Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 5: Correlation between radiographic outcome and function

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In an effort to diminish pain or progressive instability, due to either the pathological process or as a result of surgical decompression, one of the primary goals of a fusion procedure is to achieve a solid arthrodesis. Assuming that pain and disability result from lost mechanical integrity of the spine, the objective of a fusion across an unstable segment is to eliminate pathological motion and improve clinical outcome. However, conclusive evidence of this correlation, between successful fusion and clinical outcome, remains elusive, and thus the necessity of documenting successful arthrodesis through radiographic analysis remains debatable. Although a definitive cause and effect relationship has not been demonstrated, there is moderate evidence that demonstrates a positive association between radiographic presence of fusion and improved clinical outcome. Due to this growing body of literature, it is recommended that strategies intended to enhance the potential for radiographic fusion are considered when performing a lumbar arthrodesis for degenerative spine disease.

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KEY WORDS • fusion • lumbar spine • treatment outcomes • practice guidelines

Recommendations

Grade B

When performing lumbar arthrodesis for degenerative lumbar disease, strategies to achieve successful radiographic fusion should be considered, as there appears to be a correlation between successful fusion and improved clinical outcomes.

Abbreviations used in this paper: ALIF = anterior lumbar interbody fusion; DPQ = Dallas Pain Questionnaire; LBOS = Low Back Outcome Scale; LBPR = Low Back Pain Rating Scale; PLF = posterolateral lumbar fusion; VAS = visual analog scale.

Rationale

Achieving a solid arthrodesis following a spinal fusion procedure is generally believed to be an important goal; however, the relationship between successful fusion and clinical outcome has not been fully established. Therefore, the utility of exhaustive radiographic testing to determine fusion status may be questioned. The purpose of this review is to examine the literature regarding the relationship between fusion status and clinical outcome after lumbar arthrodesis procedures performed in the treatment of lumbar spinal degenerative disease. Additional information regarding the methodologies and criteria used to evaluate the evidence discussed below is

located in the *Methodology* section of the first article in this issue (Part 1: Introduction and methodology).¹¹

Search Criteria

For this update, a computerized search of the database of the National Library of Medicine between July 2003 and December 2011 was conducted using the search terms “lumbar spine fusion assessment,” “lumbar spine pseudoarthrosis,” or “lumbar spine fusion outcome.” (The spelling “pseudoarthrosis” was used in searching, but searching on this spelling also retrieves publications with the spelling “pseudarthrosis.”) The search was restricted to references in the English language involving humans. This yielded a total of 1076 references. The titles and abstracts of each of these references were reviewed. Papers not concerned with the assessment of postoperative fusion status or those not focused on adult degenerative lumbar disease (for example, papers focused on trauma-related fractures, infection, scoliosis, or isthmic spondylolisthesis) were discarded. Additional articles were obtained from the bibliographies of the selected articles. Fourteen new references were identified that provided either direct or supporting evidence relevant to the radiographic assessment of lumbar fusion status. These were considered in conjunction with the 37 references from the previous search from 1966 to July 2003.¹⁶ Reports involving Level III or better medical evidence are listed in Table 1. Supportive data are provided by additional references listed in the bibliography.

Scientific Foundation

Achievement of a solid fusion across the treated motion segments is an integral goal of any lumbar fusion procedure performed to treat low-back pain due to lumbar degenerative disease. Therefore, patients who achieve a solid fusion would be expected to have better clinical outcomes compared with those in whom osseous union does not occur (pseudoarthrosis). However, a number of authors have described patients with pseudoarthrosis with favorable clinical outcomes and patients with solid osseous unions who have poor clinical outcomes.^{3,7} The radiographic assessment of lumbar fusion status is imperfect and is not without potential downside to the patient (e.g., exposure to ionizing radiation) and society (e.g., health care resource utilization). If the clinical results associated with lumbar fusion procedures do not correlate with radiographic findings, one can question the utility of exhaustive radiographic study to demonstrate fusion. Furthermore, the incorporation of surgical techniques and adjuncts designed to increase radiographic fusion rates may be inappropriate unless a correlation between radiographic and clinical outcomes can be confirmed. The purpose of this document is to review the evidence for and against such a relationship.

A study correlating clinical outcomes with the results of the gold standard for assessment of lumbar fusion status (open surgical exploration) has not been performed. However, studies do exist in which investigators compared various radiographic fusion assessment techniques with clinical outcomes. In total, we noted 10 Level II and

III (4 Level II and 6 Level III) studies relating to correlation between clinical and radiographic outcome. Of these, 7 (3 Level II and 4 Level III) studies, showed a positive correlation between successful arthrodesis on radiographs and good clinical outcome. The remaining 3 studies did not show a positive correlation between radiographic fusion and good clinical outcome. We noted another 7 Level IV and V studies, and 5 of them did not show correlation between radiographic fusion and good clinical outcome.^{4,8–10,14,18,19}

The Level II studies included the studies by Christensen et al. (2002),¹ Kornblum et al. (2004),¹³ Kim et al. (2006),¹² and Thalgott et al. (2009).¹⁷ In 2002, Christensen and colleagues published a prospective randomized 2-year follow-up study of 148 patients randomized to posterolateral lumbar fusion (PLF) plus pedicle screw fixation or anterior lumbar interbody fusion (ALIF), PLF, and pedicle screw fixation.¹ Clinical outcome was assessed using the Dallas Pain Questionnaire (DPQ), the Low Back Pain Rating Scale (LBPR), and a work status survey. The authors found that patients in both treatment groups exhibited highly significant improvements in all 4 categories of quality of life (DPQ) as well as in the back pain and leg pain index (LBPR) compared with their preoperative status. They identified a significant positive relationship between fusion status and functional outcome: patients with successful radiographic fusion did significantly better than those without solid fusions on 3 of 4 subsections of the DPQ (there was also a nonsignificant improvement on the social concerns subsection).

Kornblum et al.¹³ retrospectively reviewed data from a randomized trial comparing instrumented to uninstrumented posterolateral lumbar fusion, and they looked specifically at the uninstrumented patients. They found that good/excellent outcomes in 86% of the patients with successful fusion versus 56% in those with pseudoarthrosis ($p = 0.01$), and similarly VAS scores (for both back pain and leg pain) were statistically higher in patients with successful fusion. It is unclear whether outcomes in patients with uninstrumented pseudoarthrosis can be generalized to patients with instrumented pseudoarthrosis. Kim et al.,¹² randomized a heterogeneous patient population to 1- or 2-level PLF, posterior lumbar interbody fusion (PLIF), or PLIF+PLF. They found that 91% of patients with fusion had superior clinical results as compared with 41% of patients with nonunion. Thalgott et al.,¹⁷ randomized 50 patients undergoing ALIF with posterior instrumentation to receive either frozen or freeze-dried femoral allograft. In contrast to the previous 2 Level II studies, this study showed no statistically significant difference in ODI and VAS scores between patients with fusion and those with nonunion.

Of the 6 Level III studies, 4 showed a positive correlation between radiographic fusion and good clinical outcome: the 1995 study by Christensen et al.² and the studies by Zdeblick,²¹ Wetzel et al.,²⁰ and Djurasovic et al.⁵ The remaining 2 studies—the study by Penta and Fraser¹⁵ and the study by Epstein⁶—failed to show a correlation. Christensen et al.² studied 120 consecutive patients who underwent ALIF. Clinical outcome was evaluated 5–13 years after surgery by using the DPQ. At 2 years postop-

TABLE 1: Correlation between radiographic outcome and function: summary of evidence*

Authors & Year	Level of Evidence	Description	Comment
Christensen et al., 2002	II	Prospective 2-yr follow-up of 148 pts randomized to PLF+PS or ALIF+PLF+PS. Clinical outcome was assessed w/ DPQ, LBPR, & work status survey scales. Both groups showed highly significant improvement in all 4 categories of life quality (DPQ), back pain, & leg pain index (LBPR) compared w/ preop status. The circumferential fusion pts showed a higher posterolateral fusion rate (92%) than the PLF group (80%) ($p = 0.04$). Circumferential lumbar fusion produced a higher fusion rate w/ tendency toward better functional outcome.	Correlation was found btwn fusion status & functional outcome. Downgraded to Level III because of heterogeneous pt population (isthmia spondylolisthesis, DDD, previous surgeries) & use of static radiographs.
Kornblum et al., 2004	II	Retrospective review of data from randomized trial comparing uninstrumented to instrumented PLF, looking at uninstrumented cohort. Homogeneous population: all had 1-level degenerative spondylolisthesis, w/ good follow-up (81%). Standardized outcome measures & dynamic radiographs. Good/excellent outcomes in 86% of pts w/ fusion vs 56% in pts w/ pseudarthrosis ($p = 0.01$); pts w/ fusion had significantly better VAS scores for back pain ($p = 0.02$) & leg pain ($p = 0.001$).	Correlation found btwn fusion status & better pain scores. Study was graded Level II because it was retrospective.
Kim et al., 2006	II	184 pts w/ back w/ or w/o leg pain randomized to 1- or 2-level PLF, PLIF, or PLF+PLIF. Heterogeneous population included pts w/ spinal stenosis & isthmia & degenerative spondylolisthesis. Validated outcome measures & dynamic radiographs. Of 17 pts w/ nonunion, 41% had superior clinical results as compared to 91% of pts w/ fusion.	91% of pts w/ fusion had superior clinical results as compared to 41% of pts w/ nonunion. Downgraded to Level II because of heterogeneous pt population.
Thalgott et al., 2009	II	50 pts randomized to ALIF + post instrumentation w/ frozen vs freeze-dried FRA. 80% follow-up. Heterogeneous population: DDD, HNP, iatrogenic instability, spinal stenosis, degenerative spondylolisthesis. Study used dynamic radiographs, ODI, VAS. Freeze-dried allograft had significantly ($p = 0.026$) higher rate of pseudarthrosis. Differences in ODI, VAS btwn pts w/ & w/o fusion was not significant.	Higher rates of pseudarthrosis in the freeze-dried allograft group did not correlate w/ worsened clinical outcome. Study was downgraded to Level II because of the heterogeneous pt population.
Zdeblick, 1993	III	124 lumbar fusion pts were prospectively studied. Fusion status was determined using AP & flexion-extension radiography at 1 yr. Clinical results were rated as excellent, good, fair, or poor.	Groups w/ higher fusion rates did better. Downgraded to Level III due to heterogeneity of pt population & lack of validated outcomes.
Christensen et al., 1996	III	120 consecutive pts, w/ clinical outcome evaluated 5–13 yrs postop using DPQ. At 2 yrs postop, radiological outcome was determined by independent observers: 52% complete fusion, 24% questionable fusion, & 24% definitive pseudarthrosis. Pts w/ complete or questionable union had significantly better results than those w/ nonunion ($p < 0.01$).	DPQ scores correlated well w/ radiological outcome. Downgraded to Level III due to heterogeneity of pt population & use of static radiographs to assess fusion.
Penta & Fraser, 1997	III	103 ALIF pts (from a consecutive series of 125) had clinical (LBOS, VAS, MSPQ, ZDS) outcome assessment & 87 pts also had radiographic fusion assessment (AP/lat radiographs w/ or w/o MRI) ~10 yrs postop. 78% rated themselves as having "complete relief" or "a good deal of relief," but only 34% had excellent or good LBOS. Clinical outcome was not associated w/ the presence of radiological fusion & was not influenced by the compensation status. Psychological disturbance at review & reop, however, was significantly correlated w/ LBOS. Conclusions: ALIF outcome was strongly affected by psychological makeup of pt; however, the negative effect of compensation observed at 2 yrs seems to dissipate w/ time & becomes insignificant at 10 yrs.	Long-term (~10-yr) presence of radiological fusion was not associated w/ clinical outcome. Downgraded to Level III due to heterogeneity of pt population & retrospective nature of study.
Wetzel et al., 1999	III	74 consecutive cases of lumbar fusion. Nonvalidated outcome scores on pain relief & medication usage were used. Patients were observed postop at 5 intervals for ~2 yrs (range 24–35 mos, mean 27 mos). Fusion status was based on flexion–extension radiographs in all cases, w/ selective use of other techniques. Overall fusion rate was 61%. At final follow-up, 60% had improved back pain & 70% had improved leg pain. Fusion ($r = 3.3$, $p = 0.010$) correlated positively w/ a successful clinical outcome; the presence of pseudarthrosis negatively correlated w/ a successful clinical outcome.	Solid fusion ($r = 3.3$, $p = 0.010$) correlated positively w/ successful clinical outcome. Pseudarthrosis was negatively correlated w/ successful clinical outcome. Downgraded to Level III due to heterogeneous pt population & use of nonvalidated outcome scale.

(continued)

TABLE 1: Correlation between radiographic outcome and function: summary of evidence* (continued)

Authors & Year	Level of Evidence	Description	Comment
Epstein, 2008	III	Prospective study of 75 pts undergoing multilevel laminectomy + uninstrumented fusion (mean no. of levels = 2). Heterogeneous: variable no. of levels, half w/ degenerative spondylolisthesis, some had previous surgery, some smokers, age range 44–82 yrs. Used SF-36 & dynamic radiographs; 100% follow-up. Pseudarthrosis in 13 pts, leading to revision surgery in 1. Reports “nearly identical maximum improvement on SF-36” & no correlation btwn fusion & clinical outcome.	Found no correlation btwn pseudarthrosis & clinical results. The lesser quality prospective study was downgraded to Level III because of the heterogeneous pt population.
Djurasic et al., 2011	III	Cohort of 193 pts (data collected from 3 trials) w/ heterogeneous diagnoses: spondylolisthesis, instability, DDD, ASD, nonunion; all underwent instrumented PLF. Used CT scans instead of radiographs, ODI, medical outcomes study (MOS), SF-36. No loss to follow-up reported. Compared outcomes in pts w/ & w/o fusion; SF-36 & VAS (back & leg) scores did not show significant btwn-groups difference at 2 yrs. But 65% of pts w/ fusion achieved MCID on ODI vs 32% of pts w/o fusion ($p = 0.004$) & similar for SCB on ODI. 67% vs 50% reached SF-36 MCID ($p = 0.152$) & 63% vs 41% SCB for SF-36 ($p = 0.111$). Authors concluded that solid fusion contributes to better outcome.	Presence of solid fusion contributes to improved clinical outcome. Study was downgraded to Level III because of the heterogeneous pt population.

* ALIF = anterior lumbar interbody fusion; AP = anteroposterior; ASD = adjacent-segment disease; DDD = degenerative disc disease; DPQ = Dallas Pain Questionnaire; FRA = femoral ring allograft; HNP = herniated nucleus pulposus; LBOS = Low Back Outcome Scale; LBPR = Low Back Pain Rating Scale; MCID = minimum clinically significant difference; MSPQ = Modified Somatic Perception Questionnaire; ODI = Oswestry Disability Index; PLF = posterolateral lumbar fusion; pt = patient; SCB = substantial clinical benefit threshold; SF-36 = 36-Item Short Form Health Survey; VAS = visual analog scale; ZDS = Zung Depression Scale.

eratively, fusion outcome was assessed using static plain radiography assessed by independent observers. These authors reported complete fusion in 52% of patients, questionable fusion in 24%, and definitive pseudarthrosis in 24%. Patients with complete or questionable union had significantly better DPQ scores than those with nonunion ($p < 0.01$). The authors concluded that DPQ scores correlated well with radiological outcome. This study is considered to provide Level III medical evidence supporting fusion status as a predictor of functional outcome because the radiographic and clinical follow-up evaluations were obtained at widely separated time points (between 3 and 11 years apart) and because the study relied on static plain radiography to determine fusion status and this modality has been shown to have limited accuracy.¹⁶

Wetzel and colleagues prospectively evaluated 74 consecutive patients who underwent lumbar fusion.²⁰ Outcomes were measured using subjective clinical outcome scores pertaining to pain relief and medication usage. The patients were observed at 5 intervals after surgery during a minimum 2-year follow-up period (range 24–35 months, mean 27 months). Fusion status was evaluated using lateral flexion-extension radiography in all cases, with the selective use of other techniques. The authors noted a 61% fusion rate. At final follow-up examination, 60% of patients had improvement in back pain and 70% had improvement in leg pain. The presence of radiographic fusion correlated positively with a successful clinical outcome ($r = 3.3$, $p = 0.010$). Similarly, in a prospective study of 124 lumbar fusion patients assigned to 3 different surgical treatment groups, Zdeblick assessed fusion status by performing static and flexion-extension lateral radiography at 1 year.²¹ The clinical outcomes were rated as excellent, good, fair, or poor. The study showed that patients in the groups with higher fusion rates had better clinical outcomes. These studies, although prospective, are considered to provide Level III medical evidence in support of the correlation between radiographic and clinical outcome because of the use of nonvalidated clinical outcome measures.¹⁹

Djurasic et al.⁵ studied data on 193 patients collected from 3 clinical trials in which the patients underwent instrumented PLF for diverse indications. The authors compared outcomes in the patients with fusion versus those with nonunion and found that 65% of the patients with fusion achieved MCID on the ODI as compared with 32% of those with nonunion (a statistically significant difference).

In contrast, other studies have failed to demonstrate a statistically significant correlation between clinical and radiographic outcome in patients following lumbar arthrodesis surgery.

In a long-term outcome study (> 10 years), Penta and Fraser¹⁵ reported on 103 patients who underwent ALIF (from a consecutive series of 125 cases). Clinical outcome assessment involved various validated outcome measures, including the Low Back Outcome Scale (LBOS). Eighty-seven patients also underwent fusion assessment with anteroposterior and lateral radiography. The authors reported that 78% of patients rated themselves as having “complete relief” or “a good deal of relief,” but only 34%

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had excellent or good LBOS scores. The patients' clinical outcomes could not be correlated with the presence of radiographic fusion. This study also provides Level III medical evidence against a correlation between radiographic fusion status and clinical outcome following lumbar fusion surgery.

Similarly, Epstein⁶ prospectively studied 75 patients with heterogeneous diagnoses who underwent multilevel decompression and uninstrumented fusion. She reported "nearly identical maximum improvement of SF-36" and that there was not a correlation between radiographic fusion and good clinical outcome.

Summary

There are a total of 10 Level II and III studies regarding this topic. Of these, 7 showed a positive correlation between radiographic presence of fusion and good clinical outcome. Based on the North American Spine Society (NASS) criteria used in the methodology for these guidelines, these are sufficient data to make a Grade B recommendation that strategies that lead to successful radiographic fusion lead to improved clinical outcomes.

Key Issues for Further Investigation

A prospective observational study involving categorization of patients based on multiple validated outcome instrument-derived outcomes and multimodal radiographic outcome assessment would provide Level II medical evidence supporting or refuting the importance of radiographic fusion.

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