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Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: Lumbar fusion for stenosis with spondylolisthesis

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Patients presenting with stenosis associated with a spondylolisthesis will often describe signs and symptoms consistent with neurogenic claudication, radiculopathy, and/or low-back pain. The primary objective of surgery, when deemed appropriate, is to decompress the neural elements. As a result of the decompression, the inherent instability associated with the spondylolisthesis may progress and lead to further misalignment that results in pain or recurrence of neurological complaints. Under these circumstances, lumbar fusion is considered appropriate to stabilize the spine and prevent delayed deterioration. Since publication of the original guidelines there have been a significant number of studies published that continue to support the utility of lumbar fusion for patients presenting with stenosis and spondylolisthesis. Several recently published trials, including the Spine Patient Outcomes Research Trial, are among the largest prospective randomized investigations of this issue. Despite limitations of study design or execution, these trials have consistently demonstrated superior outcomes when patients undergo surgery, with the majority undergoing some type of lumbar fusion procedure. There is insufficient evidence, however, to recommend a standard approach to achieve a solid arthrodesis. When formulating the most appropriate surgical strategy, it is recommended that an individualized approach be adopted, one that takes into consideration the patient's unique anatomical constraints and desires, as well as surgeon's experience.

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KEY WORDS • fusion • lumbar spine • spondylolisthesis • stenosis • practice guidelines

Recommendations

There is no evidence that conflicts with the previous recommendations formulated from the first iteration of the Lumbar Fusion Guidelines.

Abbreviations used in this paper: ODI = Oswestry Disability Index; PLF = posterolateral lumbar fusion; PLIF = posterior lumbar interbody fusion; SPORT = Spine Patient Outcomes Research Trial; TLIF = transforaminal lumbar interbody fusion; VAS = visual analog scale.

Grade B

Surgical decompression and fusion is recommended as an effective treatment alternative for symptomatic stenosis associated with a degenerative spondylolisthesis in patients who desire surgical treatment.

Although there is insufficient evidence to recommend a standard fusion technique, the patient's anatomy, desires, and concerns as well as surgeon experience should all be factored into the decision-making process when determining the optimal strategy for an individual patient to maximize fusion potential while minimizing risk of complications.

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Rationale

Patients presenting with clinically relevant stenosis associated with a spondylolisthesis may report signs and symptoms consistent with neurogenic claudication, radiculopathy, and/or low-back pain. A decompressive procedure is often required to alleviate the symptoms associated with the neurological compression syndrome; however, decompression alone can result in progression of the vertebral misalignment. In the original version of the Lumbar Fusion Guidelines, incorporating a posterolateral lumbar fusion (PLF) as an adjunct to a lumbar decompression was considered an appropriate treatment alternative to prevent deformity progression and improve patient outcomes. Supplementation of the PLF with pedicle screw stabilization was considered an appropriate option in the presence of a kyphosis or if instability was suspected.²⁶ The purpose of the current Guideline Update was to examine the current literature investigating the role of surgical intervention for patients with symptomatic stenosis associated with spondylolisthesis and focus on the utility of lumbar fusion in this patient population.

Literature Search

Several well-publicized randomized controlled clinical trials have been published since the last systematic review published in 2005.²⁵ Accordingly, the literature search strategy was designed to reflect the existence of potentially high-quality evidence. The National Library of Medicine and the Cochrane Library were searched for articles published between July 2003 and December 2011, using an electronic literature search engine (PubMed and the Cochrane Search Engine, respectively) with the following subject headings: (((“Lumbosacral Region”[MeSH] OR “Lumbar Vertebrae”[MeSH]) AND “Spinal Fusion”[MeSH]) OR “lumbar fusion”[All Fields] OR (“lumbar”[title] AND “fusion”[title])) AND (“Spondylolisthesis”[MeSH] OR spondylolisthesis[title]) AND (“2003”[PDAT]: “3000”[PDAT]) AND “humans” [MeSH Terms] AND English[lang]). A total of 134 references were identified. The titles and abstracts of these 134 references were reviewed. Duplicates were discarded, as were nonsystematic reviews, case series, and retrospective cohort studies with fewer than 100 patients. Studies focused on nuances of technique (i.e., choice of bone graft material for fusion) without comparison with nonoperated or nonfused patients were discarded. Studies comparing substantially different procedures (i.e., interbody vs posterolateral fusion) were included in the literature review. Non-English language references were included if there was sufficient translation of key portions of the reference to allow review. The reference lists of previously published systematic reviews were also reviewed to confirm completeness of the literature search. This strategy resulted in 26 primary references and 5 systematic reviews.^{1-25,27-32} Ten papers published since the previous review and one paper that was missed in the previous review providing Level III evidence or better are detailed in the evidentiary table (Table 1).

Scientific Foundation

Surgery Versus No Surgery

Weinstein et al.,^{29,30} through publication of the Spine Patient Outcomes Research Trial (SPORT) studies, provide the most powerful evidence supporting the role of surgical intervention in patients with stenosis associated with degenerative spondylolisthesis. This large (> 600 patient) multicenter prospective study was originally designed as a randomized trial, but flaws in the study design and the substantial crossover rate between treatment cohorts have led most, including the authors of this study, to focus on the results of the as-treated analysis. As a result, the randomization process was abandoned and the study regarded as a large well-controlled prospective cohort study. The SPORT group demonstrated that when patients are able to select their treatment strategy based on their symptoms, values, and surgical recommendation, those who choose surgery experience superior outcomes in every clinical measure and at every time point for at least 4 years following treatment. It is important to note that surgeons treated patients with decompression and fusion and were free to offer patients whatever technique of decompression and fusion they thought appropriate.^{29,30} As a result of the study limitations, the SPORT provides Level II evidence in support of decompression and fusion for stenosis associated with a spondylolisthesis.

In a companion study, Pearson and the SPORT investigators reviewed preoperative radiographic measurements and 1-year follow-up data in an attempt to identify prognostic indicators of outcome following operative or nonoperative management.²⁴ Patients in the surgical cohort exhibited superior outcomes compared with those treated nonoperatively; however, there were no preoperative radiographic features that predicted ultimate success. This finding was confounded by the fact that the choice of fusion technique was left to the discretion of the treating surgeons. In the nonoperative arm, better outcomes were paradoxically associated with increased mobility at the level of the listhesis. Confounding factors between the “stable” and “hypermobility” groups such as sex, work status, and compensation status make it difficult to interpret these results. The strength of this study is reduced to Level III evidence supporting the role of surgery for stenosis associated with spondylolisthesis.²⁴

Surgical Technique

Abdu et al.¹ reviewed the results from the SPORT lumbar spondylolisthesis study and compared results across fusion techniques. The beneficial effects of surgery were maintained over 4 years, and patients reported significant improvement in every primary outcome measure (Oswestry Disability Index [ODI], 36-Item Short Form Health Survey, and visual analog scale [VAS]) compared with their baseline status. No differences in outcome were detected between the different fusion cohorts (noninstrumented PLF, instrumented PLF, and a 360° approach, instrumented PLF with an interbody graft). The potential for bias exist, however, because surgeons were free to choose the fusion technique, there were impor-

TABLE 1: Lumbar fusion for stenosis with spondylolisthesis: summary of evidence*

| Authors & Year | Level of Evidence | Description | Results | Conclusion |
|-------------------------------|--|--|--|---|
| Abdu et al., 2009 | III: non-controlled cohort study downgraded to III because groups not similar in several important areas. | Four-year follow-up of patients in the surgical arm of SPORT; examined effect of surgical technique on long-term outcome. | All surgical groups exhibited continued improvement in all primary outcomes measures out to 4 yrs. At 4 yrs, there were no differences in outcomes btwn different fusion techniques (noninstrumented, instrumented PLF, instrumented + interbody fusion). | All surgical groups had continued improvement in all primary outcome measures. Surgeons should choose fusion technique based on experience & patient characteristics. |
| Anderson et al., 2006 | I for select population, II for overall spondylolisthesis population. | Two-year follow-up of X-STOP vs non-operative management for patients w/ mild/moderate claudication & Grade I spondylolisthesis; subgroup analysis of overall RCT. | Patients treated w/ the X-STOP device had better outcomes on Zurich Pain Questionnaire & Patient Satisfaction Scores than patients treated nonoperatively. | Patients w/ mild-moderate claudication due to stenosis associated w/ Grade I spondylolisthesis had better outcomes following X-STOP surgery than those receiving non-operative treatment. |
| Cheng et al., 2009 | II for functional outcome, III for fusion rate. Downgraded due to inclusion of isthmic spondylolisthesis patients & use of static radiographs for fusion assessment. | RCT w/ 4-yr outcomes comparing PLF w/ PLIF for spondylolisthesis. | Fusion rates higher in the PLIF group, & instrumentation failure higher in the PLF group, but overall functional outcomes the same in both. Note high percentage of isthmic & Grade II spondylolisthesis. Use of interbody techniques may be more advantageous in higher-grade slips & in isthmic deformities. | Good outcomes associated w/ either PLF or PLIF in patients w/ spondylolisthesis. Interbody techniques may have advantages in cases of higher-grade slips or greater instability. |
| Fernández-Fairen et al., 2007 | II | RCT of 82 patients treated w/ PLF w/ either unilat or bilat pedicle screws. | No differences in fusion rates or SF-36 scores between groups. Screw malposition rate, OR time, & blood loss all lower in unilat group. | When performing PLF for low-grade degenerative spondylolisthesis, unilat screws appear to provide similar benefit to bilat screws w/ fewer complications. |
| Inamdar et al., 2006 | II for outcomes (downgraded for small size & short follow-up); III for fusion rates due to reliance on static radiographs. | Very small RCT (20 patients) looking at PLIF vs PLF as adjunct to decompression for stenosis w/ spondylolisthesis. | No significant differences in fusion rates or outcomes btwn patients treated w/ PLF or PLIF when assessed 1 year postop. | Authors recommend PLF as opposed to PLIF due to similar results w/ fewer complications & costs. |
| Kanayama et al., 2006 | III (prospective case series felt to be fused were explored). | Very small RCT looking at OP-1 vs auto-graft & ceramic as fusion substrate in spondylolisthesis population. | CT & dynamic radiographs used to assess fusion, & those patients felt to be fused were explored. Five of the 16 patients thought to be fused based on CT criteria were found to have pseudarthrosis. | Fusion status difficult to establish even w/ CT & dynamic studies. |
| Kornblum et al., 2004 | III (prospective case series or possibly case control). | Prospective series looking at longer-term outcomes (7-8 yrs) in noninstrumented group from Fischgrund et al. study. | Patients w/ solid arthrodesis following noninstrumented fusion based on dynamic radiographs had better functional outcomes than those w/ pseudarthrosis. However, patients w/ pseudarthrosis had greater preop mobility than those who achieved fusion. | Occurrence of a fusion based on dynamic radiographs associated w/ improved functional outcomes. Patients w/ increased preop mobility may benefit from adjuncts that improve fusion rates. |
| McGuire & Amundson, 1993 | III (small size, select population, nonblinded). | Small RCT in select population (mean age 35 yrs, military) evaluating influence of instrumentation on fusion rates following PLF. | No significant difference in fusion rates btwn instrumented & noninstrumented groups at 2-yr follow-up. Functional outcomes assessed w/ nonvalidated instrument. | In young healthy patients, addition of instrumentation to PLF does not appear to improve fusion rates. |

(continued)

Part 9: Lumbar fusion for stenosis with spondylolisthesis

TABLE 1: Lumbar fusion for stenosis with spondylolisthesis: summary of evidence* (continued)

| Authors & Year | Level of Evidence | Description | Results | Conclusion |
|------------------------|--|---|--|---|
| Pearson et al., 2008 | III (short follow-up & subgroup analysis). | Patients in the SPORT were evaluated in order to assess if there were pretreatment radiographic features that predicted successful treatment. | In the operative arm of the study, there were no particular radiographic features that predicted success or failure at 1 yr. Outcomes superior in the surgical group. Patients w/ greater instability improved more than others in the nonoperative group. | Patient outcomes improve w/ surgery compared to nonoperative treatment when appropriate patients are offered appropriate treatment. |
| Weinstein et al., 2007 | II (crossover resulted in large prospective cohort study). | Randomized (n = 304) & observational (n = 303) trial comparing operative & nonoperative treatment for patients w/ symptomatic stenosis w/ associated spondylolisthesis. | Patients treated surgically had better outcomes on every outcome measure & at every time point up to 2 yrs postop. | Surgical intervention associated w/ superior outcomes compared to nonsurgical measures in patients w/ symptomatic stenosis & spondylolisthesis whose symptoms warrant intervention. |
| Weinstein et al., 2009 | II (crossover resulted in large prospective cohort study). | Four-year follow-up on 2007 study. | Benefits of surgical vs nonsurgical intervention persist at 4-yr follow-up. | Surgery associated w/ superior outcomes than nonoperative measures in patients w/ symptomatic stenosis & spondylolisthesis whose symptoms warrant intervention. This benefit persists through at least 4 yrs. |

* OP-1 = osteogenic protein-1; OR = operating room; PLF = posterolateral lumbar fusion; PLIF = posterior lumbar interbody fusion; RCT = randomized controlled trial; SF-36 = 36-Item Short Form Health Survey; SPORT = Spine Patient Outcomes Research Trial.

tant demographic differences between the fusion groups (age and race for example), and there were potential differences not described (such as the degree of disc space collapse or regional kyphosis). These confounding factors limit the ability to formulate relevant conclusions regarding the equivalence or nonequivalence of the various fusion techniques.¹

Cheng and colleagues⁹ performed a randomized trial to evaluate the differences between PLF and posterior lumbar interbody fusion (PLIF) following decompression in a group of 138 patients with degenerative or isthmic spondylolisthesis (Grade I or II). They found that fusion rates were higher and instrumentation-related complication rates were lower in the PLIF group. However, functional outcomes were identical between the groups, and the study relied on static radiographs for the assessment of fusion. The fact that the majority of patients had isthmic spondylolisthesis and that a high percentage of patients had Grade II slips decreases the generalizability of these data to the degenerative population. Due to the heterogeneous patient population and questionable criteria to assess fusion status, the study was downgraded to Level II evidence in support of a PLF or PLIF following decompression for the treatment of degenerative spondylolisthesis. Consideration of interbody techniques may be appropriate in patients with higher-grade slips.⁹

Fernández-Fairen and colleagues¹² performed a randomized trial in a cohort of 82 patients in whom they examined the effect of unilateral versus bilateral screw fixation as an adjunct to PLF following decompression for degenerative spondylolisthesis. While the sample size was relatively small, the study was powered to detect significant differences on validated outcomes measures and CT scanning was used to determine fusion status 3 years after surgery. The authors group observed no differences in functional outcomes or in fusion rates between the 2 groups and found that complication rates, blood loss, and operative time were lower in the group in which unilateral screws were placed. This study provides Level II evidence that unilateral screw fixation is associated with similar outcomes as bilateral screw fixation, but because the data are generated from a single study with a relatively small patient population, the validity of this conclusion is limited.

Inamdar et al.¹⁶ performed a randomized study involving 20 patients to investigate the differences in outcomes between PLF and PLIF following decompression for stenosis associated with spondylolisthesis. Clinical and radiographic follow-up data were limited to 1 year. Fusion status was assessed using static radiographs. Although no differences were detected between the treatment groups, the small sample size, short follow-up duration, and questionable method of fusion assessment compromise the conclusions formulated by the authors; therefore, this study is downgraded to Level II evidence in support of PLF over PLIF (Level II for outcomes and Level III for fusion status).¹⁶

Kornblum and colleagues¹⁹ followed up the noninstrumented cohort from the Fischgrund et al. study¹³ for a mean of 7.7 years. They followed up 47 of the original 58 patients: only 1 patient was lost to follow-up, 8 died, 1

was disabled from a stroke, and 1 declined to participate. They found that patients in this group who were thought to have a solid arthrodesis (based on dynamic radiographs) enjoyed better functional outcomes (as measured using VAS for pain assessment and the Stucki inventory) than patients treated with the same procedure in whom a solid arthrodesis was not achieved.^{13,19} It was noted that those patients in whom arthrodesis was not achieved had significantly greater preoperative angular mobility. This paper provides Level III evidence as a case-control study showing that efforts to increase fusion rates are associated with better outcomes in patients treated with fusion as an adjunct to decompression.

McGuire and Amundson²⁰ studied a military population of patients with stenosis and spondylolisthesis and randomized a total of 27 patients to decompression and fusion with or without instrumentation. Fusion rates at 2 years, based on assessment of flexion-extension radiographs, were similar between the groups (72% without instrumentation vs 78% with instrumentation). This paper is felt to provide Level III evidence (small study, nonblinded, very select population with mean age of 35 years) that the addition of instrumentation does not improve fusion rates.²⁰ This paper was not included in the previous systematic review.²⁵

Other papers have been discussed previously or provide lower-quality evidence. Since some of these provided the basis for the past recommendations, they are briefly discussed below.

Andersen et al.² described long-term outcomes following instrumented and noninstrumented fusion for chronic low-back pain but did not separate out patients with degenerative lumbar spondylolisthesis. This is the same patient cohort previously described by Bjarke Christensen et al.⁶

Athiviraham and Yen⁵ described a cohort series of patients treated nonoperatively, with decompression alone, or with decompression and fusion. Only patients with spondylolisthesis underwent fusion. Due to this important difference between the patient groups in this prospective comparison, this paper is felt to provide only Level IV evidence.

Bridwell and colleagues⁷ performed a pseudo-randomized study involving 43 patients treated operatively for stenosis associated with spondylolisthesis. Nine patients underwent decompression alone; 10, decompression and noninstrumented PLF; and 24, decompression and instrumented PLF. Functional outcomes were better in the fusion group, and better functional outcomes were associated with arrest of slip progression and solid fusion. The use of instrumentation appeared to improve fusion rates as well as patient outcomes. The study was downgraded to a Level III study because the investigators used nonvalidated outcomes measures and relied on static radiographs for the determination of fusion.⁷ This paper was previously reviewed in the 2005 Fusion Guidelines.²⁵

Carreon and colleagues⁸ performed a systemic review of the literature to evaluate the effects of fusion on different patient populations. They found that the presence of an established diagnosis such as spondylolisthesis was associated with better functional outcomes compared

with patients treated with similar procedures for chronic low-back pain without a demonstrable deformity. Because the analysis included very few spondylolisthesis patients (96 of 2002) and because the index studies are discussed elsewhere in this Guideline Update, the Carreon et al. review does not provide unique information regarding the treatment of this patient population. It does provide supporting evidence confirming that good outcomes may be expected in patients treated with fusion for degenerative spondylolisthesis.

Chou et al.¹⁰ performed a systematic review of the literature regarding the surgical versus nonsurgical management of low-back pain. While fusion for patients with stenosis was evaluated, spondylolisthesis and nonspondylolisthesis groups were considered together. No specific information regarding the treatment of patients with stenosis and associated spondylolisthesis is given.

Christensen and colleagues¹¹ randomized 130 patients with isthmic spondylolisthesis, primary degenerative instability (back pain associated with movement and degenerative disc disease), or secondary degenerative instability (same as primary but with history of having undergone decompression) to PLF with or without instrumentation. No differences between the 2 groups were detected; however, the patient population is not relevant to a discussion of patients with stenosis and degenerative spondylolisthesis. Andersen et al.² described long-term outcomes following instrumented and noninstrumented fusion for chronic low-back pain but did not separate out patients with degenerative lumbar spondylolisthesis. This is the same patient cohort previously described by Bjarke Christensen et al.⁶

Fischgrund and colleagues¹³ performed a prospective clinical trial of 68 patients with stenosis and degenerative spondylolisthesis who were randomized into one of 2 groups: decompression and PLF in one group and decompression and PLF supplemented with pedicle screw fixation in the other. Fusion status was assessed using plain and dynamic radiography, and clinical outcomes were assessed using a VAS for pain as well as a patient satisfaction scale. The patients treated with pedicle screw fixation had a statistically significantly higher fusion rate (83%) than those treated with noninstrumented fusion (45%). Both groups demonstrated significant score improvements on the VAS for both back and leg pain ($p = 0.001$), and the majority of patients in both groups reported their outcomes as good or excellent (78% in the instrumented group and 85% in the noninstrumented group). This paper provides Level I medical evidence that pedicle screw fixation, as an adjunct to decompression and PLF, improves fusion success, and Level III medical evidence (due to the nonvalidated patient satisfaction scale and inadequate sample size), suggesting that pedicle screw fixation does not improve functional outcome following PLF in this patient population.¹³ This paper was previously discussed in the 2005 Fusion Guidelines.²⁵

Gibson and Waddell¹⁴ performed a systematic review of randomized trials for the Cochrane Review in 2005. The authors did not review any references not reviewed in the previous guidelines document and did not consider patients with stenosis and spondylolisthesis separately.²⁵

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Kanayama and colleagues¹⁷ performed a small randomized controlled trial comparing osteogenic protein-1 (OP-1) to autograft plus ceramic as fusion materials in a group of 19 patients undergoing instrumented PLF following decompression for stenosis associated with spondylolisthesis. The OP-1 group was found to have a slightly lower fusion rate as judged by CT scans, dynamic radiographs, and exploration. While new bone formation was noted in both groups, patients who underwent surgical reexploration for planned instrumentation removal were found to have a relatively high incidence of nonunion despite CT- and dynamic radiography–documented evidence of fusion. This paper does not contribute much to the discussion of treatment options for patients with stenosis and spondylolisthesis but does provide information regarding the limitations of imaging studies to provide information regarding the presence or absence of fusion (Level III diagnostic study as patients without radiographic fusion were not surgically explored to confirm/refute fusion status).

Kondrashov and colleagues¹⁸ followed up 18 patients treated with the X-STOP device and found that beneficial effects appeared to be durable for a mean of 4.2 years of follow-up in their series (Level IV evidence).

McNeely et al.²¹ performed a systematic review of the effect of physiotherapy on back pain in patients with various diagnoses including spondylolisthesis. They found that there was a paucity of evidence to support the effectiveness of physiotherapy for patients with degenerative spondylolisthesis. This paucity is the result of very few studies and the fact that patients with degenerative spondylolisthesis were not necessarily considered separately. Two randomized studies were reviewed: one on younger patients with isthmic spondylolisthesis²³ and the other on patients with chronic low-back pain and a variety of spinal alignments but without claudication.²⁷

Mirza and Deyo²² performed a systematic review of trials evaluating the surgical management of low-back pain. The review did not separately consider patients with stenosis and spondylolisthesis.

Thomsen et al.²⁸ performed a randomized controlled clinical trial of 130 patients who underwent lumbar fusion for low-back pain. The patients were randomized to instrumented (pedicle screw fixation) and noninstrumented PLF groups. Overall, there was no significant difference in functional outcome (as measured by the Dallas Pain Questionnaire). Although this paper describes a randomized controlled trial with validated outcome measures, the overall patient population was not that of stenosis and associated spondylolisthesis (isthmic spondylolisthesis, primary and secondary degenerative instability). Only a small subgroup of patients underwent decompression, and it is unclear whether these patients had associated spondylolisthesis. This paper was previously reviewed in the 2005 Fusion Guidelines.

Welch et al.³¹ provided information regarding a prospective case series of patients with stenosis and degenerative spondylolisthesis who were treated with a dynamic fixation device. Overall results appeared promising; however, no comparison cohort was described. This paper is felt to provide Level IV information regarding the poten-

tial utility of dynamic fixation in select patients with stenosis and degenerative spondylolisthesis.³¹

Zucherman et al.³² performed a prospective randomized study to assess the efficacy of the X-STOP device for the treatment of mild to moderate neurogenic claudication. The results relevant to this discussion have been presented by Anderson et al.³ and discussed previously.

Summary

The current medical evidence continues to support the role of surgery over nonoperative therapies for patients with symptomatic stenosis associated with spondylolisthesis. The vast majority of patients across these studies underwent an instrumented PLF. The achievement of a solid arthrodesis is associated with superior outcomes, and therefore, efforts to maximize fusion potential should be considered. A variety of surgical alternatives may be considered. Surgeons should choose the technique based on their own experience, the risk of complications, and the individual patient's anatomical and physiological characteristics, comorbidities, and preference. It is recognized, however, that within this patient population significant heterogeneity exists that may have an impact on treatment response.

Key Issues for Future Investigation

The utility of surgical intervention in this patient population is well established. Future work should focus on identifying prognostic indicators of surgical outcome and stratify these factors among the various fusion techniques. Establishing well-designed randomized control trials to address these issues will be extremely difficult if not impractical (as exemplified by the SPORT), but relevant data may be obtained by establishing a prospective diagnosis-based registry.

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