J Neurosurg: Spine 2:658–661, 2005

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 5: correlation between radiographic and functional outcome

Daniel K. Resnick, M.D., Tanvir F. Choudhri, M.D., Andrew T. Dailey, M.D., Michael W. Groff, M.D., Larry Khoo, M.D., Paul G. Matz, M.D., Praveen Mummaneni, M.D., William C. Watters III, M.D., Jeffrey Wang, M.D., Beverly C. Walters, M.D., M.P.H., and Mark N. Hadley, M.D.

Department of Neurosurgery, University of Wisconsin, Madison, Wisconsin; Department of Neurosurgery, Mount Sinai Medical School, New York, New York; Department of Neurosurgery, University of Washington, Seattle, Washington; Department of Neurosurgery, Indiana University, Indianapolis, Indiana; Departments of Orthopedic Surgery and Neurosurgery, University of California at Los Angeles, California; Department of Neurosurgery, University of Alabama at Birmingham, Alabama; Department of Neurosurgery, Emory University, Atlanta, Georgia; Bone and Joint Clinic of Houston, Texas; and Department of Neurosurgery, Brown University, Providence, Rhode Island

Key Words • fusion • lumbar spine • treatment outcome • radiography • practice guidelines

Recommendations

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

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

Options. It is recommended that when performing lumbar arthrodesis for degenerative lumbar disease, strategies to achieve successful radiographic fusion should be considered. There appears to be a correlation between successful fusion and improved clinical outcomes; however, it should be noted that the correlation between fusion status and clinical outcome is not strong, and in a given patient fusion status may be unrelated to clinical outcome.

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.

Search Criteria

A computerized search of the database of the National Library of Medicine of articles published between 1966 and July 2003 was conducted using the search terms "lumbar spine fusion assessment" or "lumbar spine pseudarthrosis," or "lumbar spine fusion outcome." 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, trauma-related fractures, infection, scoliosis, and isthmic spondylolisthesis) were discarded. Additional articles were obtained from the bibliographies of the selected articles. Thirty-seven references were identified that provided either direct or supporting evidence relevant to the clinical utility of the radiographic assessment of lumbar fusion status. These papers and references were obtained and reviewed. Papers providing Class III or better medical evidence regarding the relationship between fusion status and clinical outcome following lumbar arthrodesis procedures for degenerative disease are listed in Table 1. Supportive data are provided by additional references as listed in the *Reference* section.

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

Scientific Foundation

One of the integral goals of any lumbar fusion procedure performed to treat low-back pain due to lumbar degenerative disease is the achievement of a solid fusion across the treated motion segments. Intuitively, one would expect that patients who achieve a solid fusion would tend to have better clinical outcomes compared with those in whom pseudarthrosis develops; however, several authors have described patients with pseudarthrosis with favorable clinical outcomes and patients with solid osseous unions who have poor clinical outcomes.[3,5] The radiographic assessment of lumbar fusion status is imperfect, consumes healthcare resources, and exposes the patient to ionizing radiation. If the clinical results associated with lumbar fusion procedures do not correlate with radiographic findings, one must 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 open surgical assessment of lumbar fusion status has not been performed; however, studies do exist in which investigators compared various radiographic fusion assessment techniques with clinical outcomes. Several studies have shown correlation between clinical and radiographic outcomes after lumbar fusion. Christensen, et al.,[2] studied 120 consecutive patients who underwent ALIF. Clinical outcome was evaluated 5 to 13 years after surgery by using the DPQ. At 2 years postoperatively, 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 Class 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 3–11 years apart) and because the study relied on static plain radiography to determine fusion status.

In 2002, the same group published a prospective randomized 2-year follow-up study of 148 patients randomized to PLF plus pedicle screw fixation or ALIF, PLF, and pedicle screw fixation.[1] Clinical outcome was assessed using the DPQ, the LBPR Scale, and a work status survey. The authors found that patients in both treatment groups exhibited highly significant improvements in all four 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 relationship between fusion status and functional outcome. Patients judged to have solid fusions did significantly better than those without solid fusions on three of four subsections of the DPQ (there was also a nonsignificant improvement on the social concerns subsection). Because of the reliance on static plain radiography to determine fusion status, this study is thought to provide Class III medical evidence supporting the importance of fusion status as a predictor of functional outcome.

Vamvanij, et al.,[8] reported on 56 consecutive patients treated with one of four different lumbar fusion procedures. Clinical outcome was assessed using a postoperative pain survey and an independent clinical assessment. The radiographic outcome was assessed using AP and lateral static plain radiography and flexion–extension radiography in selected cases in which the static x-ray films were thought to be equivocal for fusion success. Patients in whom successful lumbar fusion was achieved experienced better clinical outcomes and had a better chance of returning to work. The authors concluded that there was a positive correlation between solid fusion and successful clinical outcome. This study provides Class III medical evidence in support of the correlation between radiographic and clinical outcome.

Wetzel and colleagues[9] prospectively evaluated 74 consecutive patients who underwent lumbar fusion. Outcomes were measured using subjective clinical outcome scores pertaining to pain relief and medication usage. The patients were observed at five 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 improved back pain and 70% had improved leg pain. The presence of radiographic fusion correlated positively with a successful clinical outcome ($r = 3.3$, $p = 0.010$). In a prospective study of 124 lumbar fusion patients assigned to three different surgical treatment groups, Zdeblick[10] assessed fusion status by performing static and flexion–extension lateral radiography at 1 year; the clinical outcomes were rated as excellent, good, fair, or poor. They found that patients in the groups with higher fusion rates had better clinical outcomes. These studies, although prospective (and randomized in the case of the study by Zdeblick) are considered to provide Class III medical evidence in support of the correlation between radiographic and clinical outcome because of the use of nonvalidated clinical outcome measures.[9]

A number of other studies reporting similar trends have failed to demonstrate a statistically significant correlation between clinical and radiographic outcome in patients following lumbar arthrodesis surgery. For example, in a retrospective review of 83 patients who underwent posterior lumbar interbody fusion, Diedrich, et al.,[4] obtained follow-up data in 64 patients. Clinical outcome was assessed using a Hambly score based on pain intensity, medication use, and patient activity. Their results were stratified into a four-point scale (excellent, good, fair, poor). Assessment of fusion was performed using AP and lateral plain radiography. Using standard radiographic criteria for fusion, the authors identified fusion rates of 51.5% at 12 months, 61.4% at 24, 66.7% at 36, and 77.8% at 48 months postoperatively. A comparison of the radiographic fusion rates and clinical outcomes revealed that in 64% of patients with excellent or good outcomes radiographic fusion was achieved. In patients with fair or poor outcomes the rate of successful fusion was 58% (p value not significant). The authors concluded there was slight nonsignificant correla-

TABLE 1

*Summary of studies involving the relatioship of clinical and radiographic outcomes**

Authors & Year	Class	Description	Comment
Zdeblick, 1993	III	124 lumbar fusion patients were prospectively studied. Fusion status was determined using AP & flex–ext radiography at 1 yr. Clinical results were rated as excellent, good, fair, or poor.	Groups w/ higher fusion rates did better.
Christensen, et al., 1996	III	120 consecutive patients, 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 PA. Patients w/ complete or questionable union had significantly better results than those w/ nonunion ($p < 0.01$).	DPQ scores correlated well w/ radiological outcome.
Penta & Fraser, 1997	III	103 ALIF patients (from a consecutive series of 125) had clinical (LBOS, VAS, MSPQ, ZDS) outcome assessment & 87 patients 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 and reop, however, were significantly correlated w/ LBOS. Conclusions: ALIF outcome was strongly affected by psychological makeup of patient; 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/ the clinical outcome.
Greenough, et al., 1998	III	Prospective case series of 135 patients who underwent instrumented PLF. Clinical outcome was assessed using LBOS, radiological outcome by AP/lat plain radiography. Fusion rate was 82% & clinical improvement rate (self-assessment) only 19% good or excellent (LBOS). Compensation status & psychological distress were significantly associated w/ outcome.	No difference in outcome was demonstrated btwn patients w/ fusion & those w/o regarding LBOS scores, patient satisfaction score, or pain VAS.
Vamvanij, et al., 1998	III	56 consecutive patients underwent 1 of 4 lumbar fusion procedures. Clinical outcome was assessed by postop pain survey & independent clinical exam. Radiographic outcome was assessed w/ AP/lat plain radiography & w/ flex–ext views in selected cases where the former was equivocal. Cases w/ successful lumbar fusion had better clinical outcomes & a better chance of work resumption.	Correlation btwn solid fusion & successful clinical outcome.
Wetzel, et al., 1999	III	74 consecutive cases of lumbar fusion. Standard 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 flex–ext radiographs in all cases, w/ selective use of other techniques. Overall fusion rate was 61%. At final FU, 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 PA negatively correlated w/ a successful clinical outcome.	The presence of a solid fusion ($r = 3.3$, $p = 0.010$) correlated positively w/ successful clinical outcome. The presence of PA was negatively correlated w/ a successful clinical outcome.
Diedrich, et al., 2001	III	64 patients following PLIF were evaluated w/ plain radiography: fusion rates of 51.5% at 12, 61.4% at 24, 66.7% at 36, & 77.8% at 48 mos postop. Clinical status was evaluated by Hambly score (pain, medication use, & activity). The clinical outcome was stratified into 4-point scale. Fusion rate was 64% in patients w/ excellent or good outcome & 58% in those w/ fair or poor outcome (NS). There was slight NS correlation btwn radiographic fusion & patient-assessed clinical outcome.	No significant correlation btwn fusion rate & clinical outcome.
Christiansen, et al., 2002	III	Prospective 2-yr FU of 148 patients 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 patients showed a higher PLF 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.

* flex–ext = flexion–extension; FU = follow up; MRI = magnetic resonance imaging; MSPQ = Multiple Somatic Perception Questionnaire; NS = not significant; PA = pseudarthrosis; PLIF = posterior lumbar interbody fusion; PS = pedicle screw; ZDS = Zung Depression Scale.

tion between radiographic fusion and patient-assessed clinical outcome. There were several flaws in this study related to choice of the radiographic assessment tool, the clinical outcome tool, and patient dropout.

In several studies other authors have failed to demonstrate any correlation at all between radiographic fusion status and clinical outcome. In a prospective case series of 135 patients who underwent instrumentation–augmented PLF, Greenough and associates[6] assessed clinical outcome with the LBOS and radiographic outcome with static plain radiography. They found an overall fusion rate of 82% but only a 65% clinical improvement rate based on patient self-assessment. Based on the LBOS, only 19% of the patients made significant improvements. The authors did not identify a difference between patients with fusion and those without regarding LBOS scores, patient satisfaction scores, or the VAS. This study is considered to provide Class III medical evidence refuting the importance of fusion as a determinant of outcome based on the study's use of plain radiography alone for the assessment of fusion status. The discrepancy between the LBOS scores and the patient satisfaction ratings illustrates the problems associated with the use of nonvalidated outcomes measures.

In a long-term outcome study (> 10 years), Penta and Fraser[7] reported on 103 patients who underwent ALIF (from a consecutive series of 125). Clinical outcome assessment involved various validated outcome measures including the LBOS. Eighty-seven patients also underwent fusion assessment with AP 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% had excellent or good LBOS scores. Their clinical outcomes could not be correlated with the presence of radiographic fusion. This study also provides Class III medical evidence against a correlation between radiographic fusion status and clinical outcome following lumbar fusion surgery.

Summary

At the present time, there is no Class I or II medical evidence to indicate that the appearance of a radiographic fusion is significantly associated with improved functional outcomes. The majority of Class III medical evidence does suggest that successful radiographic fusion is associated with improved clinical outcomes. It is widely acknowledged that this relationship is not perfect.

Key Directions for Future Research

A case control study involving categorization of patients based on multiple validated outcome instrument–derived outcome and multimodal radiographic outcome assessment would provide Class II medical evidence supporting or refuting the importance of radiographic fusion.

References

1. Christensen FB, Hansen ES, Eiskjaer SP, et al: Circumferential lumbar spinal fusion with Brantigan cage versus posterolateral fusion with titanium Cotrel-Dubousset instrumentation: a prospective, randomized clinical study of 146 patients. **Spine 27:** 2674–2683, 2002
2. Christensen FB, Karlsmose B, Hansen ES, et al: Radiological and functional outcome after anterior lumbar interbody spinal fusion. **Eur Spine J 5:**293–298, 1996
3. DePalma AF, Rothman RH: The nature of pseudarthrosis. **Clin Orthop Relat Res 59:**113–118, 1968
4. Diedrich O, Perlick L, Schmitt O, et al: Radiographic characteristics on conventional radiographs after posterior lumbar interbody fusion: comparative study between radiotranslucent and radiopaque cages. **J Spinal Disord 14:**522–532, 2001
5. Flatley TJ, Derderian H: Closed loop instrumentation of the lumbar spine. **Clin Orthop Relat Res 196:**273–278, 1985
6. Greenough CG, Peterson MD, Hadlow S, et al: Instrumented posterolateral lumbar fusion. Results and comparison with anterior interbody fusion. **Spine 23:**479–486, 1998
7. Penta M, Fraser RD: Anterior lumbar interbody fusion. A minimum 10-year follow-up. **Spine 22:**2429–2434, 1997
8. Vamvanij V, Fredrickson BE, Thorpe JM, et al: Surgical treatment of internal disc disruption: an outcome study of four fusion techniques. **J Spinal Disord 11:**375–382, 1998
9. Wetzel FT, Brustein M, Phillips FM, et al: Hardware failure in an unconstrained lumbar pedicle screw system. A 2-year follow-up study. **Spine 24:**1138–1143, 1999
10. Zdeblick TA: A prospective, randomized study of lumbar fusion. Preliminary results. **Spine 18:**983–991, 1993

Manuscript received December 7, 2004.
Accepted in final form March 7, 2005.
Address reprint requests to: Daniel K. Resnick, M.D., Department of Neurological Surgery, University of Wisconsin Medical School, K4/834 Clinical Science Center, 600 Highland Avenue, Madison, Wisconsin 53792. email: Resnick@neurosurg.wisc.edu.