

# 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.

### Rationale

The use of instrumentation as an adjunct to lumbar fusion procedures has increased over the past two decades.<sup>5,12</sup> 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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*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.

“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.,<sup>3</sup> 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<sup>8,9</sup> performed a randomized multicenter clinical trial in which 294 patients with low-back pain due to DDD at L4–S1, 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.,<sup>6</sup> 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 colleagues<sup>17</sup> 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