur in the older patient and neurogenic claudication in the younger subjects.

In critique of this study, this is a characterization of a subset of patients with degenerative lumbar spondylolisthesis referred for evaluation of neurological symptoms. These data offer Level IV prognostic evidence for the neurological symptoms associated with degenerative lumbar spondylolisthesis.

Fitzgerald et al[8] conducted a study of 43 patients with symptomatic spondylolisthesis which examined various parameters. It is unclear if the patients represented a consecutive or nonconsecutive series. In addition to a description of plain radiographic findings of the spine, as well as concomitant hip arthritis, the authors provided a detailed description of the presentation (symptom) pattern of the patients. In summary, they found that 34 patients had back pain without leg pain and signs of nerve root compression, five cases with leg pain with or without back pain with signs of nerve root compression and four cases in which patients reported neurogenic claudication.

In critique of this study, one must presume that the patients were enrolled nonconsecutively. As a diagnostic history and physical examination study, the study presents a spectrum of symptoms and signs in patients with degenerative lumbar spondylolisthesis. This study offers Level IV prognostic evidence of the clinical spectrum of signs and symptoms of degenerative spondylolisthesis.

Postacchini et al[19] performed a retrospective study which reported on the clinical features of 77 patients. Within these patients, 18% reported chronic low back pain as the only symptom; 12% had lower extremity symptoms felt to be nonvertebral in origin (eg, hip arthritis), and reported no low back pain; 47% had radicular symptoms and low back pain; and 23% reported only radicular symptoms. Radiculopathy presented as pain alone, pain and sensory symptoms, or pain and sensorimotor changes. Lasegue test was negative in almost all cases. The most common neurological signs were absent ankle jerks, weak extensor hallucis longus (EHL), weak anterior tibialis or loss of knee jerk reflex.

The authors reviewed five clinical patterns and three radiographic patterns as defined by Fitzgerald and MacNab. Clinical patterns included the following: (1) no symptoms, occasional back pain; (2) chronic low back pain with no radicular symptoms; (3) radicular symptoms with no root compression, with or without back pain; (4) radicular symptoms with neurologic deficit; or (5) intermittent claudication. Radiological findings included slight central stenosis, lateral root canal stenosis or combined central and root canal stenosis. The authors concluded that degenerative lumbar spondylolisthesis is not always symptomatic. Patients may complain of low back pain, but the etiology is uncertain. Patients largely complain of radicular symptoms or intermittent claudication, which is secondary to an associated stenosis.

In critique of this study, data were collected retrospectively and tests were not uniformly applied across patients. Because of these weaknesses, this potential Level II study was downgraded to Level III. These data provide Level III prognostic evidence of clinical signs and symptoms of degenerative lumbar spondylolisthesis.

Rosenberg et al[20] conducted a retrospective study which characterized symptoms in 200 consecutive patients with degenerative lumbar spondylolisthesis. Back, buttock or thigh pain were the principal complaints in a large majority of patients and were rarely severe. Of the 200 patients, 61 had leg symptoms. Some patients described gait abnormalities. Seven patients had sacral nerve root symptoms. Acute radiculopathy occurred in 19 instances and a disc herniation was confirmed on myelography. Symptoms included aching, pulling, weakness, heaviness, numbness or burning. Lower extremity symptoms could be unilateral, bilateral or alternating. Neurogenic claudication was uncommon. Examination of the patients demonstrated that many were supple and able to touch toes, 10% had back spasms and 42% had neurologic deficits, primarily L5 with decreased sensation in the lateral thigh or inability to walk on heels. Atrophy occurred occasionally and 20% had altered deep tendon reflexes.

In critique of this study, data were collected retrospectively and tests were not uniformly applied across patients. Because of these weaknesses, this potential Level II study was downgraded to Level III. These data provide Level III prognostic evidence of the typical clinical signs and symptoms which may be associated with degenerative lumbar spondylolisthesis.

Vogt et al[26] described a retrospective, cross-sectional, prognostic study of 788 women greater than 65 years of age enrolled in the Study of Osteoporotic Fractures. The incidence of olisthesis (degenerative spondylolisthesis and retrodisplacement) was defined as greater than 3 mm of translational change. Of the women enrolled in the study, 29% had anterior olisthesis (degenerative spondylolisthesis) and 14% had retrolisthesis. Ninety percent of degenerative spondylolisthesis and 88% of retrolisthesis occurred at one level. Prevalence was not associated with smoking status, diabetes or oophorectomy. Unlike retrolisthesis, degenerative spondylolisthesis was not associated with back pain.

In critique of this study, data was collected retrospectively from a study conducted for other epidemiological purposes. This study offers Level II prognostic evidence that degenerative spondylolisthesis is relatively common in elderly Caucasian women and does not correlate with back pain.

Future Directions for Research

The work group recommends a high quality, prospective study identifying specific aspects of the history and physical examination and characterizing the subgroups of patients with degenerative spondylolisthesis. The study would enroll a large number of patients, screen for symptomatic and asymptomatic degenerative lumbar spondylolisthesis, and have greater than 80% follow-up. Subgroups for evaluation could include patients with or without instability, radiculopathy, neurogenic intermittent claudication and back pain.

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Diagnosing Spondylolisthesis with Imaging

What are the most appropriate diagnostic tests for degenerative lumbar spondylolisthesis?

The most appropriate, noninvasive test for detecting degenerative lumbar spondylolisthesis is the lateral radiograph.

Grade of Recommendation: B

Brown et al[6] reported findings from a retrospective study of patients with degenerative spondylolisthesis, which examined a number of different parameters, including diagnostic features on plain radiographs. These patients were selected from a review of 2348 consecutive charts of patients with low back pain; 132 (5.6%) had radiographic evidence of degenerative spondylolisthesis. Of patients included in the study, 88 were female and 44 were male. The average age was 63.5 years for the female group and 65.2 years for the male group. Seventy-eight percent had back pain with proximal leg referral lasting between one week and 40 years; 17% had instability symptoms (eg, catch in the back, tiredness in back, inability to walk one hour, limitation of forward bend, inability to lift weights, back pain with coughing or sneezing, significant back pain with twisting).

In critique, this study does not present peer-reviewed data. There was no comparison of diagnostic tests. As the study was performed in the early 1980s, the primary radiographic modality was plain radiographs. These data offer Level III diagnostic evidence that plain radiographs are a useful test for identifying patients with degenerative spondylolisthesis.

Cauchioux et al[7] conducted a diagnostic evaluation on 26 patients with degenerative spondylolisthesis which included plain radiographs and myelography. Specifically, the authors stated that they made the diagnosis based on the "presence of a slip of one vertebra on the vertebra below in the absence of a defect of the pars interarticularis." The study included 26 patients with nerve root compression secondary to degenerative slip, with 80% reporting back pain, 46% reporting chronic sciatica and 54% reporting neurogenic claudication. Sciatica tended to occur in the older patient and neurogenic claudication in the younger subjects. Myelography was performed in 17 patients to detect nerve root/cauda equina compression. Although not supported by statistical analysis, the authors claimed that lateral recess stenosis was "most important."

In critique of this study, the authors did not state whether patients were consecutively selected, thus it was assumed that they were nonconsecutive patients. The study did not include comparison of diagnostic modalities. Admittedly, in the mid to late 1970s, plain radiograph and myelography were the most advanced imaging methods available. By default, they would have been considered gold standard diagnostic tests for degenerative spondylolisthesis and spinal stenosis. These data offer Level III diagnostic evidence that plain radiographs and myelography are useful diagnostic tests for this disorder.

Fitzgerald et al[16] described a study of 43 patients with symptomatic spondylolisthesis. It is unclear if the patients represented a consecutive or nonconsecutive series. In addition to a description of plain radiographic findings of the spine, as well as concomitant hip arthritis, the authors provided a detailed description of the presentation (symptom) pattern of the patients. In summary, they found that 34 patients had back pain without leg pain and signs of nerve root compression, five cases with leg pain with or without back pain with signs of nerve

root compression, and four cases in which patients reported neurogenic claudication. As a diagnostic study, the primary imaging method was plain radiographs; however, plain myelography was also performed in seven of the nine patients with neurological symptoms.

In critique of this study, one must presume that the patients were not consecutively enrolled. The only two imaging methods used were plain radiographs and myelography, which were not uniformly performed in all patients. This study provides Level III diagnostic evidence that plain radiographs and myelography are useful modalities with which to diagnose and evaluate degenerative spondylolisthesis in the lumbar spine.

While standing radiographs are commonly used, few studies assess the relative value of this technique compared with supine lateral radiographs. Limited data support the use of dynamic views (flexion-extension or axially loaded) in the evaluation of degenerative spondylolisthesis. Lowe et al[32] showed increased sagittal displacement with the use of standing rather than supine lateral radiographs. However, only one of 13 patients had degenerative spondylolisthesis. Wood et al[58] also found that the degree of static spondylolisthesis was greater with the patient in the standing lateral rather than the supine position, however, they included postlaminectomy patients in the degenerative spondylolisthesis group. Because the paper did not present a subgroup analysis specific to the degenerative spondylolisthesis group, the work group was unable to use this paper to address this question.

Kanayama et al[26] reviewed a case series of 19 patients with symptomatic degenerative lumbar spondylolisthesis who were candidates for instrumented lumbar arthrodesis and decompression. Patients were assessed according to radiographic parameters including disc angle, range of motion (ROM), percent slip, percent posterior height, which were then compared with distraction stiffness in the operating room. The authors concluded that disc angle in flexion and ROM were highly correlated with distraction stiffness. Patients with segmental kyphosis with flexion showed lower stiffness compared to those with lordosis in flexion.

In critique of this study, it assessed an intraoperative and nonvalidated test. The clinical application of such a test remains unknown. Although the study presents potential Level II diagnostic evidence, the authors failed to mention whether the patients were consecutively assigned, thus the study was downgraded to Level III evidence. The study provides Level III diagnostic evidence that standing flexion and extension radiographs are predictive of instability.

Postacchini et al[44] described a study of 77 patients with degenerative spondylolisthesis in which flexion-extension radiographs, CT and/or MRI, and myelography were obtained. The various findings were reported. The authors found that radiographs used for imaging quantified the degree of slips observed. Dynamic radiographs "showed hypermobility of L4 in approximately half of the cases." Myelography revealed neural structure compression in the spinal canal in all cases in which it was performed. (Note: myelography may have only been performed if patients had neurologic symptoms.) CT was useful for assessing the facet joint. MRI, CT and myelography were useful in identifying stenosis in patients with neurological symptoms.

In critique, the diagnostic studies were applied inconsistently across patients. Not all patients received all studies, preventing comparison between diagnostic modalities. This article presented comprehensive descriptions of the findings with each of the diagnostic modalities. These data offer Level III diagnostic evidence of the utility of dynamic radiographs, CT, MRI and myelography for evaluation of degenerative spondylolisthesis.

The most appropriate, noninvasive test for imaging the stenosis accompanying degenerative lumbar spondylolisthesis is the MRI.

Work Group Consensus Statement

Based on NASS' Clinical Guideline for Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis (2007), MRI was demonstrated to be the most effective noninvasive diagnostic tool to detect degenerative lumbar spinal stenosis. As many patients included in the review had degenerative spondylolisthesis, it is logical to conclude that MRI would be useful in this group as well. However, no disease-specific studies were found to confirm this conclusion.

Plain myelography or CT myelography are useful studies to assess spinal stenosis in patients with degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

Cauchioux et al[7] conducted a diagnostic evaluation of 26 patients with degenerative spondylolisthesis which included plain radiographs and myelography. Specifically, the authors stated that they made the diagnosis based on the "presence of a slip of one vertebra on the vertebra below in the absence of a defect of the pars interarticularis." The study included 26 patients with nerve root compression secondary to degenerative slip, with 80% reporting back pain, 46% reporting chronic sciatica and 54% reporting neurogenic claudication. Sciatica tended to occur in the older patient and neurogenic claudication in the younger subject. Myelography was performed in 17 patients to detect nerve root/cauda equina compression. Although not supported by statistical analysis, the authors claimed that lateral recess stenosis was "most important."

In critique of this study, the authors did not state whether patients were consecutively selected, thus it was assumed that they were nonconsecutive patients. There was no comparison of diagnostic modalities. Admittedly, in the mid to late 1970s, plain radiographs and myelography were the most advanced imaging methods available. By default, they would have been considered gold standard diagnostic tests for degenerative spondylolisthesis and spinal stenosis. These data offer Level III diagnostic evidence that plain radiographs and myelography are useful diagnostic tests for this disorder.

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In critique of this study, one must presume that the patients were not consecutively enrolled. The only two imaging methods used were plain radiographs and myelography, which were not uniformly performed in all patients. This study provides Level III diagnostic evidence that plain radiographs and myelography are useful modalities with which to diagnose and evaluate degenerative spondylolisthesis in the lumbar spine.

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radiographs used for imaging quantified the degree of slips observed. Dynamic radiographs "showed hypermobility of L4 in approximately half of the cases." Myelography revealed neural structure compression in the spinal canal in all cases in which it was performed. (Note: Myelography may have only been performed if patients had neurologic symptoms.) CT was useful for assessing the facet joint. MRI, CT and myelography were useful in identifying stenosis in patients with neurological symptoms.

In critique, the diagnostic studies were applied inconsistently across patients. Not all patients received all studies, preventing comparison between diagnostic modalities. This article presented comprehensive descriptions of the findings with each of the diagnostic modalities. These data offer Level III diagnostic evidence of the utility of dynamic radiographs, CT, MRI and myelography for evaluation of degenerative spondylolisthesis.

Rosenberg et al[47] conducted a retrospective study which characterized 200 consecutive patients with degenerative lumbar spondylolisthesis. This cohort contained a subgroup of 39 patients with severe unremitting symptoms; 29 underwent myelography and showed an hourglass constriction of the dura at the level of slippage. Seven patients also had a protrusion. Surgical findings include absence of epidural fat, pale pulseless dura and decreased capacity of the spinal canal.

In critique of this study, data were collected retrospectively and tests were not uniformly applied across patients. However, from the diagnostic perspective, this small subgroup of 29 patients provides a consecutive series of patients that was retrospectively analyzed. These subgroup data provide Level II diagnostic evidence that myelography is useful in identifying stenosis in patients with degenerative spondylolisthesis and neurological symptoms.

Satomi et al[51] reported findings from a retrospective case series of patients with degenerative spondylolisthesis who were evaluated with CT myelography in order to plan the optimal surgical procedure. CT myelograms were compared with plain radiographic myelograms to evaluate the sites of dural compression.

Patients who underwent anterior lumbar interbody fusion (ALIF) were included in Group A. Patients were selected for the posterior decompression group (Group B) if their imaging showed displacement at two or more discs, had CT myelographic findings indicating lateral stenosis or were deemed inappropriate candidates for ALIF because of age. Group A consisted of 27 patients; discography was performed in 22. Based on the novel CT myelogram classification used in the study, 38% of these patients had stage 3 stenotic changes. Group B consisted of 14 patients, five of whom underwent fusion. Of these patients, four reported back pain; neurogenic intermittent claudication was more severe in group B. Discography was performed in two patients. Based on myelogram classification used in the study, 62% of these patients had stage 3 stenotic changes. Stenosis over two disc space levels was present in 92% of these patients. The authors concluded that information on CTM was useful for identifying pathologic processes and for planning surgery.

In critique of this study, the authors did not evaluate a list of diagnostic criteria a priori. The authors failed to indicate whether patients were selected consecutively. These data offer Level III diagnostic evidence that CT myelography is a useful imaging study for this disorder.

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.

Work Group Consensus Statement

Based on NASS' *Clinical Guideline for Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis* (2007), CT was demonstrated to be an effective diagnostic tool to detect degenerative lumbar spinal stenosis. As many patients included in the review had degenerative spondylolisthesis, it is logical to conclude that CT would be useful in this group as well. However, only one disease-specific study was found, necessitating reference to the NASS Clinical Guideline on Lumbar Spinal Stenosis to support this consensus statement.

Rothman et al[48] conducted a retrospective review of the CT findings of 150 patients with degenerative spondylolisthesis. The authors described the pathological findings, which included canal stenosis, facet overgrowth, joint-capsule hypertrophy, ligamentum flavum enlargement and gas within the facet joints.

All patients were examined on GE 8800 CT scanners using axial scans of 5 mm-thick sections at 3 mm spacing, with sagittal and coronal reformats. The authors found only 19% had subluxation greater than 6 mm. Severe facet degeneration with marked hypertrophy, erosive changes or gas within an irregular joint was noted in 91 patients. Severe canal stenosis was detected in 15 patients as a result of narrowing of the central canal secondary to a combination of subluxation, facet boney overgrowth, joint-capsule hypertrophy, ligamentous hypertrophy, bulging and end plate osteophyte formation. Foraminal stenosis was observed in 38 patients. Anterior soft tissue bulge/herniation of greater than 5 mm was present in only three patients. The authors concluded that CT is useful in evaluating the severity of stenosis in patients with symptomatic degenerative spondylolisthesis. Stenosis is frequently secondary to soft tissue changes and facet hypertrophy, and does not always correlate with the severity of slip.

In critique, this was a study of nonconsecutive patients, radiological findings were not correlated with clinical signs or symptoms, and no gold standard was employed. The data present Level IV diagnostic evidence that CT is a useful modality in the diagnosis of stenosis in patients with degenerative spondylolisthesis.

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 degenerative lumbar spondylolisthesis. These studies should assess a set of diagnostic criteria established a priori.

Recommendation #1:

The work group recommends a prospective, appropriately powered study assessing the utility of supine (gold standard), standing and dynamic flexion-extension lateral radiographs in the evaluation of patients with degenerative spondylolisthesis.

Recommendation #2:

The work group recommends a prospective, appropriately powered study assessing the utility of supine recumbent (gold standard), axial loaded and positional MRI in the detection and evaluation of stenosis via analysis of the dural sac area in patients with degenerative spondylolisthesis.

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B. Outcome Measures for Medical/Interventional and Surgical Treatment

What are the appropriate outcome measures for the treatment of degenerative lumbar spondylolisthesis?

Asking this question about the treatment of degenerative lumbar spondylolisthesis is intrinsically valuable. Our review of the literature on degenerative lumbar spondylolisthesis with symptoms of spinal stenosis confirmed that outcome studies are valuable in determining the course of treatment.

When evaluating studies in terms of the use of outcome measures, the work group evaluated this literature as prognostic in nature. Prognostic studies investigate the effect of a patient characteristic on the outcome of a disease. Studies investigating outcome measures, by their design, are prognostic studies.

An appropriate clinical outcome measure must be validated. Further, the validated outcome measure must be used in a high quality, prospective outcome trial in order to be useful. The literature review yielded no validated outcome measures utilized for the subset of patients with back pain and degenerative lumbar spondylolisthesis.

The Zurich Claudication Questionnaire (ZCQ)/Swiss Spinal Stenosis Questionnaire (SSS), Oswestry Disability Index (ODI), Likert Five-Point Pain Scale and 36-Item Short Form Health Survey (SF-36) are appropriate measures for assessing treatment of degenerative lumbar spondylolisthesis.

Grade of Recommendation: A

Note: The Zurich Claudication Questionnaire (ZCQ) represents an evolution of Swiss Spinal Stenosis Questionnaire (SSS). Conclusions made about either questionnaire have a high likelihood of being applicable to the other.

Anderson et al[1] described a randomized (post hoc) controlled trial of patients with neurogenic claudication secondary to degenerative spondylolisthesis. Of the 75 spondylolisthesis patients included in the study, 42 received the X STOP device and 33 were included in the control group assigned to medical/interventional treatment consisting of at least one epidural steroid injection, drugs, analgesic agents and physical therapy as needed. Two-year follow-up data were obtained for 70 of the 75 patients.

The outcome measures implemented in the study included the Zurich Claudication Questionnaire (ZCQ), patient satisfaction on a scale from 0-5, 36-Item Short Form Health Survey (SF-36) and radiographic assessment. Successful treatment was defined as improvement in ZCQ of 15 points, patient satisfaction of greater than 2.5 and no additional surgery. The authors reported that success was noted in 63.4% of the surgically treated individuals, which was statistically significant between preoperative and postoperative scores. Only 12.9% of medically/interventionally treated patients were considered successes which was not statistically significant between pretreatment and posttreatment patients. The authors concluded that the clinical success for the X STOP surgically treated patients compared with the medically/interventionally treated controls was highly significant.

In critique, this study was a cohort analysis of a randomized prospective trial for spinal stenosis. The cohort studied consisted of patients who had grade I spondylolisthesis as well as spinal stenosis. The outcome measures used included both validated and nonvalidated outcome measures including

the validated Zurich Claudication Questionnaire (ZCQ) and an arbitrary patient satisfaction survey at follow-up visits. Although the authors obtained SF-36 outcome data, these data were not used in the study to determine clinical success.

This study provides Level II prognostic evidence supporting use of the Zurich Claudication Questionnaire (ZCQ) and the SF-36 outcome measures as sensitive tools in distinguishing the outcome differences between surgically treated (X STOP) and medically/interventionally treated individuals.

Frazier et al[7] reported a prospective, observational study evaluating the prognostic factors affecting clinical outcomes as correlated to the presence or absence of the deformities of degenerative scoliosis and spondylolisthesis. The outcome measure implemented in the study included a questionnaire administered preoperatively, and at six and 24 months postoperatively. Patients rated the severity of back pain, leg pain, overall pain and difficulty ambulating using a Five Point Likert Pain Scale. A Walking Capacity Scale was calculated using the average responses to five questions on walking difficulty in general, outdoor, indoor, shopping and bedroom to bathroom walking. The patient satisfaction scale was generated by using the average for six questions concerning satisfaction with pain relief, functional improvement and other domains. The authors stated that these scales had been shown to be reproducible, internally consistent and valid for patients with spinal stenosis. No statistical support for these statements was provided.

The authors reported that the spondylolisthesis subgroup showed no correlation of slip magnitude and patient outcomes. An increase in the slip postoperatively was significantly correlated with improved leg pain relief and borderline improvement in walking capacity. Satisfaction with the procedure and back pain relief was positively, but not significantly, correlated with slip progression. The authors concluded that surgery was beneficial, but that fusion rationale may be questioned.

In critique, this study was not designed to validate the Walking Capacity Scale or the Five Point Likert Pain Scale as sensitive measures for degenerative spondylolisthesis. However, these measures have been previously validated by Stucki et al38 as the SSS, currently referred to as the ZCQ.

This study offers Level II prognostic evidence that the ZCQ/SSS is sensitive enough to show differences between surgically and medically/interventionally treated patients with degenerative spondylolisthesis and symptomatic spinal stenosis.

Gaetani et al[8] described a prospective, prognostic study of 76 patients treated with decompression and bilateral instrumented fusion and followed for two years. There were 25 males and 51 females with a mean age of 59.6 years (+/-12.2) and mean duration of symptoms of 23.42 months. The outcome measures used in the study included the Roland Morris Disability Questionnaire (RMDQ); Oswestry Disability Index (ODI) for quality of life patient centered outcomes; Visual Analog Scale (VAS) for leg and back pain; preoperative dynamic X-ray studies, CT, and MRI; and postoperative X-ray studies.

The authors reported a fusion rate of 85.5%, improvement in ODI scores of less than 20 points in 35.7% of patients and greater than 20 points in 55.7%. Scores on the RMDQ improved greater than five points in 59.4% of patients, 2-4 points in 13.1%, and remained unchanged in 27.5%. There was no difference between solid fusion and pseudoarthrosis. The authors concluded that instrumented fusion was effective in improving the quality of life, as exhibited by the reduced disability scores.

In critique of this study, this study provides only 24-month follow-up data. This time frame may not be long enough to fully evaluate the effect of pseudoarthrosis on patient outcomes. This study

provides Level I prognostic evidence suggesting correlation of RMDQ and ODI scores with symptoms and slippage. The RMDQ appears to be a sensitive tool to assess degenerative spondylolisthesis outcome data. This study shows improvement in the quality of life scores in both outcome tools. The study also supports the conclusion that the presence or absence of fusion was not a prognostic indicator of patient outcome improvements.

Ghogowala et al[10] conducted a prospective study assessing the outcomes of decompression alone in 20 patients and decompression with instrumented fusion in 14 patients with degenerative grade I lumbar spondylolisthesis. The outcome measures implemented included the ODI and the SF-36.

The authors reported that fusion occurred at a 93% rate in the arthrodesis group. The ODI improved 27.5 points in the fusion group and 13.6 points in the decompression only group. The difference was statistically significant. The SF-36 data was also significantly different between the two groups. Both instruments, SF-36 and ODI, demonstrated poorer outcomes in older patients at 12 months.

In critique of this study, this was a small pilot study demonstrating a clear need for future Level I randomized controlled trials utilizing these measures. This study provides Level II prognostic evidence supporting the use of the ODI and SF-36 as tools to assess outcomes after surgery for degenerative spondylolisthesis. These two outcome tools identify similar and parallel changes in outcomes of the treatment groups, and this study supports the use of these two outcome measures together to effectively assess outcomes in this population. Evidence of the ability to discriminate between treatment outcomes using the ODI and SF-36 is supported by the findings in this study that older patients demonstrated poorer outcomes than younger patients.

Kornblum et al[20] reported on 58 patients extracted from a prospective, randomized, controlled trial of posterior decompression and fusion to determine the relationship of presence or absence of pseudoarthrosis to outcomes. Of the 118 patients originally randomized to decompression or decompression with a noninstrumented fusion, 58 patients underwent fusion, of which 47 were available for review. The outcome measures used in this study included the Visual Analog Scale (VAS) (modified), a rudimentary outcome scale (excellent, good, fair, poor) and the Swiss Spinal Stenosis Questionnaire (SSS). The authors reported that arthrodesis does result in better outcomes on the SSS at five to14 years as opposed to earlier follow-up.

In critique of this study, the bundling of these patients and subsequent evaluation at three year follow-up represents a significant weakness of the study. The SSS was not applied preoperatively, but was only administered postoperatively. This study provides Level I prognostic evidence suggesting that the SSS is a sensitive, validated instrument which correlates well with patient outcome, and is appropriate for use in the assessment of clinical outcomes for degenerative lumbar spondylolisthesis.

Pratt et al[29] conducted a prospective, prognostic study evaluating outcome instruments in all patients who attended the Nuffield Orthopaedic Center. These were patients with spinal stenosis, which included patients with degenerative spondylolisthesis.

Of the 52 patients approached to participate in the study, 13 declined involvement and seven were excluded because of comorbidities, ie, limiting walking distance. To determine reliability, the 32 clinic patients with lumbar spinal stenosis were assessed twice, with one week between assessments. Retrospective data from 17 patients assessed before surgery and 18 months after surgery for lumbar spinal stenosis were used to investigate the use of reliability in a clinical setting.

The patients were assessed using the Oswestry Disability Index (ODI) and three instruments designed specifically for use in patients with lumbar spinal stenosis: the Swiss Spinal Stenosis (SSS) Questionnaire, the Oxford Claudication Score (OCS) and a functional test, the Shuttle Walk Test (SWT). Patient outcomes were studied by the previously validated outcome studies, the SSS and ODI. The OCS and SWT were studied in relation to these previously validated outcome measures.

Data analysis included a test against normality using the Komolgorov-Smirnov-Goodness-of-Fit test. The test-retest reliability of the SSS, OCS, ODI and SWT were assessed with an internal correlation coefficient test in which the reliability was the subject variability/ (subject variability + measurement error). The 95% confidence intervals for each outcome instrument were reported.

The internal consistency of the scales and their subsections was assessed using Cronbach's coefficient alpha, which summarizes interitem correlations. The relationship between the four tests was assessed using scatter plots, according to the method of Bland and Altmann, and the Pearson product–moment correlation coefficient (two-tailed). Bonferroni's correction was used for multiple tests to reduce the chance of Type 1 error.

Test–retest reliability in terms of the intraclass correlation coefficient (ICC) was 0.92 for the SWT, 0.92 for the SSS, 0.83 for the OCS and 0.89 for the ODI. The mean percentage scores were 51 for the SSS, 45 for the OCS, and 40 for the ODI. To achieve 95% certainty of change between assessments for a single patient, the SSS would need to change by 15, the OCS by 20 and the ODI by 16.

The mean SWT was 150 m, with a change of 76 m required for 95% confidence. Cronbach's alpha was 0.91 for the SSS, 0.90 for the OCS, and 0.89 for the ODI. The change in ODI correlated most strongly with patient satisfaction after surgery (0.80; $P \leq 0.001$).

In critique of this study, the subset of patients with degenerative spondylolisthesis was not broken out and analyzed separately from the stenosis group. Fluctuations in a patient's symptoms resulted in wide individual confidence intervals. Performance on the SSS, OCS and ODI questionnaires are broadly similar, the most precise being the condition-specific SSS. The SWT gives a snapshot of physical function, which is acceptable for group analysis. Use of the SWT for individual assessment after surgery is feasible.

This study offers Level I prognostic evidence that the ODI, SSS, OCS and SWT tests reliably and validly evaluate patients with symptomatic spinal stenosis within which a subgroup of degenerative spondylolisthesis patients reside.

Stucki et al[38] described a prospective, prognostic study of the Zurich Claudication Questionnaire (ZCQ) or Swiss Spinal Stenosis (SSS) Questionnaire, an outcome instrument specific to spinal stenosis. The measurement properties and validity of this newly-developed patient questionnaire for the assessment of patients with lumbar spinal stenosis was tested in an ongoing prospective multicenter observational study of patients undergoing decompressive surgery in three teaching hospitals.

The internal consistency of the scales was assessed with Cronbach's coefficient alpha on cross-sectional data from 193 patients before surgery. The test-retest reliability was assessed on data from a random sample of 23 patients using Spearman's rank correlation coefficient. The responsiveness was assessed on 130 patients with six-month follow-up data using the standardized response mean. The test-retest reliability of the scales ranged from 0.82 to 0.96, the internal consistency from 0.64 to 0.92, and the responsiveness from 0.96 to 1.07. The direction, statistical significance and strength of hypothesized relationships with

external criteria were as expected.

In critique, of the 193 patients included in this study, only 23 had pretest and posttest validation of the SSS. The follow-up on 130/193 patients for test responsiveness at six months is arguably short. Because of these shortcomings, this potentially Level I prospective study was downgraded to a Level II study. Although the reproducibility, internal consistency, validity and responsiveness of this test were established by comparison with known validated outcome measurement instruments, these instruments are not necessarily specific to degenerative lumbar spondylolisthesis. In addition, the extent of stenosis and associated pathology was not clear. Patients with language barriers and cognitive difficulties were excluded.

This study provides Level II prognostic evidence that the devised questionnaire scales of symtom severity, physical function and satisfaction are reproducible, internally consistent, valid and responsive measures of outcome in patients with degenerative lumbar spondylolisthesis with symptomatic spinal stenosis. This instrument is currently referred to as the Zurich Claudication Questionnaire (ZCQ) or Swiss Spinal Stenosis Questionnaire (SSS).

Vaccaro et al[39] reported a prospective, randomized control trial comparing surgical outcomes in patients randomly assigned to receive either OP1 putty (24 patients) or autograft bone (12 patients) in conjunction with decompressive laminectomy for the treatment of degenerative lumbar spondylolisthesis. The outcome measures utilized in this study included the ODI, SF-36 and radiographic assessment.

At one year, of the 36 patients studied, 32 were available for clinical follow-up (18 in the OP1 group and eight in the autograft group) and 29 received radiographic assessment (14 in the OP1 group and six in the autograft group). ODI success was defined by greater than 20% improvement in scores at one year. An 86% success rate was reported for the OP1 putty group, and a 73% success rate was reported for the patients receiving autograft. According to radiographic criteria, fusion was achieved in 74% of patients in the OP1 group and 60% of patients in the autograft group. Of the 29 patients evaluated radiographically, 15 were defined as both radiographically and clinically successful, while five were categorized as radiographically successful with clinical failure and eight were classified as radiographic failures, but achieved clinical success.

In critique of this study, clinical success was arbitrarily defined as a 20% improvement in ODI scores. The authors failed to justify the choice of this benchmark. The study does not correlate any outcome instruments to the ODI. This study provides Level II prognostic evidence that the ODI can be used to assess clinical outcome after surgical treatment of degenerative spondylolisthesis.

Weinstein et al[42] conducted a prospective, randomized control trial evaluating the outcomes of surgical treatment of degenerative spondylolisthesis compared with medical/interventional treatment in 304 patients. The study also included a second observational cohort of 303 patients who refused randomization, but agreed to participate in the study.

The primary outcome measures used in the study included the Medical Outcomes Study SF-36 bodily pain and physical function scores and the modified Oswestry Disability Index. Data were collected at six weeks, three months, six months, one year and two years. Secondary outcomes measures included patient reported improvement, satisfaction with current symptoms and care, Stenosis Bothersome Index and LBP Bothersome Index.

Within the randomized arm of the study, the authors reported a 40% crossover in each direction. Intention-to-treat analysis showed no significant

differences in any outcome. As-treated analysis for both cohorts showed significant advantages at three months that increased at one year and was durable at two years. Treatment effects at two years were 18.1 for bodily pain (95%, CI 14.5-21.7) 18.3 for physical function (95%, CI 14.6-21.9) and -16.7 for ODI (95%, CI -19.5 to -13.9). There is little evidence suggesting harm with either surgical or medical treatment.

In critique of this study, the secondary outcome measures, Stenosis Bothersome Index and LBP Bothersome Index, have not been specifically validated for degenerative lumbar spondylolisthesis. This study provides Level I prognostic evidence from both the randomization and observational cohorts that the primary outcome measures, Medical Outcomes Study SF-36 bodily pain and physical function scores and the modified Oswestry Disability Index, are appropriate instruments to use in detecting treatment effects in patients with degenerative lumbar spondylolisthesis.

The Japanese Orthopedic Association (JOA) Score and the calculated Recovery Rate may be useful in assessing outcome in degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

Kawakami et al[16] performed a retrospective case control study of 47 patients (15 males / 32 females) who had undergone decompression and fusion with and without instrumentation. Pedicle screw fixation was used in those cases with a fixed kyphosis at the involved segment. The outcome measures used included the Japanese Orthopedic Association (JOA) score, VAS, recovery rate (Hirabayashi's method), slippage, L1 axis S1 distance (LASD), lumbar lordosis, lordosis at the fused segment, bony union and adjacent segment changes.

Patients with degenerative lumbar spondylolisthesis were divided into two groups according to the LASD value and the changes in slippage during the follow-up period: the patients with LASD greater than 35 mm (Group A) and those with LASD less than 35 mm (Group B). The patients in Group A were divided into two subgroups: the patients with in situ fusion (Group A1) and patients with reduced slippage (Group A2).

The authors reported that the JOA scores were 12.6 points +/- 4.8 preoperatively and 21.7 points +/- 4.9 postoperatively, and the recovery rate was 55.1% +/- 27.8%. There were no differences in the prognostic factors of preoperative slip, lumbar lordosis, lordosis of fused segment and recovery rates. LASD and recovery rate were negatively correlated. Patients in Group A1 had poorer JOA scores and recovery rates than those in Groups A2 and B.

In critique, this study utilized a validated outcome measure commonly used in Japan that has not gained universal acceptance. The paper was designed as a clinical outcome study, rather than a prognostic study evaluating the JOA outcome measure, specifically. This study provides Level III prognostic evidence suggesting that the JOA score and recovery rate may be sensitive outcome tools in assessing treatment for degenerative lumbar spondylolisthesis.

Okuda et al[24] conducted a comparative retrospective prognostic study including 101 elderly patients with degenerative spondylolisthesis treated with posterior lumbar interbody fusion (PLIF). Patients were divided into two groups based upon age. Group 1 included patients aged 70 years and older, while Group 2 included patients from 55 years to 69 years of age at the time of the index procedure. The authors compared treatment outcomes between both groups to determine differences in outcome based upon age. The outcome measures used in this study included the JOA score, VAS, complication rates, recovery rate (Hirabayashi method) and radiographic evaluation.

The authors reported that in Group 1, the JOA improved from 12 to 23; the recovery rate was 63%; and general complications, delirium and brain infarct occurred in 10% of patients. In Group 2, the JOA improved from 12 to 24 and the recovery rate was 70%.

In critique of this study, 39% of the cases were not independently reviewed. This study provides Level II prognostic evidence that the JOA shows improvement in functional outcome with surgical treatment regardless of age, but is not correlated with other measures of functional outcomes. Older patients, despite higher definable complication rates (approaching 10%) showed similar recovery rates and JOA scores to younger patients.

The Shuttle Walking Test (SWT), Oxford Claudication Score (OCS), Low Back Pain Bothersome Index and Stenosis Bothersome Index are potential outcome measures in studying degenerative lumbar spondylolisthesis.

Grade of Recommendation: I (Insufficient Evidence)

Pratt et al[29] conducted a prospective prognostic study evaluating outcome instruments in all patients who attended the Nuffield Orthopaedic Center. These were patients with spinal stenosis, which included patients with degenerative spondylolisthesis.

Of the 52 patients approached to participate in the study, 13 declined involvement and seven were excluded because of comorbidities limiting walking distance. To determine reliability, the 32 clinic patients with lumbar spinal stenosis were assessed twice, with one week between assessments. Retrospective data from 17 patients assessed before surgery and 18 months after surgery for lumbar spinal stenosis were used to investigate the use of reliability in a clinical setting.

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In critique of this study, the secondary outcome measures, Stenosis Bothersome Index and LBP Bothersome Index, have not been specifically validated for degenerative lumbar spondylolisthesis. This study provides Level I prognostic evidence from both the randomization and observational cohorts that the primary outcome measures, Medical Outcomes Study SF-36 bodily pain and physical function scores and the modified Oswestry Disability Index, are appropriate instruments to use in detecting treatment effects in patients with degenerative lumbar spondylolisthesis.

Future Directions for Research

Further studies are needed to validate additional outcome measures (Stenosis Bothersome Index, LBP Bothersome Index, Oxford Claudication Score, Shuttle Walking Test, JOA and Calculated Recovery Rate) for the treatment of degenerative lumbar spondylolisthesis. Currently, the best outcome measure for degenerative spondylolisthesis with symptoms of spinal stenosis is the ZCQ/SSS as a disease-specific outcome tool. General health outcome tools that are appropriate for degenerative lumbar spondylolisthesis are the SF-36 and ODI.

Degenerative lumbar spondylolisthesis with back pain alone needs to be defined as a stand-alone clinical entity by outcomes research. The use of these outcome measures in this subgroup of patients needs to be studied.

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C. Medical and Interventional Treatment

A systematic review of the literature yielded no studies to adequately address any of the medical/interventional treatment questions posed below:

1. Do medical/interventional treatments improve outcomes in the treatment of degenerative lumbar spondylolisthesis compared to the natural history of the disease?

2. What is the role of pharmacological treatment in the management of degenerative lumbar spondylolisthesis?

3. What is the role of physical therapy/exercise in the treatment of degenerative lumbar spondylolisthesis?

4. What is the role of manipulation in the treatment of degenerative lumbar spondylolisthesis?

5. What is the role of epidural steroid injections for the treatment of degenerative lumbar spondylolisthesis?

6. What is the role of ancillary treatments such as bracing, traction, electrical stimulation and transcutaneous electrical stimulation (TENS) in the treatment of degenerative lumbar spondylolisthesis?

7. What is the long-term result of medical/interventional management of degenerative lumbar spondylolisthesis?

Unfortunately, a thorough literature search targeted at the subset of stenotic patients with degenerative lumbar spondylolisthesis yielded a paucity of evidence addressing medical/interventional treatment. A thorough literature search identified a total of 47 articles related to medical/interventional treatment. Work group members reviewed all abstracts and identified nine articles to review in order to address the questions above and to identify any other relevant articles cited in the reference sections.

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). Patients with degenerative lumbar spondylolisthesis can be asymptomatic, present exclusively with axial back pain or present with neurogenic claudication and/or radicular pain with or without accompanying axial back pain. Treatment for each of these patient populations will be different. Identifying relevant studies and formulating evidence-based treatment recommendations for subpopulations of the degenerative lumbar spondylolytic patients (eg, axial back pain only, combination of axial back pain and radiculopathy) was not feasible as none of the studies presented results stratified by symptomatology.

Medical/interventional treatment for degenerative lumbar spondylolisthesis, when the radicular symptoms of stenosis predominate, most logically should be similar to treatment for symptomatic degenerative lumbar spinal stenosis.

Work Group Consensus Statement

Treatment recommendations and the supporting evidence are available in the NASS guideline *Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis* (2007) available on the NASS Web site at (www.spine.org).

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 degenerative lumbar spondylolisthesis.

Recommendation #1:

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

Recommendation #2:

Future outcome studies of degenerative lumbar spondylolisthesis should include results specific to each of the medical/interventional treatment methods, presenting results stratified by patient symptomatology (eg, axial back pain only, combination of axial back pain and radiculopathy).

Recommendation #3:

Although the review was devoid of studies examining the benefits of physical therapy with a directional preference (eg, avoiding extension) in patients with degenerative lumbar spondylolisthesis, this appears to be an area of growing interest. Accordingly, the group suggests that a randomized controlled study comparing the benefits of physical therapy with directional preference versus nonpreferential therapy for the treatment of degenerative lumbar spondylolisthesis would be useful.

Medical/Interventional Treatment References

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D. Surgical Treatment

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

Surgery is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: B

Anderson et al[1] reported subgroup analysis data from a large, randomized controlled trial dealing with spinal stenosis. As such, this represents a prospective, comparative study of 75 patients with neurogenic claudication from lumbar spinal stenosis and low grade (less than 25% translation) spondylolisthesis who were treated either with the X STOP device (an interspinous process spacer) or with medical/interventional treatment. The medical/interventional (control) group did receive treatment, which included at least one epidural steroid injection, medications and physical therapy. Thus, this group was not truly representative of the natural history of the disorder. At two-year follow-up, there were statistically significant improvements in the Zurich Claudication Questionnaire (ZCQ) score and patient satisfaction in those treated with X STOP; there were no statistically significant improvements in the medical/interventional group.

In critique of this study, the cohort of 75 patients was derived from a larger pool of candidates with spinal stenosis (and not necessarily spondylolisthesis) that were randomized into the X STOP treatment group and medical/interventional group. However there were no significant baseline differences detected between the groups. Five patients in the X STOP group and four patients in the medical/interventional group subsequently underwent a laminectomy. It is unclear if the data from these patients were included as an intention-to-treat analysis.

If one were to equate medical/interventional treatment including injections, therapy and medications with natural history, this study offers Level III therapeutic evidence that surgical treatment in the form of an interspinous spacer improves upon the natural history of neurogenic claudication and spinal stenosis with low grade degenerative spondylolisthesis.

Weinstein et al[6] conducted a multicenter, prospective, randomized controlled trial comparing surgery and medical/interventional treatment for neurogenic claudication from spinal stenosis and degenerative spondylolisthesis. In addition, there was a nonrandomized observational arm that compared the two treatment options. Eligible patients had symptoms for at least 12 weeks and could have had medical/interventional treatment prior to enrollment. Surgical treatment included laminectomy with or without fusion; however, few patients underwent laminectomy alone. Medical/interventional treatment included at least active physical therapy, education/counseling and medications. In critique of this study, there was a high crossover rate between study groups. For instance, 49% of those patients assigned to medical/interventional treatment had undergone surgery at two-year follow-up. Likewise, only 64% of those who were assigned to the surgical group had undergone surgery by two years. Because of the high degree

of crossover, this study is more appropriately considered a prospective, comparative study. The as-treated analysis showed statistically better outcomes with surgery that were maintained at the two year follow-up. Medical/interventional treatment included at least active physical therapy, education/counseling and medications; however, this was not standardized by any particular protocol.

If one were to equate medical/interventional treatment including injections, therapy and medications with natural history, this study offers Level II therapeutic evidence that surgical treatment in the form of a laminectomy with or without fusion improves upon the natural history of neurogenic claudication and spinal stenosis with degenerative spondylolisthesis.

Future Directions for Research

The SPORT study demonstrated the intrinsic difficulties in conducting RCTs comparing surgical to medical/interventional treatment in the North American patient population. It is unlikely that higher quality data are achievable for the comparison of surgical and medical/interventional treatment.

Surgical Treatment Versus Natural History References

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

Direct surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Matsudaira et al[17] conducted a retrospective comparative study of 53 patients with spinal stenosis and grade I degenerative spondylolisthesis. Nineteen underwent decompression with instrumented fusion, 18 underwent decompressive laminoplasty without fusion, and 16 had medical/interventional treatment. At a minimum of two years follow-up, patients in both surgical treatment groups showed significantly better improvements in Japanese Orthopaedic Association (JOA) scores than the medical/interventional group.

In critique of this study, the sample was modest, particularly considering there were only 16 patients in the medical/interventional group. To be used to answer the current question, one has to assume that medical/interventional treatment is equivalent to natural history. In support of the study, patients uniformly had grade I degenerative spondylolisthesis. This paper provides Level III therapeutic evidence that decompressive surgery alone in the form of a decompressive laminoplasty results in better outcomes than the natural history of spinal stenosis with grade I degenerative spondylolisthesis.

Indirect surgical decompression is recommended for treatment of patients with symptomatic spinal stenosis associated with low grade degenerative lumbar spondylolisthesis whose symptoms have been recalcitrant to a trial of medical/interventional treatment.

Grade of Recommendation: I (Insufficient Evidence)

Anderson et al[1] performed a subgroup analysis of 75 patients with grade I degenerative spondylolisthesis who were originally included in the pivotal randomized controlled trial comparing the X STOP device and medical/interventional treatment for spinal stenosis with neurogenic claudication that was relieved by flexion and sitting. Although examined prospectively, this subgroup was not appropriated to surgical and medical/interventional treatment in a truly randomized fashion.

Forty-two patients had the X STOP device placed, while 33 had medical/interventional treatment that included at least one epidural steroid injection, medications and physical therapy as needed. Only 70 of 75 patients had a minimum of two year follow-up. Of patients in the X STOP group, 63% had significant improvements in the Zurich Claudication Questionnaire (ZCQ) score, while 12% in the medical/interventional group had significant improvements.

In critique of this study, although labeled by the authors as a randomized controlled trial, it was not such for patients with degenerative spondylolisthesis. Patient numbers were relatively low. In support of their findings, there was a low attrition rate (7% at two year follow-up). Furthermore, the investigators utilized a validated outcome instrument, the

ZCQ. This study offers Level III therapeutic evidence that an interspinous distraction device that provides indirect decompression leads to better outcomes in patients with spinal stenosis and grade I degenerative spondylolisthesis than does medical/interventional intervention.

Future Directions for Research

Because of the lack of clarity of the ideal candidate for decompression alone, a large scale randomized controlled trial may be logistically and ethically difficult to perform. The work group acknowledges that recently published high profile studies (SPORT trials) demonstrated the intrinsic difficulties in conducting RCTs comparing surgical to medical/interventional treatment in the North American patient population. It is unlikely that higher quality data are achievable for the comparison of surgical and medical/interventional treatment.

A greater number of nonindustry-sponsored, independent, randomized controlled trials need to be done to validate what appears to be an effective and minimally invasive means (interspinous spacers) of decompressing the spinal canal in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Surgical Decompression Versus Natural History or Medical Treatment References

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

Surgical decompression with fusion is recommended for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis to improve clinical outcomes compared with decompression alone.

Grade of Recommendation: B

Bridwell et al[4] described a prospective, comparative study of 44 surgically treated patients with degenerative lumbar spondylolisthesis followed for a minimum of two years. Of the 44 patients, nine underwent laminectomy alone, 10 had laminectomy and instrumented fusion and 24 had laminectomy and instrumented fusion (18 single level, six two-level). Patients were radiographically assessed and a functional assessment was conducted by asking whether they felt their ability to walk distances was worse (-), the same (0) or significantly better (+). Of the 44 patients, 43 were followed for two years or more.

The authors determined that instrumented fusion had higher fusion rates than noninstrumented fusion (ρ=0.002). The authors further observed greater progression of spondylolisthesis in patients treated with laminectomy alone (44%) and in laminectomy without instrumented fusion (70%) compared to patients who received laminectomy with instrumented fusion (4%,ρ=0.001). A higher proportion of the patients without slippage progression reported that they were helped by the surgery than those whose slippage progressed postoperatively (ρ<0.01).

In critique, this was a small study in which selection bias entered into the randomization process, reviewers were not masked to patient treatment and validated outcome measures were not utilized. Because of these weaknesses, this potential Level II study was downgraded to Level III. This study provides Level III therapeutic evidence that instrumented fusion patients had less chance of progressive slippage postoperatively than laminectomy alone or noninstrumented fusions and a higher proportion of patients with stable or unchanged spondylolisthesis reported greater improvement after surgery.

Herkowitz et al[15] conducted a prospective, comparative study of 50 patients with degenerative lumbar spondylolisthesis who were studied clinically and radiographically to determine if concomitant intertransverse process arthrodesis provided better results than decompression alone. Outcomes were assessed using a rudimentary outcome scale (excellent, good, fair, poor) with a mean follow-up of three years.

The authors reported that of the 25 patients treated with decompression and fusion, 11 reported excellent results, 13 good, one fair and zero poor. Of the 25 patients treated with decompression alone, two reported excellent results, nine good, 12 fair and two poor. Improved results in the patients who had an arthrodesis concomitantly with decompression were significant by the Fisher exact test (ρ=0.0001). The authors concluded that in patients who had a concomitant arthrodesis, the results were significantly better with respect to relief of low back pain and lower limb pain.

In critique, this was a small study which did not utilize validated clinical outcome measures or describe baseline characteristics of the groups.

Because of these weaknesses, this potential Level II study was downgraded to Level III. This study offers Level III therapeutic evidence that decompression with arthrodesis in patients with degenerative lumbar spondylolisthesis provides significantly better relief of low back pain and leg pain than decompression alone.

Mardjetko et al[23] performed a meta-analysis of primarily Level III studies. The objective of the study was to analyze the published data on degenerative spondylolisthesis to evaluate the feasibility of its use as a literature control to compare with the historical cohort pedicle screw study data.

The authors conducted a comprehensive literature search to identify studies published in English peer-reviewed journals between 1970 and 1993 addressing degenerative spondylolisthesis with radicular leg pain or neurogenic claudication. Inclusion criteria included a minimum of four cases reviewed and reporting of the primary outcome variable of fusion in articles in which this was part of the treatment. Clinical outcome variables of back pain, leg pain, function, neurogenic claudication and global outcome scores were recorded when available. A total of 25 papers representing 889 patients were accepted for inclusion. Twenty-one were retrospective, nonrandomized and uncontrolled. One paper was retrospective and nonrandomized, but compared two different treatments. Three prospective, randomized studies were included.

The primary outcome variable, fusion, was determined by each author. The most constant clinical outcome variable reported was pain with 16 papers reporting pain only, six papers reporting pain and function, and two papers reporting patient-determined outcomes. Patient function was reported in six papers and referred to the presence or absence of neurogenic claudication. In addition to these clinical outcomes, four papers reported a global evaluation. Two used Kaneda's rating system and two used the Japanese Orthopedic Association (JOA) score. Excellent and good results were reassigned as satisfactory; poor results were classified as unsatisfactory.

The authors reported that in the decompression alone category, 11 papers representing 216 patients were accepted. Sixty-nine percent of patients had a satisfactory outcome. The incidence of worsened postoperative slip was 31% but was not associated with a poorer clinical result in the majority of patients.

In the category of decompression with fusion and no instrumentation, six papers qualified for inclusion. In one paper, only fusion data were broken out for the diagnosis of degenerative spondylolisthesis and were used just for this outcome variable. Ninety percent of the patients in this category had a satisfactory outcome; 86% achieved solid spinal fusion. With regard to clinical outcome, the difference between patients treated with decompression without fusion (69% satisfactory) and those treated with decompression and fusion without instrumentation (90% satisfactory) was statistically significant ($P < 0.0001$).

In the decompression with fusion and pedicle screws category, five studies met the inclusion criteria. Fusion status was analyzed in 101 patients. Eighty-five patients were analyzed with respect to clinical outcome. One paper did not separately analyze clinical data, but did so for fusion data; therefore, only fusion data were included. The proportionally weighted fusion rates for this group were 93%. When comparing the fusion without instrumentation group to the fusion with pedicle screw group, there was not a statistically significant increase in fusion rate ($P = 0.08$). Analysis of the clinical outcomes reveals an 86% satisfactory rating for the pedicle screw group. This compares favorably to the 69% satisfactory rate in the decompression without fusion group ($P <0.0001$).

In the anterior spinal fusion category, three papers

presenting the results for 72 patients who received anterior spinal fusion for the treatment of degenerative spondylolisthesis were included. Pooling the data from these three studies yielded a 94% fusion rate with an 86% rate of patient satisfaction.

The authors concluded that the meta-analysis results support the clinical impression that, in the surgical management of degenerative lumbar spondylolisthesis, spinal fusion significantly improves patient satisfaction.

In critique of this study, only three Level II studies were reviewed and data was very heterogeneous. This paper offers Level III therapeutic evidence that the addition of fusion with or without instrumentation to decompression improves clinical outcomes.

Martin et al[24] conducted a systematic review designed to identify and analyze comparative studies that examined the surgical management of degenerative lumbar spondylolisthesis, specifically the differences in outcomes between fusion and decompression alone, and between instrumented fusion and noninstrumented fusion.

Relevant randomized controlled trials (RCTs) and comparative observational studies were identified in a comprehensive literature search (1966 to June 2005). The inclusion criteria required that a study be an RCT or comparative observational study that investigated the surgical management of degenerative lumbar spondylolisthesis by comparing: (1) fusion to decompression and/or (2) instrumented fusion to noninstrumented fusion. A minimum one-year follow-up was required. Studies also had to include at least five patients per treatment group. A study was excluded if it included patients who had received previous spine surgery or patients with cervical injuries, spinal fractures, tumors or isthmic spondylolisthesis. A study was also excluded if it was not possible to analyze patients with degenerative spondylolisthesis separately from another included patient population or if it was not clearly a comparative study.

Data from the included studies were extracted by two independent reviewers using a standard data abstraction sheet. The data abstraction sheet identified the following information: (1) patient population's age, gender, symptoms and degree of spondylolisthesis; (2) type of decompression, fusion, instrumentation, bone graft material, and preoperative and postoperative treatment; (3) study design and methodological quality using the Cochrane RCT/CCT/Crossover Studies Checklist, modified by the additional criterion that observational studies state the use of a consecutive series of patients; and (4) study outcomes.

The main abstracted outcomes were clinical outcome, reoperation rate and solid fusion status. An attempt was made to compare patient-centered, validated and disease-specific outcomes, complications and spondylolisthesis progression, but because of heterogeneity in reporting these outcomes in the primary studies, no pooled analysis could be performed on these outcomes. When appropriate, a study's clinical outcome rating scale was altered to match a dichotomous rating scale of "satisfactory" or "unsatisfactory" clinical outcome, and results were entered into Review Manager 4.2 for weighted grouped analyses.

The authors reported that eight studies were included in the fusion versus decompression alone analysis, including two RCTs. Limitations were found in the methodologies of both RCTs and most of the observational studies.

Grouped analysis detected a significantly higher probability of achieving a satisfactory clinical outcome with spinal fusion than with decompression alone (relative risk, 1.40; 95% confidence interval, 1.04–1.89; $P < 0.05$). The clinical benefit favoring fusion decreased when analysis was limited to studies where the majority of patients were reported

to be experiencing neurologic symptoms such as intermittent claudication and/or leg pain.

Six studies were included in the instrumented fusion versus noninstrumented fusion analysis, including three RCTs. The use of adjunctive instrumentation significantly increased the probability of attaining solid fusion (relative risk, 1.37; 95% confidence interval, 1.07–1.75; $P < 0.05$), but no significant improvement in clinical outcome was recorded (relative risk, 1.19; 95% confidence interval, 0.92–1.54). There was a nonsignificant trend towards a lower repeat operation rate in the fusion group compared with both decompression alone and instrumented fusion.

The authors concluded there is moderate evidence that fusion may lead to a better clinical outcome compared with decompression alone. Evidence that the use of adjunctive instrumentation leads to improved fusion status and less risk of pseudoarthrosis is also moderate. No conclusion could be made about the clinical effectiveness of instrumented fusion versus noninstrumented fusion.

In critique of this study, it was a systematic review of studies ranging down to Level III, and is thus classified as a Level III systematic review. Limitations were found in the methodologies of all RCTs, specifically in the pseudorandomization, absence of masking and/or the lack of validated outcome measures to assess clinical outcomes.

This paper offers Level III therapeutic evidence that fusion leads to a better clinical outcome compared with decompression alone and the use of adjunctive instrumentation leads to improved fusion status and less risk of pseudoarthrosis. Their data does not demonstrate any difference in clinical outcomes between instrumented and noninstrumented fusions.

Matsudaira et al[25] described a retrospective, comparative study of 55 patients with spinal stenosis in grade I degenerative lumbar spondylolisthesis. Of the 55 patients, 20 underwent laminectomy plus posterolateral fusion and pedicle screw instrumentation (Group 1), 19 underwent laminoplasty alone (Group 2) and 16 refused surgery and received medical/interventional treatment (Group 3). One patient in each surgical group was lost to follow-up. Outcomes were assessed by the Japanese Orthopedic Association (JOA) score, along with radiographic evaluation at minimum two-year follow-up.

The authors reported that alleviation of symptoms was noted in the fusion and laminoplasty groups but not in the medical/interventional treatment group. No statistically significant difference in clinical improvement was noted between the fusion and laminoplasty groups. The percent slip increased significantly in groups 2 and 3, whereas spondylolisthesis was stabilized in Group 1. The authors concluded that decompression with preservation of the posterior elements can be useful in treating patients with symptomatic lumbar spinal stenosis resulting from grade I degenerative spondylolisthesis.

In critique of this study, the numbers were small, patients were not randomized and no clearly defined indications for specific treatment selections were included. This paper offers Level III therapeutic evidence that decompression with posterolateral fusion and instrumentation, as well as laminoplasty alone yield improved outcomes in the treatment of symptomatic lumbar spinal stenosis resulting from grade I degenerative spondylolisthesis as compared with medical/interventional treatment alone.

Future Directions for Research

Because of the lack of clarity of the ideal candidate for decompression alone, a large scale randomized controlled trial may be logistically and ethically difficult to perform in comparison to decompression and fusion.

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Does the addition of instrumentation to decompression and fusion for degenerative lumbar spondylolisthesis improve surgical outcomes compared with decompression and fusion alone?

The addition of instrumentation is recommended to improve fusion rates in patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

The addition of instrumentation is not recommended to improve clinical outcomes for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: B

Bridwell et al[4] described a prospective comparative study of 44 surgically treated patients with degenerative lumbar spondylolisthesis followed for a minimum of two years. Of the 44 patients, nine underwent laminectomy alone, 10 had laminectomy and noninstrumented fusion and 24 had laminectomy and instrumented fusion (18 single level, six two-level). Patients were radiographically assessed and a functional assessment was conducted by asking whether they felt their ability to walk distances was worse (-), the same (0) or significantly better (+). Of the 44 patients, 43 were followed for two years or more.

The authors reported that instrumented fusion had higher fusion rates than noninstrumented fusion (ρ=0.002) and observed greater progression of spondylolisthesis in patients treated with laminectomy alone and laminectomy without instrumented fusion compared to patients who received laminectomy with instrumented fusion (ρ=0.001). A higher proportion of the patients without slippage progression reported that they were helped by the surgery than those whose slippage progressed postoperatively (ρ<0.01).

In critique, this was a small study in which selection bias entered into the randomization process, reviewers were not masked to patient treatment and validated outcome measures were not utilized. Because of these weaknesses, this potential Level II study was downgraded to Level III. This study provides Level III therapeutic evidence that addition of instrumentation to fusion results in higher fusion rates and subjective improvement in walking distance when compared with fusion alone.

Fischgrund et al[9] conducted a prospective, randomized comparative study of 76 consecutive patients with symptomatic spinal stenosis associated with degenerative lumbar spondylolisthesis who underwent posterior decompression and posterolateral fusion. Patients were randomized into a transpedicular fixation group or noninstrumented group. Outcomes were assessed at two-year follow-up using a five-point visual analog scale (VAS) and an operative result rating (excellent, good, fair, poor) based on examiner assessment of pain and functional level.

The authors reported that of the 76 patients included in the study, 68 (89%) were available for two-year follow-up. Clinical outcome was excellent or good in 76% of instrumented patients and 85% of noninstrumented patients (ρ=0.45). Successful arthrodesis occurred in 82% of instrumented versus 45% of noninstrumented patients (ρ=0.0015). Overall, successful fusion did not correlate with patient outcome (ρ=0.435). The authors concluded that for single-level degenerative lumbar spondylolisthesis, use of instrumentation may lead to a higher fusion rate, but clinical outcome showed no

improvement in low back pain and lower limb pain with their nonvalidated outcome measures.

In critique of this study, the follow-up may have been too short to detect the effects of pseudoarthrosis in this nonmasked study. Validated outcome measures were not utilized to assess clinical outcomes. Because of these weaknesses, this potential Level II study was downgraded to Level III.

This study offers Level III therapeutic evidence that the addition of instrumentation to posterolateral fusion for the treatment of degenerative lumbar spondylolisthesis increases the likelihood of obtaining a solid arthrodesis, but does not correlate with improved clinical outcomes at two-year follow-up.

Gibson et al[14] performed a systematic review of 31 randomized controlled trials (RCT) looking at all forms of surgical treatment for degenerative lumbar spondylosis. The authors reported eight trials showing that instrumented fusion produced a higher fusion rate, but any improvement in clinical outcomes is probably marginal. Other evidence suggests instrumentation may be associated with a higher complication rate. The authors concluded that although fusion rates improve with instrumentation, there does not appear to be any correlation with clinical outcomes.

In critique of this study, it was a systematic review of primarily Level II studies and is thus classified as a Level II systematic review. Limitations were found in the methodologies of all RCTs, specifically in the randomization, absence of masking and/or the lack of validated outcome measures to assess clinical outcomes. Studies were heterogeneous in nature and lacked long-term outcome studies.

In the work group's review of the specific studies cited in this paper, many were downgraded to Level III; therefore, the work group classified this review as Level III evidence. This paper offers Level III therapeutic evidence that although instrumentation improves the fusion rate, clinical outcome is probably only marginally improved at a potential risk of higher complication rates.

Kimura et al[19] described a retrospective, comparative study of 57 patients with grade I or II L4-5 degenerative lumbar spondylolisthesis. Group A consisted of 28 patients who underwent decompression and posterolateral fusion without instrumentation. Group B was comprised of 29 patients who had decompression and posterolateral fusion with pedicle screw instrumentation. Following surgery, Group A was immobilized with bed rest and a cast for 4-6 weeks, whereas Group B was mobilized much more quickly. Outcomes were assessed using the Japanese Orthopedic Association (JOA) scores and radiographs with mean follow-up in Group A of six years and in Group B of three years.

The authors indicated that patients in Group A (noninstrumented) reported 72.4% satisfaction rate, with an 82.8% fusion rate. Patients in Group B (instrumented) reported an 82.1% satisfaction rate, with a 92.8% fusion rate. The authors did not find any significant differences in outcomes between the two groups, except that Group B (instrumented) had less low back pain.

In critique of this study, patients were not randomized and there was varying duration of follow-up between groups. Although there was a trend toward improved satisfaction and fusion rates with instrumentation, with the numbers available no significant difference was detected. This paper offers Level III therapeutic evidence of no significant benefit with the addition of instrumentation for L4-5 degenerative lumbar spondylolisthesis.

Mardjetko et al[23] performed a meta-analysis of primarily Level III studies. The objective of the study was to analyze the published data on degenerative spondylolisthesis to evaluate the feasibility

of its use as a literature control to compare with the historical cohort pedicle screw study data.

The authors conducted a comprehensive literature search to identify studies published in English peer-reviewed journals between 1970 and 1993 addressing degenerative spondylolisthesis with radicular leg pain or neurogenic claudication. Inclusion criteria included (1) a minimum of four cases reviewed and (2) reporting of the primary outcome variable of fusion in articles in which this was part of the treatment. Clinical outcome variables of back pain, leg pain, function, neurogenic claudication and global outcome scores were recorded when available. A total of 25 papers representing 889 patients were accepted for inclusion. Twenty-one were retrospective, nonrandomized and uncontrolled. One paper was retrospective and nonrandomized, but compared two different treatments. Three prospective, randomized studies were included.

The primary outcome variable, fusion, was determined by each author. The most constant clinical outcome variable reported was pain with 16 papers reporting pain only, six papers reporting pain and function, and two papers reporting patient-determined outcomes. Patient function was reported in six papers and referred to the presence or absence of neurogenic claudication. In addition to these clinical outcomes, four papers reported a global evaluation. Two used Kaneda's rating system and two used the Japanese Orthopedic Association (JOA) score. Excellent and good results were reassigned as satisfactory; poor results were classified as unsatisfactory.

In the decompression alone category, 11 papers representing 216 patients were accepted for inclusion. Sixty-nine percent of patients had a satisfactory outcome. The incidence of worsened postoperative slip was 31%, but was not associated with a poorer clinical result in the majority of patients.

In the category of decompression with fusion and no instrumentation, six papers qualified for inclusion. In one paper, only fusion data were broken out for the diagnosis of degenerative spondylolisthesis and were used just for this outcome variable. Ninety percent of the patients in this category had a satisfactory outcome; 86% achieved solid spinal fusion. With regard to clinical outcome, the difference between patients treated with decompression without fusion (69% satisfactory) and those treated with decompression and fusion without instrumentation (90% satisfactory) was statistically significant ($P < 0.0001$).

In the decompression with fusion and pedicle screws category, five studies met the inclusion criteria. Fusion status was analyzed in a total of 101 patients. Eighty-five patients were analyzed with respect to clinical outcome. One paper did not separately analyze clinical data, but did so for fusion data; therefore, only fusion data were included. The proportionally weighted fusion rates for this group were 93%. When comparing the fusion without instrumentation group to the fusion with pedicle screw group, there was not a statistically significant increase in fusion rate ($P = 0.08$). Analysis of the clinical outcomes reveals an 86% satisfactory rating for the pedicle screw group. This compares favorably to the 69% satisfactory rate in the decompression without fusion group ($P <0.0001$).

In the anterior spinal fusion category, three papers presenting the results for 72 patients who received anterior spinal fusion for the treatment of degenerative spondylolisthesis were included. Pooling the data from these three studies yielded a 94% fusion rate with an 86% rate of patient satisfaction.

The authors concluded that the meta-analysis results support the clinical impression that in the surgical management of degenerative lumbar spondylolisthesis, spinal fusion significantly improves patient satisfaction.

In critique of this study, only three Level II studies

were reviewed and data was very heterogeneous. This paper offers Level III therapeutic evidence that addition of instrumentation to fusion does not result in improved clinical outcome or fusion rate. Martin et al[24] conducted a systematic review designed to identify and analyze comparative studies that examined the surgical management of degenerative lumbar spondylolisthesis, specifically the differences in outcomes between fusion and decompression alone, and between instrumented fusion and noninstrumented fusion.

Relevant randomized controlled trials (RCTs) and comparative, observational studies were identified in a comprehensive literature search (1966 to June 2005). The inclusion criteria required that a study be an RCT or comparative observational study that investigated the surgical management of degenerative lumbar spondylolisthesis by comparing: (1) fusion to decompression and/or (2) instrumented fusion to noninstrumented fusion. A minimum one-year follow-up was required. Studies also had to include at least five patients per treatment group. A study was excluded if it included patients who had received previous spine surgery, or patients with cervical injuries, spinal fractures, tumors or isthmic spondylolisthesis. A study was also excluded if it was not possible to analyze patients with degenerative spondylolisthesis separately from another included patient population, or if it was not clearly a comparative study.

Data from the included studies were extracted by two independent reviewers using a standard data abstraction sheet which identified the following information: (1) patient population's age, gender, symptoms and degree of spondylolisthesis; (2) type of decompression, fusion, instrumentation, bone graft material, and preoperative and postoperative treatment; (3) study design and methodological quality using the Cochrane RCT/CCT/Crossover Studies Checklist, modified by the additional criterion that observational studies state the use of a consecutive series of patients; and (4) study outcomes.

The main abstracted outcomes were clinical outcome, reoperation rate and solid fusion status. An attempt was made to compare patient-centered, validated and disease-specific outcomes, complications and spondylolisthesis progression, but because of heterogeneity in reporting these outcomes in the primary studies, no pooled analysis could be performed on these outcomes. When appropriate, a study's clinical outcome rating scale was altered to match a dichotomous rating scale of "satisfactory" or "unsatisfactory" clinical outcome, and results were entered into Review Manager 4.2 for weighted grouped analyses.

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In critique of this study, it was a systematic review of studies ranging down to Level III, and is thus classified as a Level III systematic review. Limitations were found in the methodologies of all RCTs, specifically in the pseudorandomization, absence of masking and/or the lack of validated outcome measures to assess clinical outcomes. This paper offers Level III therapeutic evidence that the use of adjunctive instrumentation leads to improved fusion rates, but failed to show a statistically significant improvement in clinical outcomes.

Future Directions for Research

A high quality randomized controlled trial is recommended to provide meaningful information about the clinical benefits of achieving a solid fusion in patients treated with instrumented and noninstrumented fusion for symptomatic spinal stenosis and degenerative lumbar spondylolisthesis. This study should utilize validated, functional, disease-specific outcome measures with long-term follow-up of four years or more.

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How do outcomes of decompression with posterolateral fusion compare with those for 360° fusion in the treatment of degenerative lumbar spondylolisthesis?

Because of the paucity of literature addressing this question, the work group was unable to generate a recommendation to answer this question.

Future Directions for Research

A high quality RCT comparing decompression with instrumented posterolateral fusion to decompression with 360° (circumferential) instrumented fusion would generate meaningful evidence to address this question.

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What is the role of reduction (deliberate attempt to reduce via surgical technique) with fusion in the treatment of degenerative lumbar spondylolisthesis?

Reduction with fusion and internal fixation of patients with low grade degenerative lumbar spondylolisthesis is not recommended to improve clinical outcomes.

Grade of Recommendation: I (Insufficient Evidence)

Although reduction and fusion can be performed, the evidence reviewed does not substantiate any improvement in clinical outcomes and may increase the risk of neurological complications.

Bednar et al[1] described a retrospective consecutive case series of 56 patients with degenerative spondylolisthesis and symptoms of back pain and/or stenosis treated with bilateral foraminotomies, reduction and instrumented fusion. The procedure had a 7% major complication rate. Outcomes measures were the Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and radiographs. Of the 56 patients, 42 were available for follow-up at an average of 33 months (range 14-53 months). Of the 42 patients, 82% experienced relief of leg pain, 75% experienced improvement in low back pain, and 77% experienced significant improvement in their ODI scores (average preoperatively of 56% versus average of 26% postoperatively).

Only 38 patients were available for late review of X-ray studies at an average of 33 months. Average preoperative slip was 16%, and of the 38 patients available at late review, 75% had perfect reduction. Of the 38 patients, 16% had minor loss of reduction. Outcome measures (VAS and ODI) were not compared based on the presence or absence of a perfect reduction.

In critique, this is a moderately small, retrospective review of a consecutive case series of surgical patients from one surgeon with no comparison group and with less than 80% follow-up. This paper offers Level IV therapeutic evidence that limited bilateral foraminotomies with instrumented reduction and fusion for symptomatic degenerative spondylolisthesis and stenosis is as effective as laminectomy and in situ fusion without as much operative exposure of neural structures.

Lee et al[14] reported on a prospective case series of 52 consecutive patients with objectively defined unstable degenerative spondylolisthesis who underwent reduction and fusion without decompression using the Fixater Interne pedicle fixation device. Forty-seven patients had low back pain, 40 patients had radicular pain and 36 patients had intermittent claudication.

Follow-up was at a minimum of 12 months (range 12-16 months). Subjective measurement of success was classified as excellent, good, fair and poor for pain. An excellent or good outcome was considered satisfactory and a fair or poor outcome was considered unsatisfactory. A satisfactory outcome (excellent and good results) occurred in 42 of 47 patients with complaints of back pain, 37 of 40 patients with radicular pain and 31of 36 patients with claudication. The authors commented that only two groups, based on their findings, are not good candidates for this procedure: (1) those with a positive Lasegue's sign and (2) those with borderline instability.

In critique of this study, this was a prospective case series of consecutive patients with degenerative spondylolisthesis undergoing reduction, fixation and fusion which lacked a comparison group. Validated outcome measures were not used. This paper presents Level IV therapeutic evidence that patients with degenerative spondylolisthesis who do not

have borderline instability or a positive Lasegue's sign can undergo reduction, fixation and fusion without decompression.

Sears et al[19] reviewed a prospective case series of 34 patients with degenerative spondylolisthesis who underwent decompression, reduction, internal fixation and fusion. Twenty-five patients had a one-level fusion and nine patients had a two-level fusion. Of the 34 patients, 32 had surgery to relieve leg pain. Outcome measures included the VAS, Low Back Pain Outcome Score (LBOS), SF-12 and patient satisfaction questionnaire. Preoperative and postoperative measurement of slips by radiograph were also recorded. Mean preoperative slip was 20% (range was12% to 33%).

Follow-up occurred at a mean of 21.2 months (range 12 to 32 months), with no dropouts. Significant improvements ($p<.001$) occurred in mean VAS and LBOS scores. Ninety-one percent of the patients considered their results excellent or good on the subjective satisfaction rating. Radiograph analysis revealed mean slip reduction from 20.2% to 1.7% and focal lordosis (available in only 17/34 patients) increased from 13.1 to 16.1 degrees. Both of these findings were clinically significant. Three of the 34 patients had postoperative nerve root irritation, with two of these persisting up to the time of final report. No procedure-related complications were reported postoperatively, but one patient required adjacent level decompression and fusion 12 months after surgery.

In critique, this is a small prospective case series on nonconsecutive patients with degenerative spondylolisthesis with no comparison group. This paper offers Level IV therapeutic evidence that reduction of a degenerative spondylolisthesis with internal fixation and posterior lumbar interbody fusion can provide good deformity correction with few complications and good short-term patient outcomes on validated patient outcome measures.

Future Directions for Research

The work group does not recommend any further studies addressing reduction with fusion and internal fixation in patients with low grade degenerative lumbar spondylolisthesis.

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What is the long-term result (four+ years) of surgical management of degenerative lumbar spondylolisthesis?

Decompression and fusion is recommended as a means to provide satisfactory long-term results for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

Grade of Recommendation: C

Booth et al[1] described a presumably retrospective study of 41 patients with neurogenic claudication from spinal stenosis and spondylolisthesis who were followed for a minimum of five years after a laminectomy and instrumented fusion. At final follow-up, there were no new neurological deficits, no recurrent stenosis at the level of surgery and no symptomatic pseudoarthroses. Three patients underwent surgery for adjacent level stenosis, which took place four to 12 years after the index procedure. Clinical outcomes were available in 36 patients: 83% reported high satisfaction, 86% reported reduced back and leg pain, and 46% had increased function at follow-up that ranged from five to 10.7 years.

In critique of this study, it had small patient numbers and there was a considerable amount of attrition (less than 80% follow-up). Of 49 consecutive patients operated during the study interval, 41 were available for follow-up (eight patients died) and only 36 had clinical outcomes measured. Attrition from death, however, is expected in the affected population. This retrospective case series provides Level IV therapeutic evidence that laminectomy and instrumented fusion for stenosis from degenerative spondylolisthesis provides a high rate of satisfaction and pain relief and moderately increased function at long-term follow-up.

Kornblum et al[32] conducted a follow-up study on 47 of 58 patients who had originally been part of a randomized controlled trial comparing instrumented versus noninstrumented fusion for spinal stenosis and degenerative spondylolisthesis. This study's cohort consisted only of the noninstrumented cases, which were followed for a minimum of five years. Clinical outcomes were analyzed based on the presence of solid fusion (22 patients) or a pseudoarthrosis (25 patients). A statistically greater percentage of patients had good or excellent results in patients with solid fusion (86%) versus pseudoarthrosis (56%). Importantly, five of the pseudoarthrosis patients and two of the fusion patients had undergone a second procedure.

In critique of this study, the authors used a less frequently implemented outcomes instrument, the Swiss Spinal Stenosis (SSS) Questionnaire, making it difficult to compare directly to other studies in which the ODI or ZCQ were used. Despite these minor limitations, as a prospective case series, the data offer Level IV therapeutic (>80% follow-up) evidence that laminectomy and attempted fusion results in longstanding symptom improvement for spinal stenosis from degenerative spondylolisthesis. Furthermore, these data suggest that those patients who achieved solid fusion have statistically better long-term outcomes than those with pseudoarthroses.

Postacchini et al[48] performed a long-term follow-up study evaluating the clinical outcomes and radiographic evidence of bone regrowth five to 19 years after laminectomy for spinal stenosis. Of the 40 patients included, 16 had degenerative spondylolisthesis, 10 of whom were treated with concomitant fusion. At final follow-up, three patients had excellent results, seven patients had good results, three had fair results and three had poor results. The proportion of satisfactory clinical results was higher in the patients who were fused compared to those who underwent laminectomy alone.
In critique of this study, clinical outcomes were

graded using a rudimentary four tier system (excellent, good, fair, poor). Furthermore, there was a high attrition rate. Of 88 patients identified during the study period, 27 died or could not be located and 21 did not have adequate radiographs, leaving the 40 study patients (45% follow-up).

Based on these limitations, this retrospective case series provides Level IV therapeutic evidence that laminectomy with fusion provides satisfactory long-term results.

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 surgical treatment for degenerative lumbar spondylolisthesis.

Recommendation #1:

Future long-term studies of the effects of surgical interventions for patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis should include an untreated control group, when ethically feasible. Continued follow-up of patients already enrolled in ongoing randomized controlled trials or prospective comparative studies will yield higher quality data regarding the relative efficacy of surgery compared to medical/interventional treatments.

Recommendation #2:

Future long-term outcome studies are necessary to compare different surgical techniques for the treatment of patients with symptomatic spinal stenosis and degenerative lumbar spondylolisthesis.

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V. Appendices

Appendix A: Acronyms

ALIF	anterior lumbar interbody fusion
CT	computed tomography
CTM	computed tomography myelography
EBM	evidence-based medicine
EHL	extensor hallucis longus
JOA	Japanese Orthopaedic Association
LASD	L1 axis S1 distance
LBOS	low back outcome score
LBP	low back pain
MR	magnetic resonance
MRI	magnetic resonance imaging
NASS	North American Spine Society
NSAIDs	nonsteroidal anti-inflammatory drugs
OCS	Oxford Claudication Score
ODI	Oswestry Disability Index
PLIF	posterior lumbar interbody fusion
RCT	randomized clinical trial
RMDQ	Roland Morris Disability Questionnaire
SF-12	12-Item Short Form Health Survey
SF-36	36-Item Short Form Health Survey
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 Recommendationfor Summaries or Reviews of Studies

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.

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:
     - o Should duplicates be eliminated between searches?
     - o Should searches be separated by term or as one large package?
     - o 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.

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 Spondylolisthesis (Work Group 1) Search Strategies

Search Strategies by Clinical Question:

1. What is the best working definition of degenerative lumbar spondylolisthesis?

   Reviewed book chapters (see reference section).

2. What is the natural history of degenerative lumbar spondylolisthesis?

   Degenerative Lumbar Spondylolisthesis – natural hx – broad
   (((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR nonoperative[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 ("Spondylolisthesis"[MeSH])) NOT ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR nonoperative[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 ("Spondylolisthesis"[MeSH]) AND (English[lang]) AND ((infant[MeSH] OR child[MeSH] OR adolescent[MeSH])) AND (Humans[Mesh]) AND ("1966"[EDat] : "3000"[EDat]))) OR ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR nonoperative[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 ("Spondylolisthesis"[MeSH]) AND (English[lang]) AND (adult[MeSH]) AND (Humans[Mesh]) AND ("1966"[PDat] : "3000"[PDat]))

   Degenerative Lumbar Spondylolisthesis – natural hx – narrow
   ((((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR nonoperative[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 ("Spondylolisthesis"[MeSH])) NOT ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR nonoperative[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 ("Spondylolisthesis"[MeSH]) AND (English[lang]) AND ((infant[MeSH] OR child[MeSH] OR adolescent[MeSH])) AND (Humans[Mesh]) AND ("1966"[EDat] : "3000"[EDat]))) OR ((natural history[Text Word] OR natural course[All Fields] OR nonsurgical[All Fields] OR nonoperative[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 ("Spondylolisthesis"[MeSH]) AND (English[lang]) AND (adult[MeSH]) AND (Humans[Mesh]) AND ("1966"[PDat] : "3000"[PDat]))) AND degenerative[All Fields]

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 Spondylolisthesis (Work Group 2) Search Strategies

Search Strategies by Clinical Question:

1. What are the most appropriate historical and physical exam findings consistent with the diagnosis of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (signs OR symptoms OR diagnosis OR diagnosis, differential OR physical findings OR exam OR historical findings)

   Search name: **DLS + diagnosis** (48 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Diagnosis"[MAJR] OR "Signs and Symptoms"[MAJR] OR "Spondylolisthesis/diagnosis"[MAJR:noexp] OR "Physical Examination"[MAJR] OR diagnosis[title])

2. What are the most appropriate diagnostic tests for degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (diagnostic tests OR physical finding OR signs) AND (accuracy OR validity OR reliability)

   Search name #1: **DLS + diagnostic tests** (124 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Diagnostic Techniques and Procedures"[Mesh] OR "Diagnostic Imaging"[Mesh])

   Search name #2: **DLS + diagnostic tests + validity – narrow** (10 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lum-

bosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND (("Reproducibility of Results"[Mesh] OR "Sensitivity and Specificity"[Mesh]) AND "Diagnostic Techniques and Procedures"[Mesh])

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

Outcome Measures for Degenerative Lumbar Spondylolisthesis (Work Group 3) Search Strategies

Search Strategies by Clinical Question:

What are the appropriate outcome measures for the treatment of degenerative lumbar spondylolisthesis?
degenerative lumbar spondylolisthesis [NOT spondylolysis] AND functional outcome measures

Search name: **DLS + functional outcome measures** (104 articles)
Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND (("Outcome Assessment (Health Care)"[Mesh] OR "Treatment Outcome"[Mesh] OR "Outcome and Process Assessment (Health Care)"[Mesh]) OR "functional outcome"[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
- EMBASE Drugs and Pharmacology

Medical/Interventional Treatment of Degenerative Lumbar Spondylolisthesis (Work Group 4) Search Strategies

Search Strategies by Clinical Question:

1. Do medical/interventional treatments improve outcomes in the treatment of degenerative lumbar spondylolisthesis compared to the natural history of the disease?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND natural history AND (medical management OR nonoperative management OR conservative management OR medical treatment OR nonoperative treatment OR conservative treatment OR nonsurgical OR rehabilitation)

   Search name #1: **DLS + nonsurgical** (41 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND (nonoperative[All Fields] OR conservative[All Fields] OR nonsurgical[All Fields] OR ("rehabilitation"[Subheading] OR "rehabilitation"[MeSH Terms] OR rehabilitation[Text Word]) OR "clinical management"[All Fields] OR "spondylolisthesis/therapy"[MeSH:noexp])

   Search name #2: **DLS + nonsurgical + natural history** (6 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND (nonoperative[All Fields] OR conservative[All Fields] OR nonsurgical[All Fields] OR ("rehabilitation"[Subheading] OR "rehabilitation"[MeSH Terms] OR rehabilitation[Text Word]) OR "clinical management"[All Fields] OR "spondylolisthesis/therapy"[MeSH:noexp]) AND ("natural history"[All Fields] OR "natural course"[All Fields] OR untreated[All Fields])

2. What is the role of pharmacological treatment in the management of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (pharmacological treatment

OR pharmacological management OR drug OR medication)

Search name: **DLS + pharmacological management** (17 articles)
Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Drug Therapy"[Mesh] OR "drug therapy "[Subheading] OR ("Analgesics"[Mesh] OR "Analgesics "[Pharmacological Action]) OR ("Anti-Inflammatory Agents"[Mesh] OR "Anti-Inflammatory Agents"[Pharmacological Action]) OR drug[text word] OR medication[text word] OR medications[text word])

3. What is the role of physical therapy/exercise in the treatment of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (physical therapy OR exercise OR exercise therapy OR rehabilitation)

   Search name: **DLS + (physical therapy or exercise OR rehab)** (13 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Physical Therapy Modalities"[Mesh] OR "Exercise"[Mesh] OR "Exertion"[Mesh] OR "Physical Fitness"[Mesh] OR "Exercise Movement Techniques"[Mesh] OR ("Rehabilitation"[Mesh] OR "rehabilitation "[Subheading]) OR "physical therapy"[title] OR "rehabilitation"[title] OR exercise[title] OR physiotherapy[title])

4. What is the role of manipulation in the treatment of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (manipulation OR chiropractic care)

   Search name: **DLS + manipulation** (3 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lum-

bosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Musculoskeletal Manipulations"[Mesh] OR ("chiropractic"[MeSH Terms] OR chiropractic[Text Word]) OR manipulat*[All Fields])

5. What is the role of epidural steroid injections in the treatment of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND injections

   Search name: **DLS + injections** (4 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Injections"[Mesh] OR injection*)

6. What is the role of ancillary treatments such as bracing, traction, electrical stimulation and transcutaneous electrical stimulation (TENS) in the treatment of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (bracing OR traction OR electrical stimulation OR transcutaneous electrical stimulation OR TENS)

   Search name: **DLS + electrical stimulation, etc.** (7 articles)
   Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND ("Braces"[Mesh] OR bracing[All Fields] OR "Traction"[Mesh] OR "Electric Stimulation"[Mesh] OR "Transcutaneous Electric Nerve Stimulation"[Mesh] OR (("transcutaneous electric nerve stimulation"[TIAB] NOT Medline[SB]) OR "transcutaneous electric nerve stimulation"[MeSH Terms] OR TENS[Text Word]) OR "Electric Stimulation Therapy"[Mesh])

7. What is the long-term result of medical/interventional management of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (medical management OR nonoperative management OR conservative management OR medical treatment OR nonoperative treatment OR conservative treatment OR nonsurgical OR rehabilitation) AND long term outcomes

   Search name: **DLS + nonsurgical + long-term outcomes** (17 articles)

Search strategy: "degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND (nonoperative[All Fields] OR conservative[All Fields] OR nonsurgical[All Fields] OR ("rehabilitation"[Subheading] OR "rehabilitation"[MeSH Terms] OR rehabilitation[Text Word]) OR "clinical management"[All Fields] OR "spondylolisthesis/therapy"[MeSH:noexp]) AND ("Time"[Mesh] OR "Longitudinal Studies"[Mesh] OR "long-term"[All Fields])

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 Spondylolisthesis (Work Group 5) Search Strategies

Search Strategies by Clinical Question:

1. Do surgical treatments improve outcomes in the treatment of degenerative lumbar spondylolisthesis compared to the natural history of the disease?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (surgery OR operation) AND natural history

   Search name #1: **DLS + surgical procedures** (222 articles)
   Search strategy: ("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Surgical Procedures, Operative"[Mesh] OR "Lumbar Vertebrae/surgery"[Mesh] OR "Lumbosacral Region/surgery"[Mesh] OR "Spondylolisthesis/surgery"[Mesh:noexp])

   Search name #2: **DLS + surgical procedures + natural history** (8 articles)
   Search strategy: ("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Surgical Procedures, Operative"[Mesh] OR "Lumbar Vertebrae/surgery"[Mesh] OR "Lumbosacral Region/surgery"[Mesh] OR "Spondylolisthesis/surgery"[Mesh:noexp]) AND (("natural history"[MeSH Terms] OR natural history[Text Word]) OR (natural[All Fields] AND course[All Fields]) OR untreated[All Fields])

   Note: There is little or none on comparisons between surgical intervention and natural history of DLS. I've included one search on surgical interventions and a second on the same with natural history.

2. Does surgical decompression alone improve surgical outcomes in the treatment of degenerative lumbar spondylolisthesis compared to medical/interventional treatment alone or the natural history of the disease?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (surgical decompression OR laminectomy OR laminotomy OR foraminotomy) AND [(medical management OR nonoperative management OR conservative management OR medical treatment OR nonoperative treatment OR conservative treatment OR nonsurgical OR rehabilitation) OR natural history]

Search name: **DLS + decompression + (nonsurgical or natural history)** (21 articles)
Search strategy: ("Decompression, Surgical"[Mesh] OR "Laminectomy"[Mesh] OR laminotomy[text word] OR foraminotomy[text word] OR surgical decompression[text word]) AND (("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("lumbar spondylolisthesis"[All Fields] AND degenerative[All Fields]) OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang]) AND (nonoperative[All Fields] OR conservative[All Fields] OR non-surgical[All Fields] OR ("rehabilitation"[Subheading] OR "rehabilitation"[MeSH Terms] OR rehabilitation[Text Word]) OR "clinical management"[All Fields] OR "spondylolisthesis/therapy"[MeSH:noexp])) OR (("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND (("natural history"[MeSH Terms] OR natural history[Text Word]) OR (natural[All Fields] AND course[All Fields]) OR untreated[All Fields])))

3. Does the addition of lumbar fusion, with or without instrumentation, to surgical decompression improve surgical outcomes in the treatment of degenerative lumbar spondylolisthesis compared to treatment by decompression alone?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (surgical decompression OR laminectomy OR laminotomy OR foraminotomy) AND (fusion OR arthrodesis) AND (instrumentation OR pedicle screw OR hardware)

   Search name: **DLS + decompression + lumbar fusion** (61 articles)
   Search strategy: (("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Decompression, Surgical"[Mesh] OR "Laminectomy"[Mesh] OR laminotomy[text word] OR foraminotomy[text word] OR surgical decompression[text word])) AND ("Arthrodesis"[Mesh] OR "Spinal Fusion"[Mesh] OR lumbar fusion[text word])

   Note: The above search does not limit to instrumentation because the question specifies "with or without instrumentation". Therefore I deviated from the search string you provided. Of course, instrumentation may still be included, but it will be broader than that, looking at fusion. The next search looks at the same string with instrumentation.

4. Does the addition of instrumentation to decompression and fusion for degenerative spondylolisthesis improve surgical outcomes compared with decompression and fusion alone?

   Same search string as #4

   Search name: **DLS + decompression + lumbar fusion** (29 articles)
   Search strategy: ((("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Decompression, Surgical"[Mesh] OR "Laminectomy"[Mesh] OR laminotomy[text word] OR foraminotomy[text word] OR surgical decompression[text word])) AND ("Arthrodesis"[Mesh] OR "Spinal Fusion"[Mesh] OR lumbar fusion[text word])) AND ("instrumentation "[Subheading] OR instrumentation[title] OR "Bone Screws"[Mesh] OR pedicle screw[text word] OR pedicle screws[text word])

5. How do outcomes of decompression with posterolateral fusion compare with those for 360° fusion (anterior-posterior OR transforaminal lumbar interbody fusion OR posterior lumbar interbody fusion) for treatment of degenerative spondylolisthesis?

   Same search string as #4

   Search name: **DLS + (posterolateral or 360 degree fusion)** (20 articles)
   Search strategy: (("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Decompression, Surgical"[Mesh] OR "Laminectomy"[Mesh] OR laminotomy[text word] OR foraminotomy[text word] OR surgical decompression[text word])) AND (anterior-posterior[All Fields] OR (transforaminal[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word]) AND interbody[All Fields] AND fusion[All Fields]) OR (posterior[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word]) AND interbody[All Fields] AND fusion[All Fields]) OR "posterolateral fusion"[text word] OR "360 degree fusion"[text word])

   Note: I didn't use the same search string as Q 4 because the terms "posterolateral", " anterior-posterior", etc. were a lot more specific than just fusion. I used these and other terms from the question itself.

6. What is the role of reduction with fusion in the treatment of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND reduction AND (slip OR listhesis OR spine) AND (fusion OR arthrodesis)

Search name: **DLS + reduction + fusion** (17 articles)
Search strategy: ("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND reduction[text word] AND (slip[All Fields] OR listhesis[All Fields] OR ("spine"[MeSH Terms] OR spine[Text Word]) OR spinal[All Fields]) AND ("Arthrodesis"[Mesh] OR "Spinal Fusion"[Mesh] OR lumbar fusion[text word])

7. What is the long-term result (4+ years) of surgical management of degenerative lumbar spondylolisthesis?

   degenerative lumbar spondylolisthesis [NOT spondylolysis] AND (surgery OR operation) AND long term outcomes

   Search name: **DLS + surgical management + long-term result** (114 articles)
   Search strategy: ("degenerative lumbar spondylolisthesis"[All Fields] OR "lumbar degenerative spondylolisthesis"[All Fields] OR ("degenerative spondylolisthesis"[All Fields] AND (("lumbosacral region"[TIAB] NOT Medline[SB]) OR "lumbosacral region"[MeSH Terms] OR lumbar[Text Word])) OR ("Spondylolisthesis"[MAJR:noexp] AND ("Lumbosacral Region"[Mesh] OR "Lumbar Vertebrae"[Mesh]) AND degenerative[All Fields]) AND ("humans"[MeSH Terms] AND English[lang])) AND ("Surgical Procedures, Operative"[Mesh] OR "Lumbar Vertebrae/surgery"[Mesh] OR "Lumbosacral Region/surgery"[Mesh] OR "Spondylolisthesis/surgery"[Mesh:noexp]) AND ("Time"[Mesh] OR "Longitudinal Studies"[Mesh] OR "long-term"[All Fields])

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

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Natural History

What is the natural history of degenerative lumbar spondylolisthesis?

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Cummins J, Lurie JD, Tosteson TD, et al. Descriptive epidemiology and prior healthcare utilization of patients in the Spine Patient Outcomes Research Trial's (SPORT) three observational cohorts: disc herniation, spinal stenosis, and degenerative spondylolisthesis. *Spine*. 2006;31(7):806-814.	Not clearly classifiable	This study represented baseline demographic data on degenerative spondylolisthesis patients with symptoms of radiculopathy and/or neurogenic claudication. A total of 303 degenerative spondylolisthesis patients meeting these criteria were enrolled in the SPORT study, and information was gathered on demographics, prior treatment and functional status (SF-36 & ODI-AAOS MODEMS version). Pain scores on SF-36 = 33.8, impairment score 41.5. Chiropractic treatment rate of 26%. Emergency room visits 4%. 27% of patients were using opiates for pain control. All of these outcomes were lower than the outcomes for the disc herniation and spinal stenosis groups. Of the symptomatic patients, female representation was 71%, with an average age of 66 years. Consistent with the older average age of the group, they had more comorbidities. 33% had symptoms lasting greater than one year.	In critique of this study, it presents the initial demographic information for a prospective study that was not yet reported during the development of this guideline. This represents the group of degenerative spondylolisthesis patients symptomatic enough to be offered surgery, thus the demographics need to be viewed in that light. This represents an evolving study, and cannot be classified currently within the NASS levels of evidence table.
Kauppila LI, Eustace S, Kiel DP, Felson DT, Wright AM. Degenerative displacement of lumbar vertebrae. A 25-year follow-up study in Framingham. *Spine*. 1998;23(17):1868-1873; discussion 1873-1864.	III, prognostic	This study was a population-based, retrospective, cohort study of 217 men and 400 women. Radiographs were taken at a mean age of 54 years and again at 79 years. Degenerative spondylolisthesis was defined as >3 mm of forward or backward slip. Twenty-three men (12%) and 100 women (25%) developed some form of "slippage" either forward or backward. Forward slip occurred in eight men and 75 women, and backward slip occurred in 16 men and 35 women. Forward slip was 18% +/- 5.5 and backward slip magnitude was 15% +/- 4.0. Olisthesis did predict back pain or stiffness on most days (32% [39/123] in the degenerative spondylolisthesis group compared with 19% [90/484] in controls). Controlling for sclerosis still accounted for pain. Patients with acquired slips reported more daily	In critique of the study, unlike most other studies in this area, a degenerative slip was defined as either a forward or backward slip. This paper offers Level III prognostic evidence that in an elderly population, back pain is correlated with the olisthesis; however, only one third with olistheses are symptomatic. Thus degenerative spondylolisthesis can be acquired in an asymptomatic population, with a higher incidence in females (4:1).

		back symptoms, but did not report more disability than controls.	
Mardjetko SM, Connolly PJ, Shott S. Degenerative lumbar spondylolisthesis. A meta-analysis of literature 1970-1993. *Spine*. 1994;19(20 Suppl):2256S-2265S.	III, prognostic	This study was a meta-analysis of degenerative lumbar spondylolisthesis from 1970-1993. It was primarily designed to study posterior fusion with and without instrumentation, but three studies included the medical/interventional/natural history with a total of 278 patients. Only one of three papers addressed slippage. Inclusion criteria included only degenerative spondylolisthesis with radicular leg pain or neurogenic claudication. Natural history papers identified where Matsunaga, Fitzgerald and Rosenberg, which were, point prevalence of pain and function in deg spondy cohorts. Only Matsunaga was considered a true natural history paper.	In critique, although this paper is a meta-analysis implementing an evidence-based approach, it only described one paper (Matsunaga, et al) relevant to this guideline. This paper is addressed in the guideline. This study provides Level III prognostic evidence for the natural history of degenerative spondylolisthesis.
Matsunaga S, Ijiri K, Hayashi K. Nonsurgically managed patients with degenerative spondylolisthesis: a 10- to 18-year follow-up study. *J Neurosurg*. 2000;93(2 Suppl):194-198.	II/III, prognostic	This was a prospective, comparative, cohort study of 145 patients with degenerative anterolisthesis who were either determined not to need surgery (110 patients) or refused surgery (35 patients). The patients were followed from 10-18 years, although only 46 were followed up longer than 10 years. Outcome measures utilized included progression of spondylolisthesis (5% or more on radiographs), frequency of transitory radicular pain, improvement or worsening of symptoms and ability to walk without help. Progression of slip was observed in 49 (34%) patients. Of the patients who were initially felt not to need surgery, 85 (77%) experienced improvement during follow-up and 25 remained the same. Of these patients, 84 (76%) continued to show no neurologic deficits on examination. Of the patients who refused surgery, 29 (83%) had worsened neurologic deficit on examination, and this was noted not to correlate with the progression of slippage. Fifteen of these patients were followed over 10 years and all of them required an assistive device to ambulate.	In critique of this study, no validated outcome measures were used. The initial sample of patients was not the group initially assigned to medical/interventional treatment; rather it consisted of patients that remained medically/interventionally treated at 10 years. This study provides Level II evidence that, in patients who initially do not have neurologic deficits, the majority will do well with conservative care. Patients who present with sensory changes, muscle weakness or cauda equina syndrome, are more likely to develop progressive functional decline without surgery. Progression of the slip does not correlate with progression of clinical symptoms. Radicular pain, accompanied by neurologic deficits, forebodes a poor outcome. This study provides Level III evidence that low back pain can be expected to improve in patients with narrowed intervertebral disc spaces.
Matsunaga S,	III,	This was a retrospective review of 40 pa-	In critique, this was a relatively small

Sakou T, Morizono Y, Masuda A, Demirtas AM. Natural history of degenerative spondylolisthesis. Pathogenesis and natural course of the slippage. *Spine*. 1990;15(11):1204-1210.	prognostic	tients with spondylolisthesis. Inclusion criteria were a slippage rate of at least 5% by Morgan and King's compass method and at least five-year follow-up of medical/interventional care. Outcome measures utilized included progression of slippage and JOA score. Joint laxity was evaluated using Carter's test of knee, elbow and wrist hypermobility. General joint laxity using Carter's criteria was noted in 65% of these patients as compared with 8% of normal individuals. Progression of slippage, defined as a slippage rate of 5% or more during the observation period, was observed in 12 (30%) of the 40 patients. The authors defined this to be the progressive group and the other 28 patients to be the nonprogressive group. Comparison of these two groups showed no difference in age at presentation, duration of illness or duration of follow-up. Further, while the lumbosacral angle, lamina angle and facet inclination angle were greater in both groups, there were no significant differences between these groups.	study, but did use a validated outcome measure. This potentially Level II retrospective, comparative study was downgraded to Level III evidence because of the small sample size and incomplete documentation of patient information. This study provides Level III evidence that slip is more likely to progress in laborers whose jobs require repetitive anterior flexion of the spine. Progression of slip is less likely in the presence of a relative intervertebral height of 20% or less, intervertebral osteophyte formation, subcartilagenous sclerosis or ligamentous ossification, suggesting that mechanisms of restabilization prevent progression of the slip. Progression of the slip does not correlate with clinical symptoms. The authors also observed that general joint laxity using Carter's criteria correlates with the presence of degenerative spondylolisthesis.
Vogt MT, Rubin D, Valentin RS, et al. Lumbar olisthesis and lower back symptoms in elderly white women. The Study of Osteoporotic Fractures. *Spine*. 1998;23(23):2640-2647.	II, prognostic	This was a cross sectional study of 788 white south central Pennsylvanian women over 65 years of age who were enrolled in a study intended to address osteoporotic fractures. Spine radiographs were digitized to retrospectively assess prevalence of anterolisthesis. Subluxation of 3 mm or more at any level (L3-4, L4-5, or L5-S1) was defined as a degenerative slip. Anterolisthesis was noted in 29% of this very specific population of white women over the age of 65. Of these patients, only a single level was involved in 90% of women with anterolisthesis. The incidence of slip was not affected by smoking, diabetes mellitus or oophorectomy.	Anterolisthesis was not associated with presence of back symptoms; however no validated outcome measure was used. This study provides Level II evidence that degenerative spondylolisthesis is found in 29% of this very specific population of white women over the age of 65. Slip is most likely to occur at a single level and does not necessarily correlate with back pain.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Diagnosis/Imaging

Question 1:

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

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Cauchoix J, Benoist M, Chassaing V. Degenerative spondylolisthesis. *Clin Orthop Relat Res.* 1976(115):122-129.	IV, prognostic	In this study, diagnostic evaluation of 26 patients with degenerative spondylolisthesis included plain radiographs and myelography. Specifically, the authors stated that they made the diagnosis based on the "presence of a slip of one vertebra on the vertebra below in the absence of a defect of the pars interarticularis." The study included 26 patients with nerve root compression secondary to degenerative slip, with 80% reporting back pain, 46% reporting primary chronic sciatica and 54% reporting primary neurogenic claudication. Sciatica tended to occur in the older patient and neurogenic claudication in the younger subjects.	In critique of this study, this is a characterization of a subset of patients with degenerative lumbar spondylolisthesis referred for evaluation of neurological symptoms. These data offer Level IV prognostic evidence for the neurological symptoms associated with degenerative lumbar spondylolisthesis.
Fitzgerald JAW, Newman PH. Degenerative spondylolisthesis. *JBone Joint Surg.* 58B:184-192, 1976.	IV, prognostic	In this study of 43 patients with symptomatic spondylolisthesis, the authors examined various parameters. It is unclear if the patients represented a consecutive or nonconsecutive series. In addition to a description of plain radiographic findings of the spine, as well as concomitant hip arthritis, the authors provided a detailed description of the presentation (symptom) pattern of the patients. In summary, they found that 34 patients had back pain without leg pain and signs of nerve root compression, five cases with leg pain with or without back pain with signs of nerve root compression and four cases in which patients reported neurogenic claudication.	In critique of this study, one must presume that the patients were enrolled nonconsecutively. As a diagnostic history and physical examination study, the study presents a spectrum of symptoms and signs in patients with degenerative lumbar spondylolisthesis. This study offers Level IV prognostic evidence of the clinical spectrum of signs and symptoms of degenerative spondylolisthesis.
Postacchini F, Perugia D. Degenerative lumbar spondylolisthesis. Part I: Etiology,	III-prognostic	The authors performed a retrospective study which reported on the clinical features of 77 patients. Within these patients, 18% reported chronic low back pain as the only symptom; 12% had lower extremity symptoms felt to be nonvertebral in	In critique of this study, data were collected retrospectively and tests were not uniformly applied across patients. Because of these weaknesses, this potential Level II study was downgraded to Level III. These

pathogenesis, pathomorphology, and clinical features. *Ital J Orthop Traumatol.* 1991;17(2):165-173.		origin (eg, hip arthritis), and reported no low back pain; 47% had radicular symptoms and low back pain; and 23% reported only radicular symptoms. Radiculopathy presented as pain alone, pain and sensory symptoms, or pain and sensorimotor changes. Lasegue test was negative in almost all cases. The most common neurological signs were absent ankle jerks, weak extensor hallucis longus (EHL), weak anterior tibialis or loss of knee jerk reflex. The authors reviewed five clinical patterns and three radiographic patterns as defined by Fitzgerald and Macnab. Clinical patterns included the following: (1) no symptoms, occasional back pain; (2) chronic low back pain with no radicular symptoms; (3) radicular symptoms with no root compression, with or without back pain; (4) radicular symptoms with neurologic deficit or (5) intermittent claudication. Radiological findings included slight central stenosis, lateral root canal stenosis or combined central and root canal stenosis. The authors concluded that degenerative lumbar spondylolisthesis is not always symptomatic. Patients may complain of low back pain, but the etiology is uncertain. Patients largely complain of radicular symptoms or intermittent claudication, which is secondary to an associated stenosis.	data provide Level III prognostic evidence of clinical signs and symptoms of degenerative lumbar spondylolisthesis.
Rosenberg NJ. Degenerative spondylolisthesis. Predisposing factors. *J Bone Joint Surg Am.* 1975;57(4):467-474.	III, prognostic	The authors described a retrospective study which characterized symptoms in 200 consecutive patients with degenerative lumbar spondylolisthesis. Back, buttock or thigh pain were the principal complaints in a large majority of patients, and were rarely severe. Of the 200 patients, 61 had leg symptoms. Some patients described gait abnormalities. Seven patients had sacral nerve root symptoms. Acute radiculopathy occurred in 19 instances and a disc herniation was confirmed on myelography. Symptoms included aching, pulling, weakness, heaviness, numbness or burning. Lower extremity symptoms could be unilateral, bilateral or alternating.	In critique of this study, data were collected retrospectively and tests were not uniformly applied across patients. Because of these weaknesses, this potential Level II study was downgraded to Level III. These data provide Level III prognostic evidence of the typical clinical signs and symptoms which may be associated with degenerative lumbar spondylolisthesis.

		Neurogenic claudication was uncommon. Examination of the patients demonstrated that many were supple and able to touch toes, 10% had back spasms and 42% had neurologic deficits, primarily L5 with decreased sensation in the lateral thigh or inability to walk on heels. Atrophy occurred occasionally and 20% had altered deep tendon reflexes.	
Vogt MT, Rubin D, Valentin RS, et al. Lumbar olisthesis and lower back symptoms in elderly white women. The Study of Osteoporotic Fractures. *Spine*. 1998;23(23):2640-2647.	II, prognostic	The authors described a retrospective, cross-sectional, prognostic study of 788 women greater than 65 years of age enrolled in the Study of Osteoporotic Fractures. The incidence of olisthesis (degenerative spondylolisthesis and retrodisplacement) was defined as greater than 3 mm of translational change. Of the women enrolled in the study, 29% had anterior olisthesis (degenerative spondylolisthesis) and 14% had retrolisthesis. Ninety percent of degenerative spondylolisthesis and 88% of retrolisthesis occurred at one level. Prevalence was not associated with smoking status, diabetes or oophorectomy. Unlike retrolisthesis, degenerative spondylolisthesis was not associated with back pain.	In critique of this study, data were collected retrospectively from a study conducted for other epidemiological purposes. This study offers Level II prognostic evidence that degenerative spondylolisthesis is relatively common in elderly Caucasian women and does not correlate with back pain.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Diagnosis/Imaging

Question 2:

What are the most appropriate diagnostic tests for degenerative lumbar spondylolisthesis?

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Brown MD, Lockwood JM. Degenerative spondylolisthesis. *Instr Course Lect*. 1983;32:162-169.	III, diagnostic	The authors reported findings from a retrospective study of patients with degenerative spondylolisthesis, which examined a number of different parameters, including diagnostic features on plain radiographs. These patients were selected from a review of 2348 consecutive charts of patients with low back pain; 132 (5.6%) had radiographic evidence of degenerative spondylolisthesis. Of patients included in the study, 88 were female and 44 were male. The average age was 63.5 years for the female group and 65.2 years for the male group. Seventy-eight percent had back pain with proximal leg referral lasting between one week and 40 years; 17% had instability symptoms (eg, catch in the back, tiredness in back, inability to walk one hour, limitation of forward bend, inability to lift weights, back pain with coughing or sneezing, significant back pain with twisting).	In critique, this study does not present peer-reviewed data. There was no comparison of diagnostic tests. As the study was performed in the early 1980s, the primary radiographic modality was plain radiographs. These data offer Level III diagnostic evidence that plain radiographs are a useful test for identifying patients with degenerative spondylolisthesis.
Cauchoix J, Benoist M, Chassaing V. Degenerative spondylolisthesis. *Clin Orthop Relat Res*. 1976;115:122-129.	III, diagnostic	The authors conducted a diagnostic evaluation on 26 patients with degenerative spondylolisthesis which included plain radiographs and myelography. Specifically, the authors stated that they made the diagnosis based on the "presence of a slip of one vertebra on the vertebra below in the absence of a defect of the pars interarticularis." The study included 26 patients with nerve root compression secondary to degenerative slip, with 80% reporting back pain, 46% reporting chronic sciatica and 54% reporting neurogenic claudication. Sciatica tended to occur in the older patient and neurogenic claudication in the younger subjects. Myelography was performed in 17 patients to detect	In critique of this study, the authors did not state whether patients were consecutively selected, thus it was assumed that they were nonconsecutive patients. There was no comparison of diagnostic modalities. Admittedly, in the mid to late 1970s, plain radiograph and myelography were the most advanced imaging methods available. By default, they would have been considered gold standard diagnostic tests for degenerative spondylolisthesis and spinal stenosis. These data offer Level III diagnostic evidence that plain radiographs and myelography are useful diagnostic tests for this disorder.

		nerve root/cauda equina compression. Although not supported by statistical analysis, the authors claimed that lateral recess stenosis was "most important."	
Fitzgerald JAW, Newman PH. Degenerative spondylolisthesis. *J Bone Joint Surg*. 1976; 58B:184-192.	III, diagnostic	The authors described a study of 43 patients with symptomatic spondylolisthesis. It is unclear if the patients represented a consecutive or nonconsecutive series. In addition to a description of plain radiographic findings of the spine, as well as concomitant hip arthritis, the authors provided a detailed description of the presentation (symptom) pattern of the patients. In summary, they found that 34 patients had back pain without leg pain and signs of nerve root compression, five cases with leg pain with or without back pain with signs of nerve root compression, and four cases in which patients reported neurogenic claudication. As a diagnostic study, the primary imaging method was plain radiographs; however, plain myelography was also performed in seven of the nine patients with neurological symptoms.	In critique of this study, one must presume that the patients were not consecutively enrolled. The only two imaging methods used were plain radiographs and myelography, which were not uniformly performed in all patients. This study provides Level III diagnostic evidence that plain radiographs and myelography are useful modalities with which to diagnose and evaluate degenerative spondylolisthesis in the lumbar spine.
Kanayama M, Hashimoto T, Shigenobu K, Oha F, Ishida T, Yamane S. Intraoperative biomechanical assessment of lumbar spinal instability: validation of radiographic parameters indicating anterior column support in lumbar spinal fusion. *Spine*. 2003;28(20):2368-2372.	III, diagnostic	The authors reviewed a case series of 19 patients with symptomatic degenerative lumbar spondylolisthesis who were candidates for instrumented lumbar arthrodesis and decompression. Patients were assessed according to radiographic parameters including disc angle, ROM, percent slip, percent posterior height, who were then compared with distraction stiffness in the operating room. The authors concluded that disc angle in flexion and ROM were highly correlated with distraction stiffness. Patients with segmental kyphosis with flexion showed lower stiffness compared to those with lordosis in flexion.	In critique of this study, it assessed an intraoperative and nonvalidated test. The clinical application of such a test remains unknown. Although the study presents potential Level II diagnostic evidence, the authors failed to mention whether the patients were consecutively assigned, thus the study was downgraded to Level III evidence. The study provides Level III diagnostic evidence that standing flexion and extension radiographs are predictive of instability.
Postacchini F, Perugia D. Degenerative lumbar spondylolisthesis. Part I: Etiology,	III, diagnostic	The authors described a study of 77 patients with degenerative spondylolisthesis in which flexion-extension radiographs, CT and/or MRI, and myelography were obtained. The various findings were reported. The authors found that radio-	In critique, the diagnostic studies were applied inconsistently across patients. Not all patients received all studies, preventing comparison between diagnostic modalities. This article presented comprehensive descrip-

pathogenesis, pathomorphology, and clinical features. *Ital J Orthop Traumatol.*1991;17(2):165-173.		graphs used for imaging quantified the degree of slips observed. Dynamic radiographs "showed hypermobility of L4 in approximately half of the cases." Myelography revealed neural structure compression in the spinal canal in all cases in which it was performed. (Note: myelography may have only been performed if patients had neurologic symptoms.) CT was useful for assessing the facet joint. MRI, CT and myelography were useful in identifying stenosis in patients with neurological symptoms.	tions of the findings with each of the diagnostic modalities. These data offer Level III diagnostic evidence of the utility of dynamic radiographs, CT, MRI and myelography for evaluation of degenerative spondylolisthesis.
Rosenberg NJ. Degenerative spondylolisthesis. Predisposing factors. *J Bone Joint Surg Am.* 1975;57(4):467-474.	II, diagnostic	This is a retrospective study which characterized 200 consecutive patients with degenerative lumbar spondylolisthesis. This cohort contained a subgroup of 39 patients with severe unremitting symptoms; 29 underwent myelography and showed an hourglass constriction of the dura at the level of slippage. Seven patients also had a protrusion. Surgical findings include absence of epidural fat, pale pulseless dura and decreased capacity of the spinal canal.	In critique of this study, data was collected retrospectively and tests were not uniformly applied across patients. However, from the diagnostic perspective, this small subgroup of 29 patients provides a consecutive series of patients that was retrospectively analyzed. These subgroup data provide Level II diagnostic evidence that myelography is useful in identifying stenosis in patients with degenerative spondylolisthesis and neurological symptoms.
Rothman SL, Glenn WV, Jr., Kerber CW. Multiplanar CT in the evaluation of degenerative spondylolisthesis. A review of 150 cases. *Comput Radiol.* 1985;9(4):223-232.	IV, diagnostic	This study was a retrospective review of the CT findings of 150 patients with degenerative spondylolisthesis. The authors described the pathological findings, which included canal stenosis, facet overgrowth, joint-capsule hypertrophy, ligamentum flavum enlargement and gas within the facet joints. All patients were examined on GE 8800 CT scanners using axial scans of 5 mm-thick sections at 3 mm spacing, with sagittal and coronal reformats. The authors found only 19% had subluxation greater than 6 mm. Severe facet degeneration with marked hypertrophy, erosive changes or gas within an irregular joint was noted in 91 patients. Severe canal stenosis was detected in 15 patients as a result of narrowing of the central canal secondary to a combination of subluxation, facet boney overgrowth, joint-capsule hypertrophy, ligamentous hyper-	In critique, this was a study of non-consecutive patients, radiological findings were not correlated with clinical signs or symptoms, and no gold standard was employed. The data present Level IV diagnostic evidence that CT is a useful modality in the diagnosis of stenosis in patients with degenerative spondylolisthesis.

		trophy, bulging and end plate osteophyte formation. Foraminal stenosis was observed in 38 patients. Anterior soft tissue bulge/herniation of greater than 5 mm was present in only three patients. The authors concluded that CT is useful in evaluating the severity of stenosis in patients with symptomatic degenerative spondylolisthesis. Stenosis is frequently secondary to soft tissue changes and facet hypertrophy, and does not always correlate with the severity of slip.	
Satomi K, Hirabayashi K, Toyama Y, Fujimura Y. A clinical study of degenerative spondylolisthesis. Radiographic analysis and choice of treatment. *Spine*. 1992;17(11):1329-1336.	III, diagnostic	The authors reported findings from a retrospective case series of patients with degenerative spondylolisthesis who were evaluated with CT myelography in order to plan the optimal surgical procedure. CT myelograms were compared with plain radiographic myelograms to evaluate the sites of dural compression. Patients who underwent anterior lumbar interbody fusion (ALIF) were included in Group A. Patients were selected for the posterior decompression group (Group B) if their imaging showed displacement at two or more discs, had CT myelographic findings indicating lateral stenosis or were deemed inappropriate candidates for ALIF because of age. Group A consisted of 27 patients; discography was performed in 22. Based on the novel CT myelogram classification used in the study, 38% of these patients had stage 3 stenotic changes. Group B consisted of 14 patients, five of which underwent fusion. Of these patients, four reported back pain; neurogenic intermittent claudication was more severe in group B. Discography was performed in two patients. Based on myelogram classification used in the study, 62% of these patients had stage 3 stenotic changes. Stenosis over two disc space levels was present in 92% of these patients. The authors concluded that information on CTM was useful for identifying pathologic processes and for planning surgery.	In critique of this study, the authors did not evaluate a list of diagnostic criteria a priori. The authors failed to indicate whether patients were selected consecutively. These data offer Level III diagnostic evidence that CT myelography is a useful imaging study for this disorder.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Outcome Measures

What are the appropriate outcome measures for the treatment of degenerative lumbar spondylolisthesis?

Note: The Zurich Claudication Questionnaire (ZCQ) represents an evolution of Swiss Spinal Stenosis Questionnaire (SSS). Conclusions made about either questionnaire can be extrapolated to the other.

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X-STOP device in patients with lumbar degenerative spondylolisthesis. *J Neurosurg Spine*. 2006;4(6): 463-471.	II, prognostic	The authors reported a randomized (post-hoc) controlled trial of patients with neurogenic claudication secondary to degenerative spondylolisthesis. Of the 75 spondylolisthesis patients included in the study, 42 received the X-STOP device and 33 were included in the control group assigned to medical/interventional treatment consisting of at least one epidural steroid injection, drugs, analgesic agents and physical therapy as needed. Two year follow-up data were obtained for 70 of the 75 patients. The outcome measures implemented in the study included the Zurich Claudication Questionnaire (ZCQ), patient satisfaction on a scale from 0-5, 36-Item Short Form Health Survey (SF-36) and radiographic assessment. Successful treatment was defined as improvement in ZCQ of 15 points, patient satisfaction of greater than 2.5 and no additional surgery. The authors reported that success was noted in 63.4% of the surgically treated individuals, which was statistically significant between preoperative and postoperative scores. Only 12.9% of medically/interventionally treated patients were considered successes which was not statistically significant between pretreatment and post-treatment patients. The authors concluded that the clinical success for the X-STOP surgically treated patients compared with the medically/interventionally treated controls was highly significant.	In critique, this study was a cohort analysis of a randomized prospective trial for spinal stenosis. The cohort studied consisted of patients who had grade I spondylolisthesis as well as spinal stenosis. The outcome measures used included both validated and nonvalidated outcome measures including the validated Zurich Claudication Questionnaire (ZCQ) and an arbitrary patient satisfaction survey at follow-up visits. Although the authors obtained SF-36 outcome data, these data were not used in the study to determine clinical success. This study provides Level II prognostic evidence supporting use of the Zurich Claudication Questionnaire (ZCQ) and the SF-36 outcome measures as sensitive tools in distinguishing the outcome differences between surgically treated (X-STOP) and medically/interventionally treated individuals.
Frazier DD, Lipson SJ,	II, prog-	The authors described a prospective, observational study evaluating the prognos-	In critique, this study was not designed to validate the Walking Capac-

Fossel AH, Katz JN. Associations between spinal deformity and outcomes after decompression for spinal stenosis. *Spine*. 1997;22(17): 2025-2029.	nostic	tic factors affecting clinical outcomes as correlated to the presence or absence of the deformities of degenerative scoliosis and spondylolisthesis. The outcome measure implemented in the study included a questionnaire administered preoperatively, and at six and 24 months postoperatively. Patients rated the severity of back pain, leg pain, overall pain and difficulty ambulating using a Five Point Likert Pain Scale. A Walking Capacity Scale was calculated using the average responses to five questions on walking difficulty in general, outdoor, indoor, shopping and bedroom to bathroom walking. The patient satisfaction scale was generated by using the average for six questions concerning satisfaction with pain relief, functional improvement and other domains. The authors stated that these scales had been shown to be reproducible, internally consistent and valid for patients with spinal stenosis. No statistical support for these statements was provided. The authors reported that the spondylolisthesis subgroup showed no correlation of slip magnitude and patient outcomes. An increase in the slip postoperatively was significantly correlated with improved leg pain relief and borderline improvement in walking capacity. Satisfaction with the procedure and back pain relief was positively, but not significantly, correlated with slip progression. The authors concluded that surgery was beneficial, but that fusion rationale may be questioned.	ity Scale or the Five Point Likert Pain Scale as sensitive measures for degenerative spondylolisthesis. However, these measures have been previously validated by Stucki et al[38] as the SSS, currently referred to as the ZCQ. This study offers Level II prognostic evidence that the ZCQ/SSS is sensitive enough to show differences between surgically and medically/interventionally treated patients with degenerative spondylolisthesis and symptomatic spinal stenosis.
Gaetani P, Aimar E, Panella L, et al. Functional disability after instrumented stabilization in lumbar degenerative spondylolisthesis: a follow-up study. *Funct*	I, prognostic	The authors described a prospective, prognostic study of 76 patients treated with decompression and bilateral instrumented fusion and followed for two years. There were 25 males and 51 females with a mean age of 59.6 years (+/-12.2) and mean duration of symptoms of 23.42 months. The outcome measures used in the study included the Roland Morris Disability Questionnaire (RMDQ); Oswestry Disability Index (ODI) for quality of life	In critique of this study, this study provides only 24-month follow-up data. This time frame may not be long enough to fully evaluate the effect of pseudoarthrosis on patient outcomes. This study provides Level I prognostic evidence suggesting correlation of RMDQ and ODI scores with symptoms and slippage. The RMDQ appears to be a sensitive tool to assess degenerative spondylolisthesis out-

Neurol. 2006; 21(1): 31-37.		patient centered outcomes; Visual Analog Scale (VAS) for leg and back pain; preoperative dynamic radiographs, CT, and MRI; and postoperative radiographs. The authors reported a fusion rate of 85.5%, improvement in ODI scores of less than 20 points in 35.7% of patients and greater than 20 points in 55.7%. Scores on the RMDQ improved greater than five points in 59.4% of patients, 2-4 points in 13.1%, and remained unchanged in 27.5%. There was no difference between solid fusion and pseudoarthrosis. The authors concluded that instrumented fusion was effective in improving the quality of life, as exhibited by the reduced disability scores.	come data. This study shows improvement in the quality of life scores in both outcome tools. The study also supports the conclusion that the presence or absence of fusion was not a prognostic indicator of patient outcome improvements.
Ghogawala Z, Benzel EC, Amin-Hanjani S, et al. Prospective outcomes evaluation after decompression with or without instrumented fusion for lumbar stenosis and degenerative Grade I spondylolisthesis. *J Neurosurg Spine.* 2004; 1(3): 267-272.	II, prognostic	The authors described a prospective study assessing the outcomes of decompression alone in 20 patients and decompression with instrumented fusion in 14 patients with degenerative grade I lumbar spondylolisthesis. The outcome measures implemented included the ODI and the SF-36. The authors reported that fusion occurred at a 93% rate in the arthrodesis group. The ODI improved 27.5 points in the fusion group and 13.6 points in the decompression only group. The difference was statistically significant. The SF-36 data were also significantly different between the two groups. Both instruments, SF-36 and ODI, demonstrated poorer outcomes in older patients at 12 months.	In critique of this study, this was a small pilot study demonstrating a clear need for future Level I randomized controlled trials utilizing these measures. This study provides Level II prognostic evidence supporting the use of the ODI and SF-36 as tools to assess outcomes after surgery for degenerative spondylolisthesis. These two outcome tools identify similar and parallel changes in outcomes of the treatment groups, and this study supports the use of these two outcome measures together to effectively assess outcomes in this population. Evidence of the ability to discriminate between treatment outcomes using the ODI and SF-36 is supported by the findings in this study that older patients demonstrated poorer outcomes than younger patients.
Kawakami M, Tamaki T, Ando M, Yamada H, Hashizume H, Yoshida M. Lumbar sagittal balance influences the clinical outcome	III, prognostic	The authors performed a retrospective case control study of 47 patients (15 males / 32 females) who had undergone decompression and fusion with and without instrumentation. Pedicle screw fixation was used in those cases with a fixed kyphosis at the involved segment. The outcome measures used included the Japanese Orthopedic Association (JOA) score,	In critique, this study utilized a validated outcome measure commonly used in Japan that has not gained universal acceptance. The paper was designed as a clinical outcome study, rather than a prognostic study evaluating the JOA outcome measure, specifically. This study provides Level III prognostic

after decompression and posterolateral spinal fusion for degenerative lumbar spondylolisthesis. *Spine*. 2002; 27(1): 59-64.		VAS, recovery rate (Hirabayashi's method), slippage, L1 axis S1 distance (LASD), lumbar lordosis, lordosis at the fused segment, bony union and adjacent segment changes. Patients with degenerative lumbar spondylolisthesis were divided into two groups according to the LASD value and the changes in slippage during the follow-up period: the patients with LASD greater than 35 mm (Group A) and those with LASD less than 35 mm (Group B). The patients in Group A were divided into two subgroups: the patients with in situ fusion (Group A1) and patients with reduced slippage (Group A2). The authors reported that the JOA scores were 12.6 points +/- 4.8 preoperatively and 21.7 points +/- 4.9 postoperatively, and the recovery rate was 55.1% +/- 27.8%. There were no differences in the prognostic factors of preoperative slip, lumbar lordosis, lordosis of fused segment and recovery rates. LASD and recovery rate were negatively correlated. Patients in Group A1 had poorer JOA scores and recovery rates than those in Groups A2 and B.	evidence suggesting that the JOA score and recovery rate may be sensitive outcome tools in assessing treatment for degenerative lumbar spondylolisthesis.
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.	I, prognostic	This paper reported on 58 patients extracted from a prospective, randomized, controlled trial of posterior decompression and fusion to determine the relationship of presence or absence of pseudoarthrosis to outcomes. Of the 118 patients originally randomized to decompression or decompression with a noninstrumented fusion, 58 patients underwent fusion, of which 47 were available for review. The outcome measures used in this study included the VAS (modified), a rudimentary outcome scale (excellent, good, fair, poor) and the Swiss Spinal Stenosis Questionnaire (SSS). The authors reported that arthrodesis does result in better outcomes on the SSS at five to 14 years as opposed to earlier follow-up.	In critique of this study, the bundling of these patients and subsequent evaluation at three year follow-up represents a significant weakness of the study. The SSS was not applied preoperatively, but was only administered postoperatively. This study provides Level I prognostic evidence suggesting that the SSS is a sensitive, validated instrument which correlates well with patient outcome, and is appropriate for use in the assessment of clinical outcomes for degenerative lumbar spondylolisthesis.
Okuda S, Oda	II,	The authors conducted a comparative	In critique of this study, 39% of the

T, Miyauchi A, Haku T, Yamamoto T, Iwasaki M. Surgical outcomes of posterior lumbar interbody fusion in elderly patients. *J Bone Joint Surg Am*. 2006; 88(12): 2714-2720.	prognostic	retrospective prognostic study including 101 elderly patients with degenerative spondylolisthesis treated with PLIF. Patients were divided into two groups based upon age. Group 1 included patients aged 70 years and older, while Group 2 included patients from 55 years to 69 years of age at the time of the index procedure. The authors compared treatment outcomes between both groups to determine differences in outcome based upon age. The outcome measures used in this study included the JOA score, VAS, complication rates, recovery rate (Hirabayashi method) and radiographic evaluation. The authors reported that in Group 1, the JOA improved from 12 to 23; the recovery rate was 63%; and general complications, delirium and brain infract occurred in 10% of patients. In Group 2, the JOA improved from 12 to 24 and the recovery rate was 70%.	cases were not independently reviewed. This study provides Level II prognostic evidence that the JOA shows improvement in functional outcome with surgical treatment regardless of age, but is not correlated with other measures of functional outcomes. Older patients, despite higher definable complication rates (approaching 10%) showed similar recovery rates and JOA scores to younger patients.
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.	I, prognostic	The authors conducted a prospective, prognostic study evaluating outcome instruments in all patients who attended the Nuffield Orthopaedic Center. These were patients with spinal stenosis which included patients with degenerative spondylolisthesis. Of the 52 patients approached to participate in the study, 13 declined involvement and seven were excluded because of comorbidities limiting walking distance. To determine reliability, the 32 clinic patients with lumbar spinal stenosis were assessed twice, with one week between assessments. Retrospective data from 17 patients assessed before surgery and 18 months after surgery for lumbar spinal stenosis were used to investigate the use of reliability in a clinical setting. The patients were assessed using the Oswestry Disability Index (ODI) and three instruments designed specifically for use in patients with lumbar spinal stenosis: the Swiss Spinal Stenosis (SSS) Questionnaire, the Oxford Claudication Score	In critique of this study, the subset of patients with degenerative spondylolisthesis was not broken out and analyzed separately from the stenosis group. Fluctuations in a patient's symptoms resulted in wide individual confidence intervals. Performance on the SSS, OCS and ODI questionnaires are broadly similar, the most precise being the condition-specific SSS. The SWT gives a snapshot of physical function, which is acceptable for group analysis. Use of the SWT for individual assessment after surgery is feasible. This study offers Level I prognostic evidence that the ODI, SSS, OCS and SWT tests reliably and validly evaluate patients with symptomatic spinal stenosis within which a subgroup of degenerative spondylolisthesis patients reside.

		(OCS) and a functional test, the Shuttle Walk Test (SWT). Patient outcomes were studied by the previously validated outcome studies, the SSS and ODI. The OCS and SWT were studied in relation to these previously validated outcome measures. Data analysis included a test against normality using the Komolgorov-Smirnov-Goodness-of-Fit test. The test-retest reliability of the SSS, OCS, ODI and SWT were assessed with an internal correlation coefficient test in which the reliability was the subject variability/ (subject variability + measurement error). The 95% confidence intervals for each outcome instrument were reported. The internal consistency of the scales and their subsections were assessed using Cronbach's coefficient alpha, which summarizes inter-item correlations. The relationship between the four tests was assessed using scatter plots, according to the method of Bland and Altmann, and the Pearson product–moment correlation coefficient (two-tailed). Bonferroni's correction was used for multiple tests to reduce the chance of Type 1 error. Test–retest reliability in terms of the intraclass correlation coefficient (ICC) was 0.92 for the SWT, 0.92 for the SSS, 0.83 for the OCS and 0.89 for the ODI. The mean percentage scores were 51 for the SSS, 45 for the OCS, and 40 for the ODI. To achieve 95% certainty of change between assessments for a single patient, the SSS would need to change by 15, the OCS by 20, and the ODI by 16. The mean SWT was 150 m, with a change of 76 m required for 95% confidence. Cronbach's alpha was 0.91 for the SSS, 0.90 for the OCS, and 0.89 for the ODI. The change in ODI correlated most strongly with patient satisfaction after surgery (0.80; P ≤0.001).	
Stucki G, Dal-	II,	The authors described a prospective,	In critique, of the 193 patients in-

troy 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.	prognostic	prognostic study of the Zurich Claudication Questionnaire (ZCQ) or Swiss Spinal Stenosis (SSS) Questionnaire, an outcome instrument specific to spinal stenosis. The measurement properties and validity of this newly-developed patient questionnaire for the assessment of patients with lumbar spinal stenosis was tested in an ongoing prospective multicenter observational study of patients undergoing decompressive surgery in three teaching hospitals. The internal consistency of the scales was assessed with Cronbach's coefficient alpha on cross-sectional data from 193 patients before surgery. The test-retest reliability was assessed on data from a random sample of 23 patients using Spearman's rank correlation coefficient. The responsiveness was assessed on 130 patients with six month follow-up data using the standardized response mean. The test-retest reliability of the scales ranged from 0.82 to 0.96, the internal consistency from 0.64 to 0.92, and the responsiveness from 0.96 to 1.07. The direction, statistical significance and strength of hypothesized relationships with external criteria were as expected.	cluded in this study, only 23 had pretest and posttest validation of the SSS. The follow-up on 130/193 patients for test responsiveness at six months is arguably short. Because of these shortcomings, this potentially Level I prospective study was downgraded to a Level II study. Although the reproducibility, internal consistency, validity and responsiveness of this test were established by comparison with known validated outcome measurement instruments, these instruments are not necessarily specific to degenerative lumbar spondylolisthesis. In addition, the extent of stenosis and associated pathology was not clear. Patients with language barriers and cognitive difficulties were excluded. This study provides Level II prognostic 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 degenerative lumbar spondylolisthesis with symptomatic spinal stenosis. This instrument is currently referred to as the Zurich Claudication Questionnaire (ZCQ) or Swiss Spinal Stenosis Questionnaire (SSS).
Vaccaro AR, Patel T, Fischgrund J, et al. A pilot study evaluating the safety and efficacy of OP-1 Putty (rhBMP-7) as a replacement for iliac crest autograft in posterolateral lumbar arthrodesis for degenerative spondylolisthesis. *Spine*.	II, prognostic	The authors reported a prospective, randomized control trial comparing surgical outcomes in patients randomly assigned to receive either OP1 putty (24 patients) or autograft bone (12 patients) in conjunction with decompressive laminectomy for the treatment of degenerative lumbar spondylolisthesis. The outcome measures utilized in this study included the ODI, SF-36 and radiographic assessment. At one year, of the 36 patients studied, 32 were available for clinical follow-up (18 in the OP1 group and eight in the autograft group) and 29 received radiographic assessment (14 in the OP1 group and six in the autograft group). ODI success was	In critique of this study, clinical success was arbitrarily defined as a 20% improvement in ODI scores. The authors failed to justify the choice of this benchmark. The study does not correlate any outcome instruments to the ODI. This study provides Level II prognostic evidence that the ODI can be used to assess clinical outcome after surgical treatment of degenerative spondylolisthesis.

2004;29(17):1885-1892.		defined by greater than 20% improvement in scores at one year. An 86% success rate was reported for the OP1 putty group, and a 73% success rate was reported for the patients receiving autograft. According to radiographic criteria, fusion was achieved in 74% of patients in the OP1 group and 60% of patients in the autograft group. Of the 29 patients evaluated radiographically, 15 were defined as both radiographically and clinically successful, while five were categorized as radiographically successful with clinical failure and eight were classified as radiographic failures, but achieved clinical success.	
Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med*. 2007; 356(22): 2257-2270.	I, prognostic	The authors conducted a prospective, randomized control trial evaluating the outcomes of surgical treatment of degenerative spondylolisthesis compared with medical/interventional treatment in 304 patients. The study also included a second observational cohort of 303 patients who refused randomization, but agreed to participate in the study. The primary outcome measures used in the study included the Medical Outcomes Study SF-36 bodily pain and physical function scores and the modified Oswestry Disability Index. Data were collected at six weeks, three months, six months, one year and two years. Secondary outcomes measures included patient reported improvement, satisfaction with current symptoms and care, Stenosis Bothersome Index and LBP Bothersome Index. Within the randomized arm of the study, the authors reported a 40% crossover in each direction. Intention-to-treat analysis showed no significant differences in any outcome. As-treated analysis for both cohorts showed significant advantages at three months that increased at one year and were durable at two years. Treatment effects at two years were 18.1 for bodily pain (95%, CI 14.5-21.7) 18.3 for physical function (95%, CI 14.6-21.9) and -16.7 for	In critique of this study, the secondary outcome measures, Stenosis Bothersome Index and LBP Bothersome Index have not been specifically validated for degenerative lumbar spondylolisthesis. This study provides Level I prognostic evidence from both the randomization and observational cohorts that the primary outcome measures — Medical Outcomes Study SF-36 bodily pain and physical function scores and the modified Oswestry Disability Index — are appropriate instruments to use in detecting treatment effects in patients with degenerative lumbar spondylolisthesis.

		ODI (95%, CI -19.5 to -13.9). There is little evidence suggesting harm with either surgical or medical treatment.	

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 1:

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

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. *J Neurosurg Spine*. 2006;4(6):463-471.	III, therapeutic	This data represent subgroup analysis data from a large, randomized controlled trial dealing with spinal stenosis. As such, this represents a prospective, comparative study of 75 patients with neurogenic claudication from lumbar spinal stenosis and low grade (less than 25% translation) spondylolisthesis who were treated either with the X STOP device (an interspinous process spacer) or with medical/interventional treatment. The medical/interventional (control) group did receive treatment, which included at least one epidural steroid injection, medications and physical therapy. Thus, this group was not truly representative of the natural history of the disorder. At two-year follow-up, there were statistically significant improvements in the Zurich Claudication Questionnaire (ZCQ) score and patient satisfaction in those treated with X STOP; there were no statistically significant improvements in the medical/interventional group.	In critique of this study, the cohort of 75 patients was derived from a larger pool of candidates with spinal stenosis (and not necessarily spondylolisthesis) who were randomized into the X STOP treatment group and medical/interventional group. However there were no significant baseline differences detected between the groups. Five patients in the X STOP group and four patients in the medical/interventional group subsequently underwent a laminectomy. It is unclear if the data from these patients were included as an intention-to-treat analysis. If one were to equate medical/interventional treatment including injections, therapy and medications with natural history, this study offers Level III therapeutic evidence that surgical treatment in the form of an interspinous spacer improves upon the natural history of neurogenic claudication and spinal stenosis with low grade degenerative spondylolisthesis.
Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med*.	II, therapeutic	This was designed as a multicenter, prospective, randomized controlled trial comparing surgery and medical/interventional treatment for neurogenic claudication from spinal stenosis and degenerative spondylolisthesis. In addition, there was a nonrandomized observational arm that compared the two treatment options. Eligible patients had symptoms for at least 12 weeks and could have had medi-	In critique of this study, there was a high crossover rate between study groups. For instance, 49% of those patients assigned to medical/interventional treatment had undergone surgery at two-year follow-up. Likewise, only 64% of those who were assigned to the surgical group had undergone surgery by two years. Because of the high degree of cross-

2007;356(22):2257-2270.		cal/interventional treatment prior to enrollment. Surgical treatment included laminectomy with or without fusion; however, few patients underwent laminectomy alone. Medical/interventional treatment included at least active physical therapy, education/counseling and medications.	over, this study is more appropriately considered a prospective, comparative study. The as-treated analysis showed statistically better outcomes with surgery that were maintained at the two-year follow-up. Medical/interventional treatment included at least active physical therapy, education/counseling and medications; however, this was not standardized by any particular protocol. If one were to equate medical/interventional treatment including injections, therapy and medications with natural history, this study offers Level II therapeutic evidence that surgical treatment in the form of a laminectomy with or without fusion improves upon the natural history of neurogenic claudication and spinal stenosis with degenerative spondylolisthesis.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 2:

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

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Anderson PA, Tribus CB, Kitchel SH. Treatment of neurogenic claudication by interspinous decompression: application of the X STOP device in patients with lumbar degenerative spondylolisthesis. *J Neurosurg Spine*. 2006;4(6):463-471.	III, therapeutic	The study represents an analysis of a subgroup of 75 patients with grade I degenerative spondylolisthesis who were originally included in the pivotal randomized controlled trial comparing the X STOP device and medical/interventional treatment for spinal stenosis with neurogenic claudication that was relieved by flexion and sitting. Although examined prospectively, this subgroup was not appropriated to surgical and medical/interventional treatment in a truly randomized fashion. Forty-two patients had the X STOP device placed, while 33 had medical/interventional treatment that included at least one epidural steroid injection, medications and physical therapy as needed. Only 70 of 75 patients had a minimum of two-year follow-up. Of patients in the X STOP group, 63% had significant improvements in the Zurich Claudication Questionnaire (ZCQ) score, whereas 12% in the medical/interventional group had significant improvements.	In critique of this study, although labeled by the authors as a randomized controlled trial, it was not such for patients with degenerative spondylolisthesis. There were relatively low patient numbers. In support of their findings, there was a low attrition rate (7% at two year follow-up). Furthermore, the investigators utilized a validated outcome instrument, the ZCQ. This study offers Level III therapeutic evidence that an interspinous distraction device which provides indirect decompression leads to better outcomes at two years in patients with spinal stenosis and grade I degenerative spondylolisthesis than does medical/interventional intervention.
Matsudaira K, Yamazaki T, Seichi A, et al. Spinal stenosis in grade I degenerative lumbar spondylolisthesis: a comparative study of outcomes following lamin-	III, therapeutic	This study was a retrospective comparative study of 53 patients with spinal stenosis and grade I degenerative spondylolisthesis. Nineteen underwent decompression with instrumented fusion, 18 underwent decompressive laminoplasty without fusion, and 16 had medical/interventional treatment. At a minimum of two years follow-up, patients in both surgical treatment groups showed significantly better improvements in Japanese Orthopaedic As-	In critique of this study, the sample was modest, particularly considering that there were only 16 patients in the medical/interventional group. To be used to answer the current question, one has to assume that medical/interventional treatment is equivalent to natural history. In support of the study, patients uniformly had grade I degenerative spondylolisthesis. This paper provides Level III

oplasty and laminectomy with instrumented spinal fusion. *J Orthop Sci.* 2005;10(3):270-276.		sociation (JOA) scores than the medical/interventional group.	therapeutic evidence that decompressive surgery alone in the form of a decompressive laminoplasty results in better outcomes than the natural history of spinal stenosis with grade I degenerative spondylolisthesis.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 3:

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

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
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, therapeutic	This is a prospective, comparative study of 44 surgically treated patients with degenerative lumbar spondylolisthesis followed for a minimum of two years. Of the 44 patients, nine underwent laminectomy alone, 10 had laminectomy and instrumented fusion and 24 had laminectomy and instrumented fusion (18 single level, six two-level). Patients were radiographically assessed and a functional assessment was conducted by asking whether they felt their ability to walk distances was worse (-), the same (0) or significantly better (+). Of the 44 patients, 43 were followed for two years or more. The authors determined that instrumented fusion had higher fusion rates than noninstrumented fusion (ρ=0.002). The authors further observed greater progression of spondylolisthesis in patients treated with laminectomy alone (44%) and in laminectomy without instrumented fusion (70%) compared to patients who received laminectomy with instrumented fusion (4%,ρ=0.001). A higher proportion of the patients without slippage progression reported that they were helped by the surgery than those whose slippage progressed postoperatively (ρ<0.01).	In critique, this was a small study in which selection bias entered into the randomization process, reviewers were not masked to patient treatment and validated outcome measures were not utilized. Because of these weaknesses, this potential Level II study was downgraded to Level III. This study provides Level III therapeutic evidence that instrumented fusion patients had less chance of progressive slippage postoperatively than laminectomy alone or noninstrumented fusions, and a higher proportion of patients with stable or unchanged spondylolisthesis reported greater improvement after surgery.
Ghogawala Z, Benzel EC, Amin-Hanjani S, et al. Prospective outcomes evaluation after decompression with or without	IV, therapeutic	This is a retrospective comparative study of 34 patients with lumbar stenosis and degenerative Grade I spondylolisthesis who underwent decompression. Of the 34 patients, 14 received posterior instrumented fusion. Outcomes were assessed using the Oswestry Disability Index (ODI) and SF 36 at six and 12 months.	In critique of this study, this was a small study with short follow-up with no clearly defined indications for specific treatment selections. Slips greater than 3 mm on flexion/extension radiographs were excluded. Because of these weaknesses, this potential Level III study was downgraded to Level IV.

instrumented fusion for lumbar stenosis and degenerative Grade I spondylolisthesis. *J Neurosurg Spine*. Oct 2004;1(3):267-272.		The authors reported an 83% fusion rate at one-year follow-up. Patients in both groups reported improvement compared to baseline status. Decompression plus fusion led to an improvement in ODI scores of 27.5 points; whereas, decompression alone was associated with a 13.6 point increase (ρ=0.02). Analysis of SF-36 also demonstrated significant intergroup difference (ρ=0.003). The authors concluded that surgery substantially improved one year outcomes based on validated outcome instruments in patients with Grade I spondylolisthesis and stenosis. Fusion was associated with significantly greater functional improvements compared with decompression alone. The authors also noted that older age was a predictor of worse outcome.	This study provides Level IV therapeutic evidence that for patients with slips less than 3mm, both decompression and decompression with fusion result in improved outcomes. Decompression with fusion results in greater improvement in functional outcomes.
Herkowitz HN, Kurz LT. Degenerative lumbar spondylolisthesis with spinal stenosis. A prospective study comparing decompression with decompression and intertransverse process arthrodesis. *J Bone Joint Surg Am*. 1991;73(6):802-808.	III, therapeutic	This is a prospective, comparative study of 50 patients with degenerative lumbar spondylolisthesis who were studied clinically and radiographically to determine if concomitant intertransverse process arthrodesis provided better results than decompression alone. Outcomes were assessed using a rudimentary outcome scale (excellent, good, fair, poor) with a mean follow-up of three years. The authors reported that of the 25 patients treated with decompression and fusion, 11 reported excellent results, 13 good, one fair and zero poor. Of the 25 patients treated with decompression alone, two reported excellent results, nine good, 12 fair and two poor. Improved results in the patients who had an arthrodesis concomitantly with decompression were significant by the Fisher exact test (ρ=0.0001). The authors concluded that in patients who had a concomitant arthrodesis, the results were significantly better with respect to relief of low back pain and lower limb pain.	In critique, this was a small study which did not utilize validated clinical outcome measures or describe baseline characteristics of the groups. Because of these weaknesses, this potential Level II study was downgraded to Level III. This study offers Level III therapeutic evidence that decompression with arthrodesis in patients with degenerative lumbar spondylolisthesis provides significantly better relief of low back pain and leg pain than decompression alone.
Laus M, Tigani D, Alfonso C, Giunti A. Degenerative	IV, therapeutic	This is a retrospective comparative study of 24 patients with degenerative lumbar spondylolisthesis divided into three groups. Group I (eight patients): those	In critique, this is a small study of only 24 patients which utilized no validated outcome measures. In addition, assignment of patients to treatment

spondylolisthesis: lumbar stenosis and instability. *Chir Organi Mov*. 1992;77(1):39-49.		with spondylotic instability; Group II (10 patients): those with lumbar stenosis and current or potential segmental instability; Group III (six patients): those with lumbar stenosis and naturally stabilized spondylolisthesis. Group I was treated by posterolateral fusion; Group II by laminectomy, removal of the medial portion of the facets and posterolateral fusion; and Group III by laminectomy and removal of the medial portion of the facets. Outcomes were assessed using a rudimentary outcome scale (excellent, good, fair, poor) with a mean follow-up of 3.5 years. The authors reported that Group I had 100% good or excellent results (5E/3G). All had solid fusion. Group II had 90% good or excellent results (6E/3G/1P). All had solid fusion. Group III had 83% good or excellent results (3E/2G/1P). The authors concluded that the long-term outcomes for the fusion group exceeded those of the laminectomy alone group, but this finding was not statistically significant.	groups was highly biased by surgeon preference. Because of these weaknesses, this potential Level III paper was downgraded to Level IV. This paper offers Level IV therapeutic evidence suggesting that fusion was superior to decompression alone, but not statistically significant because of the limited size of the study.
Lombardi, J.S., et al., Treatment of degenerative spondylolisthesis. *Spine*. 1985. 10(9): p. 821-7.	IV, therapeutic	This is a retrospective comparative study of surgical treatment outcomes in 47 degenerative lumbar spondylolisthesis patients. Of the 47 patients, six had wide laminectomy, 20 had standard laminectomy with preserved facets and 21 had laminectomy with preserved facets with fusion. Outcomes were assessed by patients utilizing a rudimentary outcome scale (excellent, good, fair, poor, failure), with radiographic analysis at a mean follow-up of 2.7 years. The authors reported that 30% of patients in the wide laminectomy group reported good/excellent results, 80% reported good/excellent results in the standard laminectomy with preserved facets group, and 90% reported good/excellent results in the decompression with facet preservation and fusion group. The authors concluded that decompression with facet preservation and fusion yielded the best clinical outcomes at two-	In critique of this study, it is a small, nonrandomized, nonmatched study which did not utilize validated outcome measures. In addition, the study did not provide detailed statistical analysis. Because of these weaknesses, this potential Level III study was downgraded to Level IV. This paper offers Level IV therapeutic evidence that posterior decompression with preservation of the facets, plus transverse process fusion, provides superior outcomes to decompression alone for surgical treatment of degenerative lumbar spondylolisthesis regardless of age.

		year follow-up.	
Mardjetko, S.M., P.J. Connolly, and S. Shott, Degenerative lumbar spondylolisthesis. A meta-analysis of literature 1970-1993. *Spine*. 1994;19(20 Suppl):2256S-2265S.	III, therapeutic	This is a meta-analysis of primarily Level III studies. The objective of the study was to analyze the published data on degenerative spondylolisthesis to evaluate the feasibility of its use as a literature control to compare with the historical cohort pedicle screw study data. The authors conducted a comprehensive literature search to identify studies published in English peer-reviewed journals between 1970 and 1993 addressing degenerative spondylolisthesis with radicular leg pain or neurogenic claudication. Inclusion criteria included a minimum of four cases reviewed and reporting of the primary outcome variable of fusion in articles in which this was part of the treatment. Clinical outcome variables of back pain, leg pain, function, neurogenic claudication and global outcome scores were recorded when available. A total of 25 papers representing 889 patients were accepted for inclusion. Twenty-one were retrospective, nonrandomized and uncontrolled. One paper was retrospective and nonrandomized, but compared two different treatments. Three prospective, randomized studies were included. The primary outcome variable, fusion, was determined by each author. The most constant clinical outcome variable reported was pain; with 16 papers reporting pain only, six papers reporting pain and function, and two papers reporting the patient-determined outcomes. Patient function was reported in six papers and referred to the presence or absence of neurogenic claudication. In addition to these clinical outcomes, four papers reported a global evaluation. Two used Kaneda's rating system and two used the Japanese Orthopedic Association (JOA) score. Excellent and good results were reassigned as satisfactory; poor results were classified as unsatisfactory. The authors reported that in the decompression-alone category, 11 papers	In critique of this study, only three Level II studies were reviewed and data were very heterogeneous. This paper offers Level III therapeutic evidence that the addition of fusion with or without instrumentation to decompression improves clinical outcomes.

		representing 216 patients were accepted for inclusion. Sixty-nine percent of patients had a satisfactory outcome. The incidence of worsened postoperative slip was 31%, but was not associated with a poorer clinical result in the majority of patients. In the category of decompression with fusion and no instrumentation, six papers qualified for inclusion. In one paper, only fusion data were broken out for the diagnosis of degenerative spondylolisthesis and were used just for this outcome variable. Ninety percent of the patients in this category had a satisfactory outcome; 86% achieved solid spinal fusion. With regard to clinical outcome, the difference between patients treated with decompression without fusion (69% satisfactory) and those treated with decompression and fusion without instrumentation (90% satisfactory) was statistically significant ($P < 0.0001$). In the decompression with fusion and pedicle screws category, five studies met the inclusion criteria. A total of 101 patients was analyzed with respect to fusion status. Eighty-five patients were analyzed with respect to clinical outcome. One paper did not separately analyze clinical data, but did so for fusion data; therefore, only fusion data were included. The proportionally weighted fusion rates for this group were 93%. When comparing the fusion without instrumentation group to the fusion with pedicle screw group there was not a statistically significant increase in fusion rate ($P = 0.08$). Analysis of the clinical outcomes reveals an 86% satisfactory rating for the pedicle screw group. This compares favorably to the 69% satisfactory rate in the decompression without fusion group ($P <0.0001$). In the anterior spinal fusion category, three papers presenting results for 72 patients who received anterior spinal fusion for the treatment of degenerative spondylolisthesis were included. Pooling the data	

		from these three studies yielded a 94% fusion rate with an 86% rate of patient satisfaction. The authors concluded that the meta-analysis supports the clinical impression, that in the surgical management of degenerative lumbar spondylolisthesis, spinal fusion significantly improves patient satisfaction.	
Martin CR, Gruszczynski AT, Braunsfurth HA, et al., The surgical management of degenerative lumbar spondylolisthesis: a systematic review. *Spine*. 2007;32(16): 1791-1798.	III, therapeutic	This is a systematic review designed to identify and analyze comparative studies that examined the surgical management of degenerative lumbar spondylolisthesis, specifically the differences in outcomes between fusion and decompression alone, and between instrumented fusion and noninstrumented fusion. Relevant randomized controlled trials (RCT) and comparative observational studies were identified in a comprehensive literature search (1966 to June 2005). The inclusion criteria required that a study be an RCT or comparative observational study that investigated the surgical management of degenerative lumbar spondylolisthesis by comparing: (1) fusion to decompression and/or (2) instrumented fusion to noninstrumented fusion. A minimum one-year follow-up was required. Studies also had to include at least five patients per treatment group. A study was excluded if it included patients who had received previous spine surgery or patients with cervical injuries, spinal fractures, tumors or isthmic spondylolisthesis. A study was also excluded if it was not possible to analyze patients with degenerative spondylolisthesis separately from another included patient population or if it was not clearly a comparative study. Data from the included studies were extracted by two independent reviewers using a standard data abstraction sheet. The data abstraction sheet identified the following information: (1) patient population's age, gender, symptoms and degree of spondylolisthesis; (2) type of: decom-	In critique of this study, it was a systematic review of studies ranging down to Level III, and is thus classified as a Level III systematic review. Limitations were found in the methodologies of all RCTs, specifically in the pseudorandomization, absence of masking and/or the lack of validated outcome measures to assess clinical outcomes. This paper offers Level III therapeutic evidence that fusion leads to a better clinical outcome compared with decompression alone; and the use of adjunctive instrumentation leads to improved fusion status and less risk of pseudoarthrosis. Their data do not demonstrate any difference in clinical outcomes between instrumented and noninstrumented fusions.

		pression, fusion, instrumentation, bone graft material, and preoperative and post-operative treatment; (3) study design and methodological quality using the Cochrane RCT/CCT/Crossover Studies Checklist, modified by the additional criterion that observational studies state the use of a consecutive series of patients; and (4) study outcomes. The main abstracted outcomes were clinical outcome, reoperation rate and solid fusion status. An attempt was made to compare patient-centered, validated and disease-specific outcomes, complications and spondylolisthesis progression; but because of heterogeneity in reporting these outcomes in the primary studies, no pooled analysis could be performed on these outcomes. When appropriate, a study's clinical outcome rating scale was altered to match a dichotomous rating scale of "satisfactory" or "unsatisfactory" clinical outcome, and results were entered into Review Manager 4.2 for weighted grouped analyses. The authors reported that eight studies were included in the fusion versus decompression-alone analysis, including two RCTs. Limitations were found in the methodologies of both RCTs and most of the observational studies. Grouped analysis detected a significantly higher probability of achieving a satisfactory clinical outcome with spinal fusion than with decompression alone (relative risk, 1.40; 95% confidence interval, 1.04–1.89; $P < 0.05$). The clinical benefit favoring fusion decreased when analysis was limited to studies where the majority of patients were reported to be experiencing neurologic symptoms such as intermittent claudication and/or leg pain. Six studies were included in the instrumented fusion versus noninstrumented fusion analysis, including three RCTs. The use of adjunctive instrumentation significantly increased the probability of	

		attaining solid fusion (relative risk, 1.37; 95% confidence interval, 1.07–1.75; P < 0.05), but no significant improvement in clinical outcome was recorded (relative risk, 1.19; 95% confidence interval, 0.92–1.54). There was a nonsignificant trend towards a lower repeat operation rate in the fusion group compared with both decompression alone and instrumented fusion. The authors concluded there is moderate evidence that fusion may lead to a better clinical outcome compared with decompression alone. Evidence is also moderate that the use of adjunctive instrumentation leads to improved fusion status and less risk of pseudoarthrosis. No conclusion could be made about the clinical effectiveness of instrumented fusion versus noninstrumented fusion.	
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, therapeutic	This is a retrospective, comparative study of 55 patients with spinal stenosis in grade I degenerative lumbar spondylolisthesis. Of the 55 patients, 20 underwent laminectomy plus posterolateral fusion and pedicle screw instrumentation (Group 1), 19 underwent laminoplasty alone (Group 2) and 16 refused surgery and received medical/interventional treatment (Group 3). One patient in each surgical group was lost to follow-up. Outcomes were assessed by the Japanese Orthopedic Association (JOA) score, along with radiographic evaluation at minimum two-year follow-up. The authors reported alleviation of symptoms in the fusion and laminoplasty groups, but not in the medical/interventional treatment group. No statistically significant difference in clinical improvement was noted between the fusion and laminoplasty groups. The percent slip increased significantly in groups 2 and 3, whereas spondylolisthesis was stabilized in Group 1. The authors concluded that decompression with preservation of the posterior elements can be useful in treating patients with symptomatic	In critique of this study, the numbers were small, patients were not randomized and no clearly defined indications for specific treatment selections were included. This paper offers Level III therapeutic evidence that decompression with posterolateral fusion and instrumentation, as well as laminoplasty alone, yield improved outcomes in the treatment of symptomatic lumbar spinal stenosis caused by grade I degenerative spondylolisthesis as compared with medical/interventional treatment alone.

		lumbar spinal stenosis as a result of grade I degenerative spondylolisthesis.	
Postacchini F, Cinotti G. Bone regrowth after surgical decompression for lumbar spinal stenosis. *J Bone Joint Surg Br.* 1992;74(6):862-869.	IV, therapeutic	This is a retrospective comparative study which included 16 patients with degenerative lumbar spondylolisthesis, of whom ten had fusions. Clinical and radiographic assessment occurred at mean follow-up of 8.5 years. The authors reported that a significant difference was found between those patients who had been fused and those who had not. Of patients who had fusions, 80% reported satisfactory results, while 33% of the unfused patients reported satisfactory results. The authors concluded that in patients with degenerative spondylolisthesis, the proportion of satisfactory results was significantly higher in patients who had spinal fusion.	In critique of this study, this subgroup was very small and lacked standardized, validated outcome measures. Because of these weaknesses, this potential Level III study was downgraded to Level IV. This paper offers Level IV therapeutic evidence that the addition of fusion to decompression results in significantly higher satisfactory results in patients with degenerative lumbar spondylolisthesis.
Postacchini F, Cinotti G, Perugia D. Degenerative lumbar spondylolisthesis. II. Surgical treatment. *Ital J Orthop Traumatol.* 1991;17(4):467-477.	IV, therapeutic	This is a retrospective comparative study of 32 patients with degenerative lumbar spondylolisthesis undergoing five surgical procedures: unilateral laminotomy, bilateral laminotomy with or without fusion, laminectomy with or without fusion, laminectomy with fusion and interspinous wiring. Outcomes were assessed using a rudimentary self-report measure (excellent, good, fair, poor) with an average of 2.8 year follow-up. The authors found that 85% of patients reported satisfactory results. Of the 32 patients, 17 had decompression and fusion and 100% (17/17) reported good to excellent results. Of the 15 patients who did not receive fusion, 67% reported excellent or good results (10/15). Both groups showed increases in slip, although not specifically quantified. None of the fusion group had an unstable slip, while 33% of the decompression alone group had "hypermobility." This hypermobility tended to be clinically associated with more symptoms. Regrowth of facet joints was seen in several patients, and much more likely to be symptomatic in patients	In critique of this study, it presented very little data and did not utilize validated outcome measures. Multiple procedures were done on a small number of patients. Because of these weaknesses, this potential Level III study was downgraded to Level IV. This paper offers Level IV therapeutic evidence that the addition of spinal fusion to decompression results in improved outcomes.

		without fusion. The authors concluded that spinal fusion is recommended to improve clinical outcomes in patients treated with decompression.	
Yone, K., Sakou T, Kawauchi Y, Yamaguchi M, Yanase M. Indication of fusion for lumbar spinal stenosis in elderly patients and its significance. *Spine*. 1996; 21(2): 242-248.	IV, therapeutic	This is a retrospective comparative study of 34 patients (age 60+) who underwent surgical treatment for lumbar spinal stenosis. Of the 34 patients, 17 had instability defined by Posner's radiographic method, of whom 10 underwent decompression and instrumented fusion and seven underwent decompression alone. Outcomes were assessed utilizing the Japanese Orthopedic Association (JOA) scores and radiographic assessment. The authors reported that the group with decompression and fusion had the best outcomes, and unstable patients undergoing decompression alone had the worst results. The authors concluded that fusion with instrumentation should be used when decompression is performed on elderly patients with instability.	In critique, this is a small non-randomized study including only 17 patients with degenerative lumbar spondylolisthesis. This paper lacked statistical analysis. Because of these weaknesses, this potential Level III study was downgraded to Level IV. This study offers Level IV therapeutic evidence that instrumented fusion should be used when decompression is performed on elderly patients with instability.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 4:

Does the addition of instrumentation to decompression and fusion for degenerative spondylolisthesis improve surgical outcomes compared with decompression and fusion alone?

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
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, therapeutic	This is a prospective comparative study of 44 surgically treated patients with degenerative lumbar spondylolisthesis followed for a minimum of two years. Of the 44 patients, nine underwent laminectomy alone, 10 had laminectomy and noninstrumented fusion and 24 had laminectomy and instrumented fusion (18 single level, six two-level). Patients were radiographically assessed and a functional assessment was conducted by asking whether they felt their ability to walk distances was worse (-), the same (0) or significantly better (+). Of the 44 patients, 43 were followed for two years or more. The authors reported that instrumented fusion had higher fusion rates than uninstrumented fusion (ρ=0.002) and observed greater progression of spondylolisthesis in patients treated with laminectomy alone and laminectomy without instrumented fusion compared to patients who received laminectomy with instrumented fusion (ρ=0.001). A higher proportion of the patients without slippage progression reported that they were helped by the surgery than those whose slippage progressed postoperatively (ρ<0.01).	In critique, this was a small study in which selection bias entered into the randomization process, reviewers were not masked to patient treatment and validated outcome measures were not utilized. Because of these weaknesses, this potential Level II study was downgraded to Level III. This study provides Level III therapeutic evidence that addition of instrumentation to fusion results in higher fusion rates and subjective improvement in walking distance when compared with fusion alone.
Fischgrund JS, Mackay M, Herkowitz HN, Brower R, Montgomery DM, Kurz LT. 1997 Volvo Award winner in clinical studies.	III, therapeutic	This is a prospective, randomized comparative study of 76 consecutive patients with symptomatic spinal stenosis associated with degenerative lumbar spondylolisthesis who underwent posterior decompression and posterolateral fusion. Patients were randomized into a transpedicular fixation group or noninstrumented group. Outcomes were assessed at two-	In critique of this study, the follow-up may have been too short to detect the effects of pseudoarthrosis in this nonmasked study. Validated outcome measures were not utilized to assess clinical outcomes. Because of these weaknesses, this potential Level II study was downgraded to Level III.

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.		year follow-up using a five-point visual analog scale (VAS) and an operative result rating (excellent, good, fair, poor) based on examiner assessment of pain and functional level. The authors reported that of the 76 patients included in the study, 68 (89%) were available for two-year follow-up. Clinical outcome was excellent or good in 76% of instrumented patients and 85% of noninstrumented patients (p=0.45). Successful arthrodesis occurred in 82% of instrumented versus 45% of noninstrumented patients (p=0.0015). Overall, successful fusion did not correlate with patient outcome (p=0.435). The authors concluded that for single level degenerative lumbar spondylolisthesis, use of instrumentation may lead to a higher fusion rate, but clinical outcome shows no improvement in low back pain and lower limb pain.	This study offers Level III therapeutic evidence that the addition of instrumentation to posterolateral fusion for the treatment of degenerative lumbar spondylolisthesis increases the likelihood of obtaining a solid arthrodesis, but does not correlate with improved clinical outcomes at two-year follow-up.
Gibson JN, Waddell G. Surgery for degenerative lumbar spondylosis. *Cochrane Database Syst Rev*. 2005(4):CD001352.	III, therapeutic	This is a systematic review of 31 randomized controlled trials (RCT) looking at all forms of surgical treatment for degenerative lumbar spondylosis. The authors reported that eight trials showed that instrumented fusion produced a higher fusion rate, but any improvement in clinical outcomes is probably marginal. Other evidence suggests instrumentation may be associated with a higher complication rate. The authors concluded that although fusion rates improve with instrumentation, there does not appear to be any correlation with clinical outcomes.	In critique of this study, it was a systematic review of primarily Level II studies and is thus classified as a Level II systematic review. Limitations were found in the methodologies of all RCTs, specifically in the randomization, absence of masking and/or the lack of validated outcome measures to assess clinical outcomes. Studies were heterogeneous in nature and lacked long-term outcome studies. In the work group's review of the specific studies cited in this paper, many were downgraded to Level III, therefore, the work group classified this review as Level III evidence. This paper offers Level III therapeutic evidence that although instrumentation improves the fusion rate, clinical outcome is probably only marginally improved at a potential risk of higher complication rates.
Kimura I, Shingu H, Mu-	III, thera-	This is a retrospective, comparative study of 57 patients with grade I or II L4-5 de-	In critique of this study, patients were not randomized and there was vary-

rata M, Hashiguchi H. Lumbar posterolateral fusion alone or with transpedicular instrumentation in L4--L5 degenerative spondylolisthesis. *J Spinal Disord*. 2001;14(4):301-310.	peutic	generative lumbar spondylolisthesis. Group A consisted of 28 patients who underwent decompression and posterolateral fusion without instrumentation. Group B was comprised of 29 patients who had decompression and posterolateral fusion with pedicle screw instrumentation. Following surgery, Group A was immobilized with bed rest followed by a cast for four to six weeks, whereas Group B was mobilized much more quickly. Outcomes were assessed using the Japanese Orthopedic Association (JOA) scores and x-ray studies with mean follow-up in Group A of six years and in Group B of three years. The authors indicated that patients in Group A (noninstrumented) reported 72.4% satisfaction rate, with an 82.8% fusion rate. Patients in Group B (instrumented) reported an 82.1% satisfaction rate, with a 92.8% fusion rate. The authors indicated they did not find any significant differences in outcomes between the two groups, except that Group B (instrumented) had less low back pain.	ing duration of follow-up between groups. Although there was a trend toward improved satisfaction and fusion rates with instrumentation, with the numbers available no significant difference was detected. This paper offers Level III therapeutic evidence that there is no significant benefit with the addition of instrumentation for L4-5 degenerative lumbar spondylolisthesis.
Mardjetko, SM, Connolly PJ, Shott S. Degenerative lumbar spondylolisthesis. A meta-analysis of literature 1970-1993. *Spine*. 1994;19(20 Suppl): 2256S-2265S.	III - therapeutic	This is a meta-analysis of primarily Level III studies. The objective of the study was to analyze the published data on degenerative spondylolisthesis to evaluate the feasibility of its use as a literature control to compare with the historical cohort pedicle screw study data. The authors conducted a comprehensive literature search to identify studies published in English peer-reviewed journals between 1970 and 1993 addressing degenerative spondylolisthesis with radicular leg pain or neurogenic claudication. Inclusion criteria included a minimum of four cases reviewed and reporting of the primary outcome variable of fusion in articles in which this was part of the treatment. Clinical outcome variables of back pain, leg pain, function, neurogenic claudication and global outcome scores were recorded when available. A total of 25 papers rep-	In critique of this study, only three Level II studies were reviewed and data were very heterogeneous. This paper offers Level III therapeutic evidence that addition of instrumentation to fusion does not result in improved clinical outcome or fusion rate.

		resenting 889 patients were accepted for inclusion. Twenty-one were retrospective, nonrandomized and uncontrolled. One paper was retrospective and nonrandomized, but compared two different treatments. Three prospective, randomized studies were included. The primary outcome variable, fusion, was determined by each author. The most constant clinical outcome variable reported was pain with 16 papers reporting pain only, six papers reporting pain and function, and two papers reporting the patient-determined outcomes. Patient function was reported in six papers and referred to the presence or absence of neurogenic claudication. In addition to these clinical outcomes, four papers reported a global evaluation. Two used Kaneda's rating system and two used the Japanese Orthopedic Association (JOA) score. Excellent and good results were reassigned as satisfactory; poor results were classified as unsatisfactory. The authors reported that in the decompression alone category, 11 papers representing 216 patients were accepted for inclusion. Sixty-nine percent of patients had a satisfactory outcome. The incidence of worsened postoperative slip was 31%, but was not associated with a poorer clinical result in the majority of patients. In the category of decompression with fusion and no instrumentation, six papers qualified for inclusion. In one paper, only fusion data were broken out for the diagnosis of degenerative spondylolisthesis and were used only for this outcome variable. Ninety percent of the patients in this category had a satisfactory outcome; 86% achieved solid spinal fusion. With regard to clinical outcome, the difference between patients treated with decompression without fusion (69% satisfactory) and those treated with decompression and fusion without instrumentation (90% satisfactory) was statistically significant (P <	

		0.0001). In the decompression with fusion and pedicle screws category, five studies met the inclusion criteria. A total of 101 patients was analyzed with respect to fusion status. Eighty-five patients were analyzed with respect to clinical outcome. One paper did not separately analyze clinical data, but did so for fusion data; therefore, only fusion data were included. The proportionally weighted fusion rates for this group were 93%. When comparing the fusion without instrumentation group to the fusion with pedicle screw group, there was not a statistically significant increase in fusion rate (P = 0.08). Analysis of the clinical outcomes reveals an 86% satisfactory rating for the pedicle screw group. This compares favorably to the 69% satisfactory rate in the decompression without fusion group (P <0.0001). In the anterior spinal fusion category, three papers presenting the results for 72 patients who received anterior spinal fusion for the treatment of degenerative spondylolisthesis were included. Pooling the data from these three studies yielded a 94% fusion rate with an 86% rate of patient satisfaction. The authors concluded the meta-analysis supports the clinical impression that, in the surgical management of degenerative lumbar spondylolisthesis, spinal fusion significantly improves patient satisfaction.	
Martin CR, Gruszczynski AT, Braunsfurth HA, Fallatah SM, O'Neil J, Wai EK.The surgical management of degenerative lumbar spondylolisthesis: a systematic review.	III , therapeutic	This is a systematic review designed to identify and analyze comparative studies that examined the surgical management of degenerative lumbar spondylolisthesis, specifically the differences in outcomes between fusion and decompression alone, and between instrumented fusion and noninstrumented fusion. Relevant randomized controlled trials (RCT) and comparative, observational studies were identified in a comprehen-	In critique of this study, it was a systematic review of studies ranging down to Level III, and is thus classified as a Level III systematic review. Limitations were found in the methodologies of all RCTs, specifically in the pseudorandomization, absence of masking and/or the lack of validated outcome measures to assess clinical outcomes. This paper offers Level III therapeutic evidence that the use of adjunctive instrumentation leads to

Spine. 2007; 32(16):1791-1798.		sive literature search (1966 to June 2005). The inclusion criteria required that a study be an RCT or comparative observational study that investigated the surgical management of degenerative lumbar spondylolisthesis by comparing: (1) fusion to decompression and/or (2) instrumented fusion to noninstrumented fusion. A minimum one-year follow-up was required. Studies also had to include at least five patients per treatment group. A study was excluded if it included patients who had received previous spine surgery or patients with cervical injuries, spinal fractures, tumors or isthmic spondylolisthesis. A study was also excluded if it was not possible to analyze patients with degenerative spondylolisthesis separately from another included patient population, or if it was not clearly a comparative study. Data from the included studies were extracted by two independent reviewers using a standard data abstraction sheet which identified the following information: (1) patient population's age, gender, symptoms and degree of spondylolisthesis; (2) type of decompression, fusion, instrumentation, bone graft material, and preoperative and postoperative treatment; (3) study design and methodological quality using the Cochrane RCT/CCT/Crossover Studies Checklist modified by the additional criterion that observational studies state the use of a consecutive series of patients; and (4) study outcomes. The main abstracted outcomes were clinical outcome, reoperation rate and solid fusion status. An attempt was made to compare patient-centered, validated and disease-specific outcomes, complications and spondylolisthesis progression. Because of heterogeneity in reporting these outcomes in the primary studies; however, no pooled analysis could be performed on these outcomes. When appropriate, a study's clinical outcome rating scale was altered to match a dichotomous rating scale of "satisfactory" or "unsatis-	improved fusion rates, but failed to show a statistically significant improvement in clinical outcomes.

		factory" clinical outcome, and results were entered into Review Manager 4.2 for weighted grouped analyses. The authors reported that eight studies were included in the fusion versus decompression alone analysis, including two RCTs. Limitations were found in the methodologies of both RCTs and most of the observational studies. Grouped analysis detected a significantly higher probability of achieving a satisfactory clinical outcome with spinal fusion than with decompression alone (relative risk, 1.40; 95% confidence interval, 1.04–1.89; P < 0.05). The clinical benefit favoring fusion decreased when analysis was limited to studies where the majority of patients were reported to be experiencing neurologic symptoms such as intermittent claudication and/or leg pain. Six studies were included in the instrumented fusion versus noninstrumented fusion analysis, including three RCTs. The use of adjunctive instrumentation significantly increased the probability of attaining solid fusion (relative risk, 1.37; 95% confidence interval, 1.07–1.75; P < 0.05), but no significant improvement in clinical outcome was recorded (relative risk, 1.19; 95% confidence interval, 0.92–1.54). There was a nonsignificant trend toward a lower repeat operation rate in the fusion group. Compared with both decompression alone and instrumented fusion, the authors concluded there is moderate evidence that fusion may lead to a better clinical outcome compared with decompression alone. Evidence is moderate that the use of adjunctive instrumentation leads to improved fusion status and less risk of pseudoarthrosis. No conclusion could be made about the clinical effectiveness of instrumented fusion versus noninstrumented fusion.	

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 5:

How do outcomes of decompression with posterolateral fusion compare with those for 360° fusion (anterior-posterior OR transforaminal lumbar interbody fusion OR posterior lumbar interbody fusion) for treatment of degenerative spondylolisthesis?

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Rousseau MA, Lazennec JY, Bass EC, Saillant G. Predictors of outcomes after posterior decompression and fusion in degenerative spondylolisthesis. *Eur Spine J.* 2005;14(1): 55-60.	IV, therapeutic	This is retrospective comparative study of 24 consecutive patients undergoing decompression and transpedicular fixation to treat symptomatic degenerative lumbar spondylolisthesis. Of the 24 patients, eight also underwent posterior lumbar interbody fusion (PLIF). Outcomes were assessed using the Beaujon scoring system with a mean follow-up of 2.87 years. The authors reported that the Beaujon score was improved in all 24 patients ($\rho<0.001$) and fusion was successful in all cases. Preoperative leg pain and the addition of PLIF were significantly correlated with greater improvement ($\rho=0.016$ and $\rho=0.003$), respectively. The authors concluded that posterior decompression and fusion is successful in treating degenerative lumbar spondylolisthesis and that the additional circumferential fusion yields significant improvement in functional outcomes.	In critique, this study was retrospective with a small sample size of non-randomized patients. Of the 24 patients included, only eight underwent PLIF. In addition, of the 24 patients included in the study, only 18 (75%) were available for follow-up beyond two years and it is unclear how many of the eight PLIF patients remained in this subset. Because of these deficiencies, this potential Level III study was downgraded to Level IV. This study provides Level IV therapeutic evidence that posterior decompression and fusion is successful in treating degenerative lumbar spondylolisthesis and that additional circumferential fusion results in slightly better outcomes than posterior decompression and fusion alone.

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 6:

What is the role of reduction (deliberate attempt to reduce via surgical technique) with fusion in the treatment of degenerative lumbar spondylolisthesis?

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, therapeutic	This study is a retrospective consecutive case series of 56 patients with degenerative spondylolisthesis and symptoms of back pain and/or stenosis treated with bilateral foraminotimies, reduction and instrumented fusion. The procedure had a 7% major complication rate. Outcomes measures were the Visual Analog Scale (VAS), Oswestry Disability Index (ODI) and X-ray studies. Of the 56 patients, 42 were available for follow-up at an average of 33 months (range 14-53 months). Of the 42 patients, 82% experienced relief of leg pain, 75% experienced improvement in low back pain and 77% experienced significant improvement in their ODI scores (average preoperatively of 56% versus average of 26% postoperatively). Only 38 patients were available for late review of X-ray images at an average of 33 months. Average preoperative slip was 16%; and of the 38 patients available at late review, 75% had perfect reduction. Of the 38 patients, 16% had minor loss of reduction. Outcome measures (VAS and ODI) were not compared based on the presence or absence of a perfect reduction.	In critique, this is a moderately small, retrospective review of a consecutive case series of surgical patients from one surgeon with no comparison group and with less than 80% follow-up. This paper offers Level IV therapeutic evidence that limited bilateral foraminotimies with instrumented reduction and fusion for symptomatic degenerative spondylolisthesis and stenosis is as effective as laminectomy and in situ fusion without as much operative exposure of neural structures.
Lee TC. Reduction and stabilization without laminectomy for unstable degenerative spondylolisthesis: a preliminary report. *Neurosurgery.*	IV, therapeutic	This is a prospective case series of 52 consecutive patients with objectively defined unstable degenerative spondylolisthesis who underwent reduction and fusion without decompression using the Fixater Interne pedicle fixation device. Forty-seven patients had low back pain, 40 patients had radicular pain and 36 patients had intermittent claudication.	In critique of this study, this was a prospective case series of consecutive patients with degenerative spondylolisthesis undergoing reduction, fixation and fusion which lacked a comparison group. Validated outcome measures were not used. This paper presents Level IV therapeutic evidence that patients with degenerative spondylolisthesis who do not

1994;35(6):1072-1076.		Follow-up was at a minimum of 12 months (range 12-16 months). Subjective measurement of success was classified as excellent, good, fair and poor for pain. An excellent or good outcome was considered satisfactory and a fair or poor outcome was considered unsatisfactory. A satisfactory outcome (excellent and good results) occurred in 42 of 47 patients with complaints of back pain, 37 of 40 patients with radicular pain and 31 of 36 patients with claudication. The authors commented that only two groups, based on their findings, are not good candidates for this procedure: (1) those with a positive Lasegue's sign and (2) those with borderline instability.	have borderline instability or a positive Lasegue's sign can undergo reduction, fixation and fusion without decompression.
Sears W. Posterior lumbar interbody fusion for degenerative spondylolisthesis: restoration of sagittal balance using insert-and-rotate interbody spacers. *Spine J.* 2005;5(2):170-179.	IV, therapeutic	This is a prospective case series of 34 patients with degenerative spondylolisthesis who underwent decompression, reduction, internal fixation and fusion. Twenty-five patients had a one-level fusion and nine patients had a two-level fusion. Of the 34 patients, 32 had surgery to relieve leg pain. Outcome measures included the VAS, Low Back Pain Outcome Score (LBOS), SF-12 and patient satisfaction questionnaire. Preoperative and postoperative measurement of slips by radiograph were also recorded. Mean preoperative slip was 20% (range was12% to 33%). Follow-up occurred at a mean of 21.2 months (range 12 to 32 months), with no dropouts. Significant improvements ($p<.001$) occurred in mean VAS and LBOS scores. Ninety-one percent of the patients considered their results excellent or good on the subjective satisfaction rating. X-ray analysis revealed mean slip reduction from 20.2% to 1.7% and focal lordosis (available in only 17/34 patients) increased from 13.1 to 16.1°. Both of these findings were clinically significant. Three of the 34 patients had postoperative nerve root irritation, with two of these persisting up to the time of final report. There were no procedure-related compli-	In critique, this is a small prospective case series on nonconsecutive patients with degenerative spondylolisthesis with no comparison group. This paper offers Level IV therapeutic evidence that reduction of a degenerative spondylolisthesis with internal fixation and posterior lumbar interbody fusion can provide good deformity correction with few complications and good short-term patient outcomes on validated patient outcome measures.

		cations postoperatively, but one patient required adjacent level decompression and fusion 12 months after surgery.	

Evidentiary Table. Degenerative Lumbar Spondylolisthesis, Surgical Treatment

Question 7:

What is the long-term result (4+ years) of surgical management of degenerative lumbar spondylolisthesis?

Article (Alpha by Author)	Level (I-V)	Description of study (Including analysis of methodological strengths/weaknesses)	Conclusion
Booth KC, Bridwell KH, Eisenberg BA, Baldus CR, Lenke LG. Minimum 5-year results of degenerative spondylolisthesis treated with decompression and instrumented posterior fusion. *Spine*. 1999; 24(16):1721-1727.	IV, therapeutic	Presumably a retrospective study of 41 patients with neurogenic claudication from spinal stenosis and spondylolisthesis who were followed for a minimum of five years after a laminectomy and instrumented fusion. At final follow-up, there were no new neurological deficits, no recurrent stenosis at the level of surgery and no symptomatic pseudoarthroses. Three patients underwent surgery for adjacent level stenosis, which took place four to 12 years after the index procedure. Clinical outcomes were available in 36 patients: 83% reported high satisfaction, 86% reported reduced back and leg pain, and 46% had increased function at follow-up that ranged from five to 10.7 years.	In critique of this study, it had small patient numbers and considerable attrition (less than 80% follow-up). Of 49 consecutive patients operated during the study interval, 41 were available for follow-up (eight patients died) and only 36 had clinical outcomes measured. Attrition from death, however, is expected in the affected population. This retrospective case series provides Level IV therapeutic evidence that laminectomy and instrumented fusion for stenosis from degenerative spondylolisthesis provides a high rate of satisfaction and pain relief and moderately increased function at long-term follow-up.
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.	IV, therapeutic	This was a follow-up study on 47 of 58 patients who had originally been part of a randomized controlled trial comparing instrumented versus noninstrumented fusion for spinal stenosis and degenerative spondylolisthesis. This study's cohort consisted only of the noninstrumented cases, which were followed for a minimum of five years. Clinical outcomes were analyzed based on the presence of solid fusion (22 patients) or a pseudoarthrosis (25 patients). A statistically greater percentage of patients had good or excellent results in patients with solid fusion (86%) versus pseudoarthrosis (56%). Importantly, five of the pseudoarthrosis patients and two of the fusion patients had undergone a second procedure.	In critique of this study, the authors used a less frequently implemented outcomes instrument, the Swiss Spinal Stenosis (SSS) Questionnaire, making it difficult to compare directly to other studies in which the ODI or ZCQ were used. Despite these minor limitations, as a prospective case series the data offer Level IV therapeutic (>80% follow-up) evidence that laminectomy and attempted fusion results in longstanding symptom improvement for spinal stenosis from degenerative spondylolisthesis. Furthermore, these data suggest that those patients who achieved solid fusion have statistically better long-term outcomes than those with pseudoarthroses.

Postacchini F, Cinotti G. Bone regrowth after surgical decompression for lumbar spinal stenosis. *J Bone Joint Surg Br.* 1992;74(6): 862-869.	IV, therapeutic	In this long-term follow-up study evaluating the clinical outcomes and radiographic evidence of bone regrowth five to 19 years after laminectomy for spinal stenosis. Of the 40 patients included, 16 had degenerative spondylolisthesis, 10 of whom were treated with concomitant fusion. At final follow-up, three patients had excellent results, seven patients had good results, three had fair results and three had poor results. The proportion of satisfactory clinical results was higher in the patients who were fused compared to those who underwent laminectomy alone.	In critique of this study, clinical outcomes were graded using a rudimentary four tier system (excellent, good, fair, poor). Furthermore, there was a high attrition rate. Of 88 patients identified during the study period, 27 died or could not be located and 21 did not have adequate radiographs, leaving 40 study patients (45% follow-up). Based on these limitations, this retrospective case series provides Level IV therapeutic evidence that laminectomy with fusion provides satisfactory long-term results.

VI. Degenerative Lumbar Spondylolisthesis Guideline References

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