Evidence-Based Recommendations for Spine Surgery

Charles G. Fisher, MD,* Alexander R. Vaccaro, MD, PhD,† Peter G. Whang, MD,‡ Alpesh A. Patel, MD,§ Ken C. Thomas, MD, MHSc,¶ Kishore Mulpuri, MBBS, MHSc,|| Peter D. Angevine, MD, MPH,** and Srinivas K. Prasad, MD††

ARTICLE 1

STUDY BACKGROUND
Postoperative visual loss (POVL) is a devastating, although rare, complication of prone spine surgery. It is most often caused by ischemic optic neuropathy (ION), yet studies have been limited because of the relative rarity of ION after spine surgery. It is estimated that ION occurs in 0.017% to 0.1%1–3 of prone spine fusion surgeries. Population-based studies have lacked the granularity necessary to identify convincing risk factors and small series have lacked the power to identify statistically significant factors. Patil et al4 identified obesity as a risk factor for ION after spine surgery using the Nationwide Inpatient Sample database. Myers et al5 examined 37 patients with postoperative visual loss of any type after spine surgery and identified higher estimated blood loss (EBL) and longer anesthesia time as risk factors for POVL. The American Society of Anesthesiologists POVL Registry represents the largest series to date of POVL cases for which detailed perioperative data were recorded. The present study abstracts from this registry 80 patients with ION after spinal fusion and compares them with procedure-matched and year-matched control subjects who underwent surgery between 1991 and 2006. The authors examine recorded registry data to identify risk factors for ION, stratifying them into 4 classes of risk factors: (1) pre-existing conditions, (2) predetermined procedural risk factors, (3) “potentially modifiable intraoperative procedural factors,” and (4) “potentially modifiable intraoperative management factors.” These findings merit strong consideration in both minimizing the risk of ION and equipping surgeons and anesthesiologists with robust data that facilitate preoperative risk discussion with patients.

METHODOLOGICAL REVIEW
This study was performed as a multi-institution case-control study drawing from the American Society of Anesthesiologists POVL registry. The study design is optimal for a rare condition. Because this was an exploratory study, and not an inference-testing study, no hypothesis was provided, although a clear research question was asked at the end of the introduction. Inclusion and exclusion criteria for ION cases abstracted from the registry are outlined in detail and seem to be rational and consistent. A total of 80 ION cases were identified meeting these criteria. Control subjects were identified from 17 high-volume, academic spine centers, randomly selecting 4 control patients for each ION case, matching by procedure CPT code and year of surgery. The same inclusion/exclusion criteria were applied to the control subjects; additionally, control subjects were excluded if they were noted to have any perioperative visual complaint other than a corneal abrasion. Individual center contributions to the control group were capped to prevent disproportionate representation from a single institution and the specifics for this are outlined in detail. In aggregate, 5 of the 320 patients were excluded, leaving 315 patients in the control group. Study size was dictated by the number of ION cases and the decision to maintain a 4:1 ratio of control subjects to ION cases.

The authors selected a number of prognostic variables from the registry comparing ION subjects with control subjects. These variables were divided into patient factors and procedural factors; patient factors were further divided into pre-existing conditions, predetermined procedural risk factors, potentially modifiable intraoperative procedural factors, and potentially modifiable intraoperative management factors.” These findings merit strong consideration in both minimizing the risk of ION and equipping surgeons and anesthesiologists with robust data that facilitate preoperative risk discussion with patients.
pre-existing conditions and other factors, such as indication for surgery and fusion location (lumbar or nonlumbar). Procedural factors were divided into “predetermined procedural factors” (e.g., type of surgical frame), potentially modifiable intraoperative procedural factors (e.g., EBL) and potentially modifiable intraoperative management factors (e.g., fluid management variables). The authors use the term “predetermined” to indicate that the presence or absence of these potentially modifiable procedural risk factors is determined by the surgeon preoperatively. Further details are outlined extensively in the article. Regression analyses were used with both forward and backward selection for variables. Bias was minimized to the extent possible with careful matching of the registry parameters as outlined above. For the univariate analysis, the effect of each factor is presented as an odds ratio with 95% confidence interval and P value.

The authors should be commended for highlighting the important difference between prognostic risk factors (which cannot be modified) and predictive risk factors (which may be potentially modified) as well presenting a comprehensive set of validation analyses for the developed models. Although this study provides valuable insight into ION risk factors, there are a few methodological weaknesses that warrant further discussion. Submission of ION cases into the POVL registry is voluntary, introducing potential for distortion with disparities across cases and control subjects were not matched by institution, that spine surgeons verify that the anesthesiology staff in their facilities understand these findings and use management strategies to the extent possible that minimize the risk of this catastrophic complication. On the basis of this study, a strong recommendation can be made to incorporate these findings into clinical practice.

CLINICAL REVIEW
The authors address a devastating, if rare, complication of prone spinal fusion surgery. By aggregating ION cases from the American Society of Anesthesiologists POVL registry they have generated a robust analysis of risk factors predisposing specifically to ION, excluding other forms of POVL including cortical blindness and central retinal artery occlusion. Literature review suggests that the majority of patients experiencing ION represent young, relatively healthy patients. Of the modifiable factors, some are more applicable to surgeons, whereas others are applicable to anesthesiologists; some are relevant preoperatively, whereas others are relevant intraoperatively. Modifiable factors must be understood and considered strongly before and during surgery to minimize the risk of this dreadful complication. As the authors have indicated, prevention is the only available option at this point because effective treatment has not been identified.

The authors have identified a number of risk factors that significantly increase the risk of ION. Pre-existing risk factors include male sex, obesity, and diabetes. Predetermined procedural risk factors include use of only the Wilson frame. Potentially modifiable intraoperative procedural risk factors include anesthesia duration (which was a rough surrogate for operative time, not available in the registry) and EBL. Finally, potentially modifiable intraoperative management risk factors include sustained hypotension more than 40% below baseline for more than 30 minutes, lowest intraoperative hematocrit, total volume replacement, total nonblood replacement, and colloid as a percentage of nonblood replacement.

Some of these risk factors are specifically modifiable by the surgeon. It seems prudent, on the basis of these data, to minimize the use of the Wilson frame, particularly in male, obese, and/or diabetic patients. This study reinforces the goal of minimizing operative and anesthesia time. Because this study did not include staged spine procedures, it is not clear whether an intraoperative decision to abbreviate and stage a procedure confers any meaningful protection against ION. This study also reinforces the value of minimizing blood loss because elevated EBL independently predisposes to ION. Because many of these risk factors are controlled intraoperatively by anesthesiologists, it is imperative that spine surgeons highlight the importance of this article and its findings to the anesthesiology staff in their facilities.

Recommendation on Impact to Clinical Practice
This important study of a rare condition identifies specific risk factors predisposing posterior spinal fusion patients to ION. It is essential that spine surgeons understand these risk factors and incorporate these findings into their preoperative discussions and intraoperative decisions. Moreover, it is important that spine surgeons verify that the anesthesiology staff in their facility understand these findings and use management strategies to the extent possible that minimize the risk of this catastrophic complication. On the basis of this study, a strong recommendation can be made to incorporate these findings into clinical practice.

ARTICLE 2

STUDY BACKGROUND
Spinal cord stimulation (SCS) is a treatment option after patients with failed back surgery syndrome (FBSS) have exhausted all possible alternate therapies. The authors speculate, on the basis of the new evidence, that more patients may enjoy benefit from SCS if it is used earlier in the management pathway. Although there are certainly patients whose symptoms are refractory even to SCS, this...
intervention has 2 important advantages: it can be tested before permanent implantation, and it is reversible should patients not experience sufficient benefits. Moreover, the fact that SCS represents a minimally invasive procedure implies that recovery may be faster and easier than with reoperation for FBSS. On the basis of this, the authors present the protocol for the evidence trial, which is a prospective, multicenter, multinational randomized controlled trial designed to compare SCS with reoperation for patients with FBSS. It represents an update to a prior single-center study comparing SCS and reoperation for FBSS,\textsuperscript{11,12} incorporates updated implant technology and surgical technique, but does little to improve the limitations of the previous design. The purpose of preliminarily reporting the study protocol is 2-fold: (1) to establish the design parameters against which its execution and results may be scrutinized later and (2) to recruit broader insight into design shortcomings that may be addressed pre-emptively.

**METHODOLOGICAL REVIEW**

This article by North et al\textsuperscript{11} presents the protocol for the evidence clinical trial. It addresses all of the steps suggested in the consort statement, with the exception of details about the randomization process. There are many strengths of the presented protocol. Randomization is 1:1 and recruitment is stratified by site and by number of previous surgical procedures. Several countries will participate in the study and recruitment caps are expected to minimize disproportionate representation from a single institution. Inclusion and exclusion criteria are detailed well and, though extensive, seem to be predicated on prior evidence and seem to be appropriate. Involvement of disinterested third parties in determining candidacy for both interventions, appropriateness of surgical plans and collection of outcomes data would be expected to fortify the results. Primary and secondary endpoints are outlined in detail and the Bonferroni correction for coprimary endpoints is appropriate. The incorporation of cost and health-related quality of life analyses is to be commended because this will be a critical component of cost-effectiveness and comparative-effectiveness determinations. The present study is unblinded, which represents a significant limitation for an intervention such as SCS. It is regrettable that some innovative technique to mimic the paresthesias, but with the capability to switch to therapeutic stimulation, could not be achieved to eliminate the placebo issue. Nevertheless this design is certainly ambitious and is expected to yield important information on the cost-effectiveness and comparative-effectiveness of SCS and reoperation for FBSS.

The presentation of a clinical study protocol is expected to enable the reader to duplicate the trial. To this end, there are a handful of ambiguities in this article that would preclude the duplication of this trial. How is leg pain defined? With anxiety/depression being established or known confounders in pain studies, it is surprising the authors would not evaluate and stratify. Explicit details about outcome measures and questionnaires are not provided. How is the pain question asked? “What do you rate your pain during the last day, week, month, on average?” How are the investigators evaluating their primary outcome? There seems to be some inconsistency with respect to “crossover.” In Figure 1, “Study Timeline,” it is indicated that “If SCS trial is not successful, crossover is permitted,” and this seems to imply that the subject can go on to surgery early in the management course, yet be counted as SCS within the intent-to-treat analysis. This is a challenging analytical issue because of numerous potential biases and warrants debate in the discussion section. In the methods section there is a statement that “if a subject asks to receive the nonrandomized treatment after undergoing the index procedure, this will constitute “crossover” and signal failure of the randomized treatment.” Sample size calculation is puzzling. The author’s state that there is a “scarcity of data” on which to base sample size, yet there have been 2 previous RCTs; these studies should provide ample estimating parameters. Sample size re-estimation is expected to be performed, but the method to be used is not described. It is unclear whether this will be done as an internal pilot, maintaining blinding, or whether the authors will re-estimate the sample size with a formal stopping rule and lose power or spend part of the final alpha. Although industry-funded studies always introduce concerns about bias, the authors have made substantial efforts to minimize this distortion. Finally, specific details about the economic and health-related quality of life analyses are not provided.

**CLINICAL REVIEW**

The authors endeavor to study an important question, using a design similar to 2 previously performed RCTs that are cited as predicate studies: 1 from a single-center study comparing reoperation and SCS for FBSS and another comparing SCS with conservative medical management.\textsuperscript{5,9,11,12} The objective of this trial is to compare clinical, economic, and health-related quality of life outcomes for reoperation and SCS for FBSS. Similar to prior studies, subjects must be candidates for either intervention with surgically remediable structural pathology and more leg pain than low back pain. Subjects randomized to SCS undergo an extensive battery of tests including a screening trial. If they meet criteria, implantation of the Precision (Boston Scientific Corporation, Valencia, CA) rechargeable SCS system is performed. Surgical intervention is verified to be appropriate by a third party and neural decompression is performed, with/without an instrumented fusion as appropriate. Outcome measures are collected at predefined time points, of which a select subset may be done by telephone or mail. Follow-up is expected to be for 36 months or more.

**Recommendation on Impact to Clinical Practice**

The authors have outlined a very ambitious clinical study protocol. Despite some ambiguities, vagueness around outcome assessment, and lack of transparency around troubling biases, this study promises to yield important insight into the cost-effectiveness and comparative-effectiveness of SCS and reoperation for FBSS. At present, on the basis of this protocol...
alone, no recommendation to change clinical practice can be made.

ARTICLE 3

STUDY BACKGROUND
Cervical spondylotic myelopathy has been reported to be the most common cause of spinal cord dysfunction. Surgical management is often recommended with favorable reported outcomes. Predicting the outcomes after treatment remains difficult. Although duration and severity of symptoms is a known predictor, objective radiographical findings have not been correlated with outcomes. Predictive factors, whether negative or positive, can influence surgical decision making and patient expectations. The purpose of this study is to assess the predictive value of postoperative magnetic resonance (MR) imaging among patients treated surgically for cervical spondylotic myelopathy.

METHODOLOGICAL REVIEW
This is a prospective case series of 52 consecutive patients with cervical spondylotic myelopathy undergoing surgery. Magnetic resonance imaging (MRI) was completed preoperatively and at 6 months postoperatively. The MRI parameters analyzed included: T1 low signal, type of high T2 signal change, area, height, number of sagittal cuts, and segmentation in T2 signal change. Signal change was categorized as focal or diffuse on the basis of an intensity scale. Additionally, maximal cord compromise and maximal spinal cord compression were measured on midsagittal magnetic resonance images. Standardized outcome measures were assessed preoperatively and 1-year postoperatively including: the modified Japanese Orthopaedic Association grade and recovery rate, the Nurick grade, Short Form 36 (SF-36) questionnaire, neck disability index, the Berg balance scale score, the 30-meter walking test (quality and cadence), and hand grip tests.

The study sample was formed from consecutively treated, adult patients with cervical spondylotic myelopathy treated at a single institution. Though exclusion criteria are appropriate and reported, a strict clinical criteria defining cervical spondylotic myelopathy was not part of the inclusion criteria nor mentioned in this article. There was, additionally, heterogeneity of disease severity at the time of study. Study subjects were selected to include complete 1-year follow-up.

Radiographical analysis of preoperative and postoperative magnetic resonance images were evaluated by 2 blinded authors. There was no formal discussion about the intra- and interobserver reliability of such measurements, but the authors do mention that there was disagreement in only 2 of 52 cases. The authors did not identify which clinical outcome measure would be the primary measurement of neurological recovery. Furthermore, although not part of the specific study question, disease severity at the time of surgery was a reported predictor of neurological recovery. Indeed, there are numerous variables being analyzed, and what confounders are controlled for is not clear. Paradoxically, the study seems underpowered for the number of variables studied, yet the statistical analysis carried out would raise concern around multiple comparisons and type 1 error.

The methodological limitations of this article are significant. Inclusion criteria, specifically strict diagnostic criteria for cervical spondylotic myelopathy, are not defined. Wide heterogeneity of baseline characteristics adds significant confounding variables. The primary clinical outcome is not well defined. The focal point of the article, a radiographical analysis, has only 2 reviewers and no intra-rater or inter-rater agreement. In aggregate, the shortcomings of the methodology significantly limit the generalizability and applicability of the article.

CLINICAL SUMMARY
The authors reported negative predictive factors on the basis of the postoperative magnetic resonance image: (1) lack of cord expansion (2) hyperintense T2 cord signal change, and (3) intensified T2 signal change. Importantly, none of the patients had continued spinal cord compression. The authors suggest that, in patients without neurological improvement after surgery, MRI, in addition to ruling out persistent compression, can provide these predictive factors for outcome at 1 year.

Although the reported changes in the T2 signal and cord expansion may predict clinical recovery at 1 year, other factors—although not specifically part of this study question—such as age and duration of symptoms are confounding variables that may impact the results of this study. In Table 4 there was an observed trend toward recovery in younger patients and those with a shorter duration of symptoms. These prognosticators may contribute equally to the understanding of postoperative clinical improvement without the need for a repeat MRI.

Recommendation on Impact to Clinical Practice
This study demonstrates that postoperative MRI after surgery for cervical spondylotic myelopathy may be predictive of outcomes at 1 year. This information serves primarily to educate patients as to anticipated outcomes. Based upon the limitations of this study, there is a strong recommendation not to change clinical practice.

ARTICLE 4

STUDY BACKGROUND
Lumbar disc herniation is a common spinal condition that has shown positive responses to both operative and nonoperative treatment. The SPORT study has additionally demonstrated safety and efficacy for surgical care. Duration of symptoms is 1 of the many factors that may influence outcomes of treatment.
of lumbar disc herniation. This is often a highly relevant topic that can impact surgical decision making and patient expectations. The potential influence of symptom duration on outcomes has been consistently reported in both low and high quality studies; with shorter duration of symptoms generally being a favorable prognostic variable. The purpose of this study is to assess the effect of the duration of symptoms on the outcomes after both operative and nonoperative treatments of lumbar disc herniation.

**METHODOLOGICAL REVIEW**

The randomized and nonrandomized patients originally included in the SPORT study, with data on symptom duration, were pooled to provide 1192 patients, which comprised the study sample. The study sample population was well described. Symptom duration was divided into less than 6 months or more than 6 months although the basis for this cut off was neither provided nor referenced. A total of 927 patients had symptoms for less than 6 months, whereas 265 had symptoms for more than 6 months. The authors noted significant baseline differences in the 2 groups: rate of depression, proportion who thought their problem was getting worse and proportion of patients who had a preference for surgery were all higher in patients with more than 6 months of symptoms. Additionally, patients with greater duration of symptoms were less likely to have a positive straight leg raise, less likely to have a neurological deficit, and less likely to have an extruded disc herniation. These baseline differences raise the question of why a multivariate regression analysis was not done to control the impact of the covariants on the dependent variable? The authors identified 3 primary outcome metrics, the SF-36 bodily pain domain, the SF-36 physical function domain, and the Oswestry Disability Index. Follow-up was sufficiently long (4 yr) to capture important changes from baseline.

**CLINICAL REVIEW**

The improvement in primary outcome measures was less for those patients with a longer duration of symptoms. The change in the scores of these patients, from baseline, was approximately 6 points less (SF-36 bodily pain); a small but clinically important difference. The benefits of surgery, beyond nonoperative care, were maintained irrespective of the duration of symptoms.

An appropriate discussion of study limitations was included. Most notably, the authors acknowledge that the baseline differences between the 2 study groups represent potentially important negative predictive factors. Depression, a negative straight leg raise, and a disc protrusion may impact the outcomes of treatment independent of the duration of symptoms. Additionally, these findings can put into question the accuracy of the diagnosis of a symptomatic lumbar disc herniation. These issues were not assessed in the study. Furthermore, the authors acknowledge that the SPORT study was not designed to detect differences between subgroups, based on symptom duration, and as such further studies should be performed to evaluate possible confounders. The consistent agreement across the literature on the findings of this study, however, suggests that further study would likely be redundant.

**Recommendation on Impact to Clinical Practice**

This study demonstrates that patients with prolonged duration of symptoms (>6 mo), may not respond well to both operative and nonoperative treatments of lumbar disc herniation. Based on this study, a weak recommendation can be made to incorporate this finding into preoperative patient counseling and surgical decision making.

**ARTICLE 5**


**STUDY BACKGROUND**

Although the majority of thoracolumbar spine fractures may be treated nonoperatively, certain injury patterns may benefit from surgical intervention in an attempt to stabilize the spinal column, relieve ongoing compression of the neural elements, avoid complications associated with prolonged immobilization, and facilitate functional rehabilitation. Instrumented arthrodesis remains the “gold standard” procedure for these patients because it confers immediate stability that allows for secure fracture reduction and prevents the development of progressive deformity. However, in addition to requiring some type of bone graft material, spinal fusion may also give rise to significant morbidity such as hardware complications, loss of valuable motion segments and nonunion. Furthermore, by decreasing segmental motion across the fracture site, these operations may also bring about adjacent segment degeneration. As a result, nonfusion techniques have been advocated as a potentially more physiological strategy for managing thoracolumbar fractures. By serving as an “internal splint,” these constructs are intended to maintain the normal range of motion of the spine and avoid many of the deleterious effects of an arthrodesis although the removal of these implants may require a subsequent procedure. Multiple prospective studies have suggested that this method of stabilizing these injuries may be a viable alternative to fusion for thoracolumbar fractures. Kim et al recently published the results of a retrospective, single-center review of patients with fractures of the thoracolumbar or lumbar spines who were treated with posterior instrumentation without fusion.

**METHODOLOGICAL REVIEW**

Unfortunately there are multiple issues related to the experimental design of this study that may limit the applicability of these findings to the general thoracolumbar trauma population. Beside the difficulties inherent to a retrospective investigation with no control group, this analysis only considers a relatively small number of patients and the authors fail to elucidate the specific clinical and radiographical criteria utilized for enrollment that would allow for the identification of a similar cohort. In particular, the preoperative radiographical evaluation was not consistent in that only a subset of these patients...
individuals underwent magnetic resonance imaging which is obviously the most sensitive modality for diagnosing injuries to the intervertebral disc or posterior ligamentous complex. Similarly, the pedicle screws were removed anywhere between 6 and 17 months after the index surgery, but the authors failed to discuss their rationale for determining the timing of this second procedure. Because of this potential selection bias, it is likely that this series includes a heterogeneous collection of fractures with varying degrees of instability, which could explain why only certain patients developed significant deformities after implant removal.

In addition, the details of the protocol used to complete the radiographical measurements (e.g., number of reviewers, method of blinding, etc.,) were not revealed nor were the inter- or intra-rater reliabilities reported. As such, any variations in these values may not be exclusively related to this specific treatment strategy. Finally, the authors did not use any validated objective or functional outcome instruments as part of their assessment, therefore the clinical relevance of these radiographical findings remains unknown.

CLINICAL REVIEW
The study sample consisted of 23 patients under the age of 40 years (mean: 28 yr) with unstable burst or flexion-distraction fractures of the thoracolumbar junction or lumbar spine with evidence of posterior ligamentous complex injury on imaging studies. Individuals with neurological deficits or severe disruption of the facet joints were excluded. As part of their surgical procedure, short-segment pedicle screw fixation was placed (i.e., 1 level above and below the fracture) through an open approach; fracture reduction was achieved indirectly through positioning and by using the instrumentation to apply anterior distraction across the fracture. Postoperatively, these individuals were immobilized in a thoraco-lumbo-sacral orthosis for 6 to 8 weeks and the implants were removed between 6 and 17 months after the index operation (mean: 9.75 mo). Patients were followed for a minimum of 18 months after the second surgery (mean: 22.75 mo). The authors assessed a number of radiographical parameters recorded at various time points (preoperative, postoperative, before and after implant removal, final follow-up) including vertebral height, angle of kyphosis, and segmental motion in both the sagittal and coronal planes. Furthermore, these patients were evaluated clinically using subjective, nonvalidated clinical outcome measures.

Vertebral height increased by a mean of 6.7 mm immediately after surgery, and there was minimal loss after implant removal. Patients exhibited an average increase of 20° of lordosis (range: 20°–32°) after the procedure, with a mean loss of 4.5° prior to implant removal. At final follow-up the mean sagittal angle was 9.8° of kyphosis, reflecting an additional loss of 7.4° from the time of hardware removal. Dynamic radiographs demonstrated mean segmental motion of 14.2° and 13.1° in the sagittal and coronal planes, respectively; these values compared favorably with the ranges calculated for 40 asymptomatic volunteers. Clinically, these subjects reported only mild subjective complaints such as stiffness and a foreign body sensation and the majority were satisfied with their overall function and cosmetic appearance. Based on these findings, the authors concluded that instrumented constructs without fusion may be a preferable method for addressing thoracolumbar fractures, particularly in younger, active individuals although caution must be exercised in situations where there is a significant disc injury that may increase the risk of recurrent kyphosis.

Recommendation on Impact to Clinical Practice
Kim et al.1 conclude that these results support the placement of pedicle screw instrumentation without fusion as a viable option for the surgical management of thoracolumbar fractures, especially in younger patients. Nevertheless, practitioners need to be aware of the possibility of early or late loss of correction that may occur with this technique. Although other prospective, randomized, controlled studies have previously been published, which have demonstrated the potential efficacy of nonfusion surgery for this indication,17–20 the current investigation is a retrospective case series with no control group for comparison that provides only level IV evidence. Furthermore, this study is insufficiently powered and the selection criteria are excessively subjective to allow for the identification of critical risk factors that should exclude patients from undergoing this procedure. Consequently, we strongly recommend no changes to clinical practice based on this study.

ARTICLE 6

STUDY BACKGROUND
Autogenous bone harvested from the iliac crest is still widely perceived to be the “gold standard” graft material for spinal fusion because it provides the 3 critical factors that are necessary to promote bone fusion—osteogenic cells, osteoinductive growth factors, and an osteoconductive matrix. In addition to increasing blood loss and operative time, the harvesting of iliac crest autograft may give rise to significant donor site morbidity such as fracture, hematoma formation, infection, and intractable pain.21–24 In an attempt to avoid many of these potential complications and minimize patient disability, a number of different materials have been advocated for spinal arthrodesis including local autograft derived from a concomitant decompression. Although the osteogenic potential of local autograft has not been rigorously characterized, multiple retrospective studies have indicated that the use of this strategy may be effective for various fusion applications.25–28 Ohtori et al.29 recently published the results of a prospective, randomized investigation comparing the radiographical and clinical outcomes of single-level decompression and instrumented posterolateral fusion for degenerative spondylolisthesis and
spinal stenosis augmented with only local bone or combined with iliac crest autograft.

**METHODOLOGICAL REVIEW**

Despite its prospective, randomized design, this investigation still exhibits some limitations, which possibly limit the applicability of these results. Although there did not seem to be any significant disparities between the baseline characteristics of the 2 treatment arms, the protocol by which these subjects were randomized was not discussed which may make it difficult to reproduce cohorts analogous to those generated in this study. Furthermore the authors’ decision to stratify on age and sex as opposed to known confounders for nonunion such as smoking is puzzling; besides the authors did not report smoking, diabetes, or comorbidities in baseline characteristics. Another potential problem is the authors’ failure to perform a power analysis, raising the possibility that a type II error occurred. This is probably unlikely given the reduced variability of a dichotomous outcome, the radiographical results slightly trending in favor of the alternative hypothesis and what surgeons would consider a clinically significant difference. Because any *a priori* testing is not adequately described, the reader must consider this when interpreting these findings.

Unfortunately the authors also do not specify the primary outcome measure of the study; thus, rather than simply comparing the pre- and postoperative clinical measures of each cohort, it may have been preferable to compare the change in scores calculated for each group. Furthermore, their consideration of the time to fusion is misleading. Although time is a continuous variable, measured in this investigation, it is more properly analyzed as a category so that mean values are not appropriate.

**CLINICAL REVIEW**

A total of 82 subjects with at least a 12-month history of lower back and leg pain secondary to a L4–L5 degenerative spondylolisthesis with spinal stenosis undergoing a single-level laminectomy and posterolateral fusion with pedicle screw instrumentation were randomized to receive either local bone consisting of the spinous processes and laminae or a mixture of local and corticocancellous iliac crest autograft obtained through a separate incision. In addition to measuring the amount of bone graft that was implanted, surgical time and estimated blood loss were also recorded for every case. Furthermore, their consideration of the time to fusion is misleading. Although time is a continuous variable, measured in this investigation, it is more properly analyzed as a category so that mean values are not appropriate.

The mean operative time was significantly less for the local autograft cohort but the amount of blood loss was similar. Individuals receiving both local bone and iliac crest autograft received more graft material compared with those who were treated only with local autograft (22.0 ± 4.5 g vs., 14.0 ± 3.0 g, respectively). There were no significant differences between the arthrodesis rates or the mean times to fusion assessed for the 2 groups; likewise, the clinical scores reported by the patients in both cohorts were essentially equivalent at 24 months. However, 8 subjects in the autograft group were experiencing sensory disturbances around their iliac crest incisions and 6 continued to complain of donor site pain at the final follow-up visit. Based on these findings, the authors conclude that the use of local bone for single-level posterolateral fusion more likely than not bring about radiographical and clinical outcomes comparable with those observed with iliac crest autograft with shorter operative times and a lower incidence of complications.

**Recommendation on Impact to Clinical Practice**

In this prospective, randomized trial, the use of local bone alone for single-level posterior instrumented fusion procedures gave rise to excellent radiographical and clinical outcomes without the morbidity inherent to the harvesting of iliac crest autograft, suggesting that these 2 bone-grafting techniques may be equivalent. Nevertheless, because of the aforementioned methodological limitations, this study provides Level II evidence supporting the efficacy of this strategy. Surgeons may consider local bone graft as a grafting source beyond the majority of the time, but there may be clinical circumstances where iliac crest bone graft or other grafting methods should be considered. Although additional high-quality data would be desirable, we think that previous studies along with this investigation justify a weak recommendation for incorporating these results into clinical practice.

**References**


