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Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine.

Part 12: pedicle screw fixation as an adjunct to posterolateral fusion for low-back pain

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Recommendations

Standard. There is insufficient evidence to recommend a treatment standard.

Guidelines. There is insufficient evidence to recommend a treatment guideline.

Options. 1) Pedicle screw fixation is recommended as a treatment option for patients with low-back pain treated with PLF who are at high risk for fusion failure because the use of pedicle screw fixation improves fusion success rates. 2) Pedicle screw fixation as a routine adjunct to PLF in the treatment of patients with chronic low-back pain due to DDD is not recommended because there is conflicting evidence regarding a beneficial effect of pedicle screw fixation on functional outcome, and there is consistent evidence that the use of pedicle screw fixation is associated with higher costs and complications.

Abbreviations used in this paper: ALIF = anterior lumbar interbody fusion; DDD = degenerative disc disease; DPQ = Dallas Pain Questionnaire; ODI = Oswestry Disability Index; PLF = posterolateral fusion; PLIF = posterior LIF; VAS = visual analog scale.

Rationale

The use of instrumentation as an adjunct to lumbar fusion procedures has increased over the past two decades.^{3,12} Multiple techniques have been described for the surgical treatment of patients with chronic low-back pain. Posterolateral fusion is one of the more widespread techniques and may be performed with or without the use of pedicle screw fixation to provide internal fixation as a surgical adjunct to the fusion procedure. The addition of instrumentation is associated with higher costs and higher complication rates. The purpose of this review is to establish whether the medical evidence in the scientific literature demonstrates a clinical benefit of internal pedicle screw fixation as an adjunct to PLF in the treatment of patients with low-back pain due to degenerative lumbar disc disease or low-grade degenerative spondylolisthesis.

Search Criteria

A computerized search of the National Library of Medicine database of the literature published from 1966 to June 2003 was performed. A search using the subject heading

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“spinal fusion, lumbar, treatment outcome, low-back pain” yielded 1030 citations. Clinical series reported in English-language journals dealing with adult patients who had fusion with instrumentation for degenerative lumbar disease were selected (333 references). Among the articles reviewed, references were included that dealt with the comparison of fusion techniques with or without instrumentation. These references are summarized in Table 1. All of these articles reported at least 1 year of clinical and radiographic follow up.

Scientific Foundation

Authors of several well-designed studies have evaluated the effect of pedicle screw fixation on radiographic and functional outcomes in patients treated with PLF for symptomatic lumbar spinal degenerative disease. Bjarke Christensen, et al.,³ performed a randomized study with a 5-year follow up of 129 patients who underwent surgery for chronic low-back pain. Sixty-four patients underwent instrumented PLF and 66 underwent noninstrumented PLF. Five-year follow up was obtained in 93% of patients. The reoperation rate for the instrumented group was 25% compared with 14% for the noninstrumented group. This difference in reoperation rate was the result of nine patients having to undergo implant removal due to either back or leg pain. Two of these nine patients had malpositioned screws. Both groups exhibited significant improvements in all outcome measures. There were no differences in work capacity, DPQ scores, or Low Back Pain Rating Scale scores between the groups. A subgroup analysis revealed that patients with primary DDD (as opposed to patients with spondylolisthesis or patients undergoing reoperation following a previous decompression) had significantly improved long-term outcomes when treated with pedicle screw instrumentation compared with those patients treated with fusion without internal fixation ($p < 0.02$). Only 20 patients with primary degenerative disease of the lumbar spine were included in each treatment arm. There was no difference in radiographic fusion rates between the groups; however, only static plain films were used to determine successful fusion. This paper is thought to provide Class II medical evidence supporting the use of pedicle screw fixation as a means to improve functional outcomes in patients with degenerative lumbar spinal disease that requires fusion because of the improvement noted in the subgroup analysis. The paper provides Class III medical evidence on the benefit (or lack thereof) of pedicle screw fixation on fusion success rates.

Fritzell and colleagues^{8,9} performed a randomized multicenter clinical trial in which 294 patients with low-back pain due to DDD at L4–5, L5–S1, or both levels were compared. Patients were divided into four treatment groups. Group 1 consisted of 73 patients treated with PLF without internal fixation; Group 2 consisted of 74 patients treated with PLF with pedicle screw fixation; and Group 3 consisted of 75 patients who had interbody fixation and posterolateral onlay fusion with pedicle fixation (56 of these patients underwent ALIF and 19 underwent PLIF). Patients in Group 4 were treated by nonsurgical means (72 patients). Follow up was performed by an independent observer and included 219 of the 222 surgically treated patients and 70 of the 72 patients treated with nonsurgical

means (overall follow-up rate of 98%). All three surgical groups had superior clinical outcomes compared with the nonoperative group. Although the group of patients treated with pedicle screw fixation had slightly greater improvements on the ODI, the General Function Score, and the Million VAS than the group treated without pedicle screw fixation, these differences were not statistically significant. Approximately 60% of patients in the PLF-alone group considered themselves to have achieved an excellent or good outcome compared with approximately 70% of patients in the PLF plus pedicle screw group. This difference was not statistically significant. Nine patients who were treated with pedicle screw fixation (with or without an interbody graft) developed a new radiculopathy following surgery. Three of these patients were found to have malpositioned screws. No patient in the noninstrumented fusion group had new radicular complaints. The overall complication rates were significantly higher among patients in the instrumented groups compared with the noninstrumented groups. Fusion success was evaluated by plain radiographs (without flexion–extension views) and was found to occur in 72% of patients in Group 1, 87% of patients in Group 2, and in 91% of patients in Group 3. The authors concluded that all surgical groups had similar clinical outcomes; however, there was an increase in both the fusion rate and the complication rate in both instrumented groups ($p = 0.004$). This paper provides Class III medical evidence suggesting that functional outcomes are not influenced by the addition of pedicle screw fixation to PLF. It also provides Class III evidence suggesting that the addition of pedicle screw fixation improves fusion success rates, albeit at the cost of a higher complication rate.

Fischgrund, et al.,⁶ performed a randomized trial in 76 patients with degenerative spondylolisthesis. Thirty-five patients underwent PLF with pedicle screw fixation and 33 patients underwent PLF without internal fixation. Two-year follow up was achieved in 67 (88%) of the 76 patients. Clinical outcome (based on a patient satisfaction survey) was excellent or good in 78% of the patients in whom instrumentation was placed and was excellent or good in 85% among those patients treated without instrumentation ($p = 0.45$). Fusion success was assessed with flexion–extension radiographs. Successful fusion occurred in 83% of the instrumented cases compared with 45% of the noninstrumented cases ($p = 0.0015$). In this study, successful fusion did not statistically significantly influence patient outcome ($p = 0.435$). The authors concluded that the use of pedicle screw fixation may lead to a higher fusion success rate but that the use of pedicle screw fixation did not improve clinical outcome. This paper provides Class I medical evidence suggesting that the addition of pedicle screw fixation improves the fusion success rate. It also provides Class III medical evidence (due to the use of a nonvalidated outcome measure) suggesting that the addition of pedicle screw fixation to PLF does not influence functional outcome.

Thomsen and colleagues¹⁷ performed a prospective randomized trial of 130 patients with Grade I or II degenerative or isthmic spondylolisthesis. Sixty-six patients underwent PLF without internal fixation and 64 patients underwent PLF with pedicle screws. Two-year follow up was available for 127 (98%) of the patients. Fusion success was evaluated by plain radiographs (without flexion–extension views) and

TABLE 1

Summary of studies involving pedicle screw fixation in patients with degenerative lumbar disease*

Authors & Year	Class	Description	Comment
Lorenz, et al., 1991	II fusion II outcome (return to work)	Prospective randomized study of 68 patients w/ ≥ 6 -mo history of disabling back pain. Group I (29) PLF w/o instrumentation. Group II (39) PLF + PS. All cases were 1 level. Mean FU 26 mos. Fusion based on flexion–extension x-ray was 59% Group I & 100% Group II. Return to similar work was 31% in Group I & 72% Group II.	PS instrumentation improves fusion rates & return to work for PLF.
Bernhardt, et al., 1992	III	Retrospective study of 47 patients w/ PLF, 21 w/ PSs & 27 w/o. 18 of 21 PS had FU. Independent retrospective review. Assignment of patients into the 2 groups is poorly defined. Pseudarthrosis did not significantly differ btwn the 2 groups (PS 22%; nonscrew group, 26%. No p value given). 12 (67%) of 18 PS & 19 (70%) of 27 uninstrumented PS patients had good or excellent results. 2 PS patients had postop leg dysesthesias, 1 requiring hardware removal (5%). No uninstrumented cases experienced dysesthesias.	PLF w/o PS is as effective & safer than fusion w/ PS.
Bridwell, et al., 1993	III fusion III outcome	Prospective randomized 44 patients w/ DS. Patients w/ $> 10^\circ$ or 3 mm movement were instrumented. Mean FU 3 yrs & 2 mos, min 24 mos. Group I no fusion (9), Group II PLF no PS (10), Group III PLF + PS (24). Fusion based on Lenke–Bridwell system (static plain x-ray). Functional outcome not validated, emphasized claudication. Results: spondylolisthesis progression worse in Group I + II than III, $p = 0.001$. Fusion rate higher in III than II, $p = 0.002$.	PLF + PS decreases chances of slip progression, increases fusion rate, & increased patient satisfaction.
Zdeblick, 1993	I fusion III outcome	A prospective randomized study of 124 patients divided into 3 groups. Group 1 w/ PLF only fusion (51), Group 2 w/ PLF w/ semirigid PS (35), Group 3 w/ PLF w/ rigid PS system (37). FU was 9–28 mos (mean 16 mos). Fusion status determined by plain radiographs: flexion–extension views at 1 yr. Fusion rates 65% Group 1, 77% Group 2, & 95% Group 3. Differences btwn 1 & 3 ($p = 0.002$) & 1 & 2 ($p = 0.034$) were statistically significant. Clinical outcomes assessed w/ a nonstandard measure grading patients as excellent, good, fair, or poor. At the latest FU, mean 16 mos, Group 1 had 49% excellent, 22% good, & 29% fair or poor. Group II was 60, 29, & 11%. Group III 70, 24, & 5%.	Clinical outcome directly related to fusion rate. Increasing stiffness of instrumentation leads to higher fusion rates.
Schwab, et al., 1995	III fusion III outcome	Retrospective cohort study w/ FU of 2 yrs. Fusion assessed w/ x-ray. Group I 126 patients w/ PLF alone. Group II 89 patients augmented w/ PS. Fusion rate assessed by dynamic x-ray: 65% & 91% ($p < 0.001$). Complications: pseudarthrosis lower in the instrumentation group. Outcomes assessed w/ nonstandardized measure w/ instrumented group faring better.	PS fixation improves fusion rate vs uninstrumented fusion. No increase in complication rate: outcome scale was nonstandard but instrumented fusions did better.
Fischgrund, et al., 1997	I fusion II outcome	Prospective randomized 76 patients spondylolisthesis & spinal stenosis. All patients had posterolateral intertransverse process arthrodesis. Patients were randomized to a segmental transpedicular instrumented or noninstrumented group. Results: 67 patients w/ 2-yr FU. Clinical outcome was excellent or good in 76% of patients w/ instrumentation & in 85% w/o instrumentation ($p = 0.45$). Fusion in 82% of the instrumented vs 45% of noninstrumented cases ($p = 0.0015$). Overall, successful fusion did not influence outcome ($p = 0.435$).	PLF w/ PS is associated w/ higher fusion rate, but no difference in clinical outcome.
Katz, et al., 1997	III	Prospective nonrandomized study of 272 patients w/ decompression for lumbar stenosis. Laminectomy vs laminectomy w/ PLF (37) vs laminectomy + PS PLF (41). Noninstrumented arthrodesis associated w/ superior relief of LBP at 6 ($p = 0.004$) and 24 mos ($p = 0.01$). Findings limited by small no. of participating surgeons; modest sample size produced p values of borderline significance & the potential confounding bias of choice of treatment w/ fusion being surgeon dependent.	Noninstrumented arthrodesis resulted in superior relief of back pain after 6 & 24 mos.
Thomsen, et al., 1997	II fusion I outcome	Prospective randomized trial of 130 patients w/ Grade 1 or 2 degenerative or isthmic spondylolisthesis: 66 patients w/ PLF & 64 patients w/ PLF + PS. 98% of patients had 2-yr FU. Fusion rates by dynamic radiographs were not significantly different btwn groups. DPQ improved significantly in both groups but no significant difference btwn groups except for the daily activities subsection of the DPQ which was improved in the instrumented group ($p < 0.05$). Instrumentation increased op time, blood loss, & early reop rate significantly. Functional outcome was not significantly improved w/ use of PS except when patients w/ PS had concomitant decompressions ($p < 0.05$).	Instrumentation does not improve results of PLF.
France, et al., 1999	III fusion & outcome	Prospective randomized 71 patients PLF \pm PS. No statistical difference in patient-reported outcome btwn the 2 groups. Slight nonsignificant trend toward increased radiographic fusion rate in the group w/ instrumentation that did not correlate w/ an increased patient-reported improvement rate. Class III due to nonstandard outcome measures, large dropout rate, & poor x-ray criteria for fusion.	No difference in outcome or arthrodesis rate of PLF vs PLF + PS.
Fritzell, et al., 2001	I functional III radiographic	Prospective randomized multicenter study of 294 patients. Group 1 (PLF, 73), Group 2 (PLF + PS, 74), & Group 3 (PLF + PS + interbody fusion, 75: ALIF [56] or PLIF [19]). Group 4 nonop (72). Results: FU 201 (91%) of 222 patients after 2 yrs. All surgical techniques reduced pain & decreased disability substantially, but no significant differences found among groups. Groups 2 & 3 consumed significantly more resources: op time, blood transfusions, & stay. Early complication rate 6% in Group 1, 16% in Group 2, & 31% in Group 3. Fusion rate by plain radiographs: 72% in Group 1, 87% in Group 2, & 91% in Group 3. High complication rate of instrumentation related to 9 patients w/ PS removal for new onset radiculopathy. At the time of reop only 3 actually had cortical wall breach.	Comparison of noninstrumented fusion vs PLF vs PLF + PS vs interbody fusion. No difference in outcome. Interbody fusion had highest fusion rates & complication rates followed by PLF + PS.

Continued

TABLE 1 Continued

Authors & Year	Class	Description	Comment
Bjarke Christensen, et al., 2002	I functional III radiographic	Prospective randomized w/ 5-yr FU. 129 patients w/ LBP had PLF w/ or w/o PSs. The DPQ, LBPRS, & questionnaire concerning work status assessed the outcome. Results: 5-yr FU of 93% reop rate in instrumented is 25% vs 14% in noninstrumented group (p < 0.03). No difference in work capacity or functional outcome as measured by both the DPQ & LBPRS. Subgroup of primary degenerative instability better outcome w/ instrumented group (p < 0.02). Fusion rates not significantly different.	In patients w/ DDD, the PF w/ PS group had better outcome (p < 0.02). Fusion rates not significantly different bwn instrumented & noninstrumented groups.
Fritzell, et al., 2002	I outcome	Multicenter prospective randomized study of 211 patients. PLF (71), PLF + PS (68), structural autograft interbody + PLF + PS (72). No significant difference in ODI, VAS, General Function Score, or Zung Depression Scale at 2 yrs (p > 0.05). Power to detect such a difference was low. Early complication rate 6, 18, & 31% (p = 0.001). Total complication rate after 2 yrs in PLF group 12%, compared w/ 22% in PS group, & 40% in 360° group (p = 0.0003). Reintervention rate was 6, 22, & 17% (p = 0.02). No fusion technique produced superior clinical outcome. The fusion assessment methodology was not presented.	Complications higher w/ use of instrumentation.
Andersen, et al., 2003	III	5-yr FU by questionnaire of prospective randomized trial of PLF w/ or w/o PS in degenerative or isthmic spondylolisthesis. 53 patients were treated w/ PS, 56 w/o PS. No difference in pain bwn groups (p = 0.007). No fusion rates presented.	No significant difference in pain bwn PLF & PLF + PS groups.
Jager, et al., 2003	III	Nonrandomized, retrospective study: 17 patients underwent PLF + PS & were compared w/ 16 patients who underwent PLF. There were no statistical differences in patient-reported, clinical, & radiographic outcome. Instrumented group had more pain postop.	No advantage to PS for lumbar fusion.

* FU = follow up; LBP = low-back pain; LBPRS = Low Back Pain Rating Scale; PS = pedicle screw.

was not significantly different between the groups. There were no reported complications associated with the placement of pedicle screws in this study. Outcome was assessed with the DPQ. The DPQ improved significantly for patients in both treatment groups. There was no statistically significant difference between the groups except for the daily activities subsection of the DPQ, which was statistically significantly better among patients in the instrumented group (p < 0.05). The use of instrumentation increased operative time, blood loss, and the early reoperation rate compared with patients treated with fusion without instrumentation. As cited in previous studies, the increased reoperation rate was due to procedures to remove instrumentation following successful fusion. These authors concluded that functional outcome was not significantly improved with the use of pedicle screw fixation with the exception of an improved score in activities of daily living as measured by the DPQ (p < 0.05). Improvements, although not statistically significant, in all functional outcome measures were noted in the patients with primary degenerative disease treated with pedicle screw fixation compared with similar patients treated without instrumentation. Because the study only included 20 patients with primary degenerative disease of the lumbar spine in each treatment group, these results never reached significance. This study therefore provides Class III medical evidence suggesting that the use of pedicle screw fixation is not associated with increased fusion rates. The study also provides Class III medical evidence indicating that pedicle screw fixation may improve functional outcome in patients with DDD of the lumbar spine.

Zdeblick¹⁸ performed a prospective study of 124 patients with degenerative spondylolisthesis and DDD who were randomized into three groups. Patients in Group 1 were treated with PLF without internal fixation (51 patients), those in Group 2 were treated with PLF with semirigid pedicle screw fixation (35 patients), and patients in Group 3 were treated with PLF with rigid pedicle screw fixation (37 patients). Nine patients initially assigned to Groups 2 and 3 were transferred to Group 1 because of osteoporosis, which prevented adequate pedicle screw fixation. Follow-up periods ranged from 9 to 28 months (mean 16 months). Fusion success was determined using plain radiographs including flexion-extension views. The fusion success rates were 65% in Group 1, 77% in Group 2, and 95% in Group 3. The differences in fusion success rates between Groups 1 and 3 (p = 0.002) and between Groups 1 and 2 (p = 0.034) were both statistically significant. Clinical outcomes were assessed with nonvalidated outcome measures, grading patients as excellent, good, fair, or poor. At last reported follow up (mean 16 months follow up), Group 1 had 49% excellent, 22% good, and 29% fair or poor outcomes. Group 2 had 60% excellent, 29% good, and 11% fair or poor outcomes. Group 3 had 70% excellent, 24% good, and 5% fair or poor outcomes (no tests of significance were done). This study provides Class I medical evidence that the addition of pedicle screw instrumentation improves fusion rates. Because of the nonvalidated functional outcome measure used, it provides Class III medical evidence supporting a beneficial effect of pedicle screw fixation on functional outcome.

France and colleagues⁷ performed a randomized prospective study of 83 patients treated with lumbar fusion for

low-back pain. The treatment groups included patients with isthmic spondylolisthesis, failed-back surgery syndrome, herniated nucleus pulposus, and degenerative spondylolisthesis. The mean follow-up interval was 29 months. Forty-one of the patients underwent PLF with pedicle screws, and the remaining 42 patients underwent PLF without internal fixation. Final clinical follow up (VAS and some elements of the DPQ) was available in 71 of the 83 patients. Only 57 of the 83 patients were available for radiographic follow up. There was an increase in the fusion success rate (based on static radiographs alone) in the instrumented group (76% instrumented group compared with 64% noninstrumented group). There were no statistically significant differences in functional outcome between the groups. The small sample size, high dropout rate, inclusion of patients with multiple diagnoses, and reliance on static plain films to assess fusion success makes it impossible to draw meaningful conclusions from this study regarding the utility of pedicle screw fixation as an adjunct to fusion in the management of patients with lumbar degenerative disease.

Lorenz and colleagues¹⁴ prospectively studied a group of 68 patients they treated with PLF. Twenty-nine patients were treated with pedicle screw fixation and 39 patients were treated without pedicle screw fixation. The patients treated with pedicle screw fixation had improved fusion success rates (100%) compared with patients treated without instrumentation (58%); fusion success was based on flexion-extension radiographs. Patients treated with instrumentation had improved relief of back pain (nonvalidated outcome measure) and higher return-to-work rates (72% compared with 31%) than patients treated without instrumentation. This report is considered to provide Class II medical evidence in favor of pedicle screw fixation as a means to improve fusion success rates and Class II medical evidence in favor of pedicle screw fixation as a means to improve return-to-work rates.

In addition to these prospective studies, retrospective cohort studies have also been performed. Some of these studies provide relevant Class III medical evidence. Schwab, et al.,¹⁶ performed a retrospective review of 215 patients treated with lumbar fusion for low-back pain. One hundred twenty-six patients were treated with PLF and 89 patients were treated with PLF with pedicle screw fixation. Fusion success rates were assessed with dynamic radiographs. The pedicle screw fixation group had a fusion success rate of 91% compared with 65% in the noninstrumented group ($p < 0.001$). Outcomes were assessed using a nonstandardized scale. The outcome in the instrumented group was superior to that in the noninstrumented group (no tests of significance were reported). This study provides Class III medical evidence suggesting that pedicle screw fixation results in higher fusion rates and better functional outcomes.

A number of retrospective cohort studies have been reported that provide less useful data. Several of these studies are widely cited and warrant discussion. Katz, et al.,¹³ performed a cohort study of 272 patients with lumbar stenosis. Of this group, 37 were treated with PLF without internal fixation and 41 were treated with PLF with pedicle screw fixation. The remaining patients were treated with decompression without fusion. Overall, the noninstrumented PLF group experienced the greatest relief of

low-back pain at 6 ($p = 0.004$) and 24 months ($p = 0.01$) following surgery. A subgroup analysis of patients with lumbar stenosis and spondylolisthesis treated with PLF revealed no significant difference in outcomes between patients treated with or without pedicle screw instrumentation. Fusion success rates were not reported. Because the selection criteria used to determine whether a patient received a decompression, a decompression and fusion, or a decompression and fusion with pedicle screw fixation was entirely surgeon dependent, no meaningful conclusions can be drawn from this study.

Bernhardt and colleagues² retrospectively reviewed a series of 47 patients of whom 27 were treated with noninstrumented PLF and 21 were treated with PLF with pedicle screw fixation (three of these 21 were lost to follow up). Pseudarthrosis rates did not significantly differ between the two groups (pedicle screw group 22%; only PLF group 26%). Twelve (67%) of the 18 patients treated with pedicle screw fixation and 19 (70%) of the 27 patients treated without fixation had good or excellent results. Two patients treated with pedicle screw fixation experienced postoperative leg dysesthesias, whereas none of the noninstrumented PLF patients experienced dysesthesias. The authors concluded that lumbar PLF without pedicle screw fixation is as effective as and safer than fusion with pedicle screw fixation. Jager, et al.,¹¹ performed a nonrandomized cohort trial of 16 patients treated with PLF and 17 patients treated with PLF with pedicle screw fixation. Outcomes were measured using the ODI. Fusion success was assessed based on plain radiographs without dynamic views. There was no statistically significant difference between the groups with respect to outcome or fusion success rate. Andersen, et al.,¹ performed a retrospective analysis by using a questionnaire mailed to patients 5 years following lumbar fusion: 53 with pedicle screw instrumentation and 56 without. There was no difference in pain reporting between the groups. Fusion rates were not assessed. All of these studies suffer from severe methodological shortcomings that prevent the development of meaningful conclusions. The most common shortcomings in these reports relate to small sample size, retrospective design, and inadequate outcome measures.

Mardjetko, et al.,¹⁵ performed a metaanalysis of the medical literature on the topic of pedicle screw fixation and concluded that pedicle screw fixation increased fusion success rates. They summarized 25 articles on the treatment of degenerative lumbar spondylolisthesis and found that the addition of pedicle screw instrumentation to a PLF enhances fusion rates (93% compared with 86%) and also improves functional outcomes (90% compared with 86%). Further supporting evidence for the role of pedicle screw instrumentation resulting in increased fusion rates is derived from studies in which PLF with or without instrumentation is analyzed using different techniques or different patient selection criteria. For example, Grubb and Lipscomb¹⁰ performed a retrospective cohort study of patients treated with either noninstrumented PLF (49 patients) or PLF with a compression U-rod (52 patients), with a mean follow up of 30 months. Fusion was assessed based on plain radiographs including dynamic films. The pseudarthrosis rate in the noninstrumented group was 35% compared with 6% in the instrumented group. In both groups of patients with chronic low-back pain sec-

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ondary to DDD, solid lumbosacral fusion was associated with decreased pain and higher return-to-work rates (no probability values reported).

Summary

This review focused on an examination of the literature on the surgical treatment of low-back pain in patients with DDD or low-grade degenerative spondylolisthesis treated with PLF, with or without the use of pedicle screw fixation. All Class I and the majority of Class II and Class III medical evidence on this topic indicates that the addition of pedicle screw fixation to PLF increases fusion success rates when assessed based on plain x-ray films with dynamic imaging. Although there does appear to be a positive relationship between radiographic fusion and clinical outcome, no convincing correlation has been demonstrated. Although several reports suggest that clinical outcomes are improved with the addition of pedicle screw fixation, there are conflicting findings from similarly classified evidence sources (primarily Class II and III). Furthermore, the largest contemporary randomized controlled study on this topic failed to demonstrate a significant beneficial effect for the use of pedicle screw fixation in patients treated with PLF for chronic low-back pain.⁸

This absence of proof should not, however, be interpreted as a proof of absence. For example, in this same study,⁸ patient satisfaction scores improved from approximately 60% to approximately 70% with the addition of pedicle screw fixation. This difference in outcome may be clinically relevant. Similarly, the improvement in ODI scores was 40% greater in the group of patients treated with pedicle screw fixation compared with those treated with PLF alone. If an analysis to determine the sample size necessary to ensure a power of 0.8 (or an 80% chance of detecting a significant effect) in a study in which the good outcome rate is 60% in the control group and 70% in the treatment group is performed, approximately 355 patients would be needed in each treatment group (<http://department.obg.cuhk.edu.hk>). Alternatively, if a similar analysis is performed using the differential scores obtained in the ODI measurements reported in the paper by Fritzell, et al.,⁹ approximately 225 patients would be needed per treatment group (<http://calculators.stat.ucla.edu/powercalc>). Although Fritzell, et al., did not detect a significant benefit associated with the use of pedicle screw fixation as an adjunct to PLF, their sample size severely limited the power of their study to detect such a benefit. All studies reviewed suffer from similar lack of power. Therefore, no definitive statement regarding the efficacy of pedicle screw fixation as a means to improve functional outcomes in patients undergoing PLF for chronic low-back pain can be made. There appears to be consistent evidence suggesting that pedicle screw fixation increases the costs and complication rate of PLF. It is recommended, therefore, that the use of pedicle screw fixation as a supplement to PLF be reserved for those patients in whom there is an increased risk of nonunion when treated with PLF. High-risk patients include, but are not limited to patients who smoke, who are undergoing revision surgery, or who suffer systemic diseases known to be associated with poor bone healing.

Key Directions for Future Research

The most important issue confronting the surgeon when deciding whether to use a particular surgical adjunct is the existence of any evidence that the inclusion of that adjunct improves functional outcome. Whereas it is clear that the addition of pedicle screw fixation improves radiographically demonstrated fusion rates, the evidence supporting its role in improving patient outcome is less clear. Most of the medical evidence encountered in this review is full of potential sources of error, including inadequate sample size, bias in accruing and assigning patients to treatments, and lack of statements about reliability and validity of outcome measures. This led to the downgrading of medical evidence in this review, particularly for the use of vague, nonvalidated functional outcome measures. Future investigators are encouraged to use any or several of the many validated measures now available for the investigation of functional gains following lumbar fusion. In addition, if the question of the usefulness of pedicle screw fixation as an adjunct to PLF is ever to be resolved, it will be in the context of randomized clinical trials that are appropriately designed and implemented.

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