

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.

Radiographic and functional outcome

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 colleagues⁹ 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, Zdeblick¹⁰ 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 Hamby 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-