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Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: Lumbar fusion for intractable low-back pain without stenosis or spondylolisthesis

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Establishing an appropriate treatment strategy for patients presenting with low-back pain, in the absence of stenosis or spondylolisthesis, remains a controversial subject. Inherent to this situation is often an inability to adequately identify the source of low-back pain to justify various treatment recommendations, such as lumbar fusion. The current evidence does not identify a single best treatment alternative for these patients. Based on a number of prospective, randomized trials, comparable outcomes, for patients presenting with 1- or 2-level degenerative disc disease, have been demonstrated following either lumbar fusion or a comprehensive rehabilitation program with a cognitive element. Limited access to such comprehensive rehabilitative programs may prove problematic when pursuing this alternative. For patients whose pain is refractory to conservative care, lumbar fusion is recommended. Limitations of these studies preclude the ability to present the most robust recommendation in support of lumbar fusion. A number of lesser-quality studies, primarily case series, also support the use of lumbar fusion in this patient population. (<http://thejns.org/doi/abs/10.3171/2014.4.SPINE14270>)

KEY WORDS • low-back pain • lumbar fusion • lumbar spondylosis • practice guidelines • lumbar spine

Recommendations

There is no evidence that conflicts with the previous recommendations published in the original version of the Lumbar Fusion Guidelines (“Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine”).

Grade B

Lumbar fusion or a comprehensive rehabilitation program incorporating cognitive therapy are recommended as treatment alternatives for patients with chronic low-back pain that is refractory to traditional conservative

treatment, such as physical therapy, and is due to 1- or 2-level degenerative disc disease without stenosis or spondylolisthesis (multiple Level II studies).

It is recommended that lumbar fusion be performed for patients whose low-back pain is refractory to conservative treatment (physical therapy or other nonoperative measures) and is due to 1- or 2-level degenerative disc disease without stenosis or spondylolisthesis (multiple Level II studies).

Rationale

Lumbar fusion has become an accepted treatment alternative for low-back pain associated with stenosis and spondylolisthesis. There is a growing body of evidence including that from the Spine Patient Outcomes Research Trial (SPORT) that consistently demonstrates improved

Abbreviations used in this paper: ODI = Oswestry Disability Index; SF-36 = 36-Item Short Form Health Survey; VAS = visual analog scale.

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clinical outcomes with lumbar fusions for patients who fail conservative care.^{1,32}

Chronic low-back pain associated with lumbar spondylosis, in the absence of stenosis or spondylolisthesis, is a common clinical problem; however, the optimal treatment strategy for this condition remains a controversial topic. Part of this uncertainty results, in many cases, from the inability to accurately determine the actual source of pain. The lack of specificity regarding the changes identified on MRI only adds to the uncertainty when formulating a management strategy. There are many conservative and several surgical treatment options available for the treatment of chronic back pain; however, consistent evidence of superior efficacy of one approach over another is lacking. When conservative measures fail to improve the patient's pain, lumbar fusion is often considered an appropriate treatment alternative. The high costs, risk of serious complications, and lack of consistent supporting evidence raise questions as to whether fusion for lumbar spondylosis is cost-effective and will lead to functional recovery. The purpose of this review is to evaluate the published literature regarding the use of lumbar fusion for the treatment of patients with intractable low-back pain without stenosis or spondylolisthesis.

Literature Search

The database of the National Library of Medicine was searched for articles published between July 2003 and December 2011 using the following search terms: ("Low Back Pain"[MeSH] OR "low back pain"[title]) AND (((("Lumbosacral Region"[MeSH] OR "Lumbar Vertebrae"[MeSH]) AND "Spinal Fusion"[MeSH]) OR "lumbar fusion"[All Fields] OR ("lumbar"[MeSH] AND "fusion"[title])) AND ("Treatment Outcome"[MeSH] OR "Patient Satisfaction"[MeSH] OR "functional outcome"[All Fields] OR "functional outcomes"[All Fields] OR "outcome"[title] OR "outcomes"[title] OR "clinical outcome"[All Fields] OR "clinical outcomes"[All Fields]) AND (("2003"[PDAT]: "3000"[PDAT]) AND "humans"[MeSH] AND English[lang])). Search results were limited to human studies, English language, and patients between the ages of 18 and 65. Duplicates, technical notes, reviews, and other publications that did not describe the use of lumbar fusion for patients with low-back pain without stenosis or spondylolisthesis were discarded. The bibliographies of the selected articles were inspected and additional relevant papers were identified. Three clinical series and one systematic review that contributed to the guideline formulation are described in Table 1. The remaining references provided additional background information and are included in the bibliography.

Scientific Foundation

A review of the Cochrane database failed to identify a randomized, controlled trial investigating the utility of lumbar fusion for the treatment of low-back pain due to spondylosis.¹⁹ Two subsequent randomized trials were summarized in the original version of the Lumbar Fusion Guidelines.²⁹ Fritzell et al. performed a randomized, controlled, multicenter trial of patients presenting with back pain presumably due to lumbar spondylosis. A total of 294

patients were randomized to one of 3 surgical groups or to physical therapy.¹⁶ At 2 years' follow-up, 289 (98%) of the initial 294 patients remained in the study, but 25 had changed treatment groups. Each of the surgical groups achieved better clinical outcomes than the conservatively treated cohort. Back pain was reduced by 33% in the surgical groups versus 7% in the control group ($p = 0.0002$). The Oswestry Disability Index (ODI) score improved by 25% in the surgically treated patients and only 6% in the controls ($p = 0.015$). The return-to-work rate was 36% in the surgically treated patients versus 13% in the controls ($p = 0.002$). The authors concluded that lumbar fusion was a more effective treatment option for patients with chronic low-back pain after failure of conservative care than traditional nonsurgical treatment. Limitations of this study included a lack of well-defined conservative treatment group and patient crossover. This study provides Level II evidence in favor of lumbar fusion over traditional nonoperative treatment for patients with low-back pain.

In a smaller study of 64 patients, Brox et al. compared instrumented fusion versus physical therapy with cognitive exercises in patients presenting with chronic low-back pain and spondylosis at L4–5 and/or L5–S1 on plain radiographs.⁷ Patients were followed for 1 year with a 97% follow-up rate. The main outcomes measure was the ODI. The mean difference between the groups was 2.3 (not significant, $p = 0.33$). Limitations of the study included a small sample size and wide variation between patients. This study provides Level II data for the equivalence between lumbar fusion and physical and cognitive therapy for patients with low-back pain.

There have been 3 prospective, randomized trials comparing lumbar fusion to conservative treatment and one systematic review of the literature since the publication of the original guidelines.^{6,9,14,26}

Brox et al. performed a prospective, randomized study comparing the clinical results of lumbar fusion versus cognitive intervention and exercises in patients with chronic back pain following surgery for lumbar disc herniation.⁶ Inclusion criteria consisted of age 25–60 years, at least 1 year of low-back pain following a lumbar discectomy, and lumbar disc degeneration at L4–5 and/or L5–S1 on plain radiographs. Patients were excluded if there was evidence of spinal stenosis, widespread myofascial pain, recurrent disc herniations, inflammatory disease, fracture, previous lumbar fusion, and/or psychiatric disease. Patients were randomized to either posterolateral instrumented fusion with autologous bone graft or cognitive intervention and exercises. The rehabilitation program lasted approximately 25 hours per week for 3 weeks. Patients were given information on the relevant anatomy and the mechanisms of pain. They were instructed that they could not harm themselves during routine activities of daily living. The specific exercise program was tailored to the individual patient. The ODI was used as the primary outcome measure. Secondary measures included the VAS, medication usage, General Function Score, Global Back Disability Questionnaire, work status, and the Prolo scale. The General Function Score consists of 9 questions used to measure back-related disability in activities of daily living and has been previously validated.²³

TABLE 1: Lumbar fusion versus conservative treatment for chronic low-back pain: summary of evidence*

Authors & Year	Level of Evidence	Description	Comments
Fritzell et al., 2001	II	Prospective, randomized, controlled, multicenter trial. 294 pts w/ LBP randomized to 1 of 3 surgical groups or PT (controls). At 2-yr follow-up 289 (98%) of the initial 294 pts remained, but 25 had changed treatment groups. Each surgical group had improved clinical outcomes compared to the PT cohort. Back pain was reduced by 33% in surgical groups vs 7% in controls ($p = 0.0002$). ODI improved 25% in the surgical groups vs 6% in controls ($p = 0.015$). Return-to-work rate was 36% in the surgical groups vs 13% in controls ($p = 0.002$). Authors concluded that lumbar fusion was more effective than traditional nonsurgical treatment for pts w/ chronic LBP after failure of conservative care.	Limitations of this study include a lack of a well-defined conservative treatment group & patient crossover. This study provides Level II evidence in favor of lumbar fusion over traditional nonoperative treatment for pts w/ LBP.
Brox et al., 2003	II	Prospective, randomized trial involving 64 pts & comparing instrumented fusion vs PT w/ cognitive exercises for chronic LBP. Pts were followed for 1 yr w/ a 97% follow-up rate. Outcomes measured w/ ODI. Mean difference btwn the groups was 2.3 (NS, $p = 0.33$).	Limitations of the study include a small sample size & wide variation btwn pts. This study provides Level II data for equivalence btwn lumbar fusion & PT w/ cognitive therapy for pts w/ LBP.
Fairbank et al., 2005	II	Prospective, randomized, multicenter trial. Outcome measures were the ODI & the shuttle walking test. Secondary outcomes included the SF-36, psychological assessment, complications, & work status. Pts evaluated at baseline & at 6, 12, & 24 mos. Lumbar fusion technique not defined & left to surgeon preference. Intensive rehabilitation program consisted of education & exercises 5 days a wk for 3 wks. Cognitive behavior therapy helped identify & overcome fears & unhelpful beliefs. 339 pts randomized across 15 centers. ODI improved from 46.5 to 34.0 in the surgical group vs 44.8 to 36.1 for control group. Improvement in surgical cohort was significant compared to the rehabilitation group ($p = 0.045$). Shuttle walking test also improved in both groups, but there were no significant differences. There were no statistically significant differences btwn the 2 groups in any of the secondary outcome measures.	Limitations of this study include a 20% loss to follow-up at 24 mos & 28% crossover from rehabilitation to surgery. The clinical significance of the difference in ODI scores is unclear, especially given the failure to observe a relevant difference in the other outcome measures. Based on these limitations, the study was downgraded to Level II evidence due to lack of benefit of lumbar fusion over intensive rehabilitation.
Brox et al., 2006	II	Prospective, randomized study comparing lumbar fusion vs cognitive intervention & exercises in pts w/ chronic back pain following surgery for lumbar disc herniation. Randomized to posterolateral instrumented fusion w/ autologous bone graft or cognitive intervention & exercises. Rehabilitation lasted approximately 25 hrs per wk for 3 wks. ODI was primary outcome measure. Secondary measures included VAS, medication usage, General Function Score, Global Back Disability Questionnaire, work status, & the Prolo Scale. Final study included 60 pts, 29 randomized to fusion & 31 to control. 97% follow-up rate at 1 yr, w/ 6 pts crossing over from surgery to the conservative treatment cohort & 2 pts in the conservative treatment group undergoing surgery. ODI significantly improved in both groups, from 47.0 to 38.1 for fusion & from 45.1 to 32.3 for control ($p = 0.001$). No significant difference btwn groups at final follow-up.	Limitations of this study include a small sample size despite the power analysis, a relatively brief follow-up period, & the study of a small subset of pts w/ chronic back pain who had a previous lumbar discectomy. The authors concluded that either treatment alternative may be considered for pts presenting w/ chronic LBP following discectomy. Based on these limitations, this study was downgraded to Level II evidence supporting the use of either lumbar fusion or intensive rehabilitation w/ cognitive therapy for the treatment of pts w/ chronic LBP w/out stenosis or spondylolisthesis.
Ohtori et al., 2011	II	Prospective study randomizing pts w/ discogenic LBP into surgical vs nonsurgical treatment groups. 41 pts w/ MRI evidence of disc degeneration at L4–5 or L5–S1 & pain provocation on discography w/ pain relief w/ discblock. Surgery consisted of ALIF unless there was difficulty w/ anterior vessels, in which case a posterolateral instrumented fusion was performed. Nonsurgical control included daily walking & exercises following individual instruction. Outcomes measures included VAS, ODI, & JOA score. Subjective outcomes were graded according to the NASS Low Back Outcome Instrument. Radiographic evaluation of fusion was performed w/ AP radiographs & CT scan by 3 blinded observers. Data were compared preoperatively & at 1 & 2 yrs. All pts had solid arthrodesis. Each of the outcomes measures was significantly better for the surgical groups at 2 yrs as compared to the nonoperative group ($p < 0.05$).	Limitations of the study include a small sample size & inconsistency in the type of surgery performed. This study provides Level II evidence in favor of surgery over walking & exercises in pts w/ chronic discogenic LBP.

(continued)

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TABLE 1: Lumbar fusion versus conservative treatment for chronic low-back pain: summary of evidence* (continued)

Authors & Year	Level of Evidence	Description	Comments
Chou et al., 2009	II	Systematic review of the literature to assess risks & benefits of surgical treatment of back pain. 1449 citations were reviewed, which led to a review of 24 full-text articles on surgery for LBP for degenerative disorders, 4 of which compared surgery to nonsurgical therapy. Guidelines suggested fusion was no more effective than an intensive rehabilitation program, but fusion was associated w/ moderate benefits as compared to traditional conservative treatment options.	This systematic review provides Level II evidence for the equivalence of surgery to an intensive rehabilitation program & moderate benefits of surgery over traditional nonoperative treatment options.

* ALIF = anterior lumbar interbody fusion; AP = anteroposterior; JOA = Japanese Orthopaedic Association; LBP = low-back pain; NASS = North American Spine Society; NS = not significant; ODI = Oswestry Disability Index; PT = physical therapy; pts = patients; SF-36 = 36-Item Short Form Health Survey; VAS = visual analog scale.

The authors initially performed a pilot study to determine the required sample size to demonstrate statistical significance. The final study consisted of 60 patients, 29 randomized to fusion and 31 receiving cognitive intervention and exercises. The percentage of male patients was significantly lower in the surgery group (38%) than in the cognitive treatment and exercise group (64%) ($p = 0.04$). There was a 97% follow-up rate at one-year, with 6 patients crossing over from surgery to the conservative cohort and 2 patients in the conservative treatment group undergoing surgery. The mean ODI scores improved significantly in both groups (from 47.0 to 38.1 in the fusion group and from 45.1 to 32.3 in the conservative treatment group, $p = 0.001$). There was no significant difference between the 2 groups at final follow-up. Limitations of this study included a small sample size despite the power analysis, a relatively brief follow-up period, and the study of a small subset of patients with chronic back pain who had a previous lumbar discectomy. The authors concluded that either treatment alternative may be considered for patients presenting with chronic low-back pain following discectomy. Based on these limitations this study was downgraded to Level II evidence in supporting the use of either lumbar fusion or intensive rehabilitation with cognitive therapy for the treatment of patients with chronic low-back pain without stenosis or spondylolisthesis.

A large, prospective, randomized, multicenter trial was performed by Fairbank et al. to assess the effectiveness of spinal fusion versus an intensive rehabilitation program for patients with chronic low-back pain.¹⁴ All patients were between 18 and 55 years of age and had at least a 1-year history of low-back pain. Exclusion criteria consisted of infection, inflammatory disease, tumor, fracture, psychiatric disorders, pregnancy, and previous spinal fusion. Outcome measures were the ODI and the shuttle walking test.³¹ Secondary outcomes included the 36-Item Short Form Health Survey (SF-36), psychological assessment, complications, and work status. Patients were evaluated at baseline and after 6, 12, and 24 months. The technique of the lumbar fusion was not defined and was left to surgeon preference. The intensive rehabilitation program consisted of education and exercises 5 days each week for 3 consecutive weeks. The program was individually tailored to each patient and modified based on the patient's response. Cognitive behavior therapy was also included to help identify

and overcome fears and unhelpful beliefs. This program educated patients on their anatomy and causes of pain and encouraged them to perform normal activities of daily living that would not cause them harm.¹⁷

The study population consisted of 339 patients randomized across 15 different centers. There were no significant baseline differences between the 2 cohorts. A significant crossover rate was observed in the conservatively treated patients. Forty-eight (28%) of the patients randomized to the intensive rehabilitation group eventually had surgery; however, only 7 (4%) of the patients randomized to surgery were treated with rehabilitation alone. There were 19 surgical complications, of which 11 required additional surgery. There were no complications attributed to the rehabilitation program. The mean ODI scores improved from 46.5 to 34.0 in the surgical group versus 44.8 to 36.1 for the rehabilitation group. The extent of improvement observed in the surgical cohort proved to be significant when compared with the outcome within the rehabilitation group ($p = 0.045$). Performance on the shuttle walking test also improved in both groups, but there were no significant differences between the 2 cohorts. There were no statistically significant differences between the 2 groups in any of the secondary outcome measures. Limitations of this study included a 20% loss to follow-up at 24 months and 28% crossover from rehabilitation to surgery. The clinical significance of the difference in ODI scores is unclear, especially given the failure to observe a relevant difference in the other outcome measures. Based on these limitations, the study was downgraded to Level II evidence because of lack of benefit of lumbar fusion over intensive rehabilitation.

Ohtori et al. performed a prospective study randomizing patients with discogenic low-back pain into surgical versus nonsurgical treatment groups.²⁶ The study consisted of 41 patients with MRI evidence of disc degeneration at either L4–5 or L5–S1 and pain provocation on discography with pain relief with discoblock (a procedure that involves injecting the disc with an anesthetic agent instead of a contrast agent in an effort to eliminate as opposed to reproducing a patient's pain). Surgery consisted of anterior lumbar interbody fusion unless there was presumed to be difficulty with the anterior vessels, in which case a posterolateral instrumented fusion was performed. The nonsurgical control group included daily walking and exercises following

individual instruction. Outcomes measures included VAS, ODI, and the JOA score. Subjective outcomes were graded according to the North American Spine Society Low Back Outcome Instrument. Radiographic evaluation of fusion was performed with anteroposterior radiographs and CT scan by 3 blinded observers. Data were compared preoperatively and at 1 and 2 years postoperatively.

All of the patients undergoing surgery went on to achieve a solid arthrodesis. Each of the outcomes measures were significantly better for the 2 surgical groups at 2 years as compared with the nonoperative group ($p < 0.05$). Limitations of the study included a small sample size and inconsistency in the type of surgery performed. This study provides Level II evidence in favor of surgery over walking and exercises in patients with chronic discogenic low-back pain.

Several other recent studies have provided additional data on outcomes of lumbar fusion in patients with chronic low-back pain.^{2-5,8,10-13,15,18,20-22,24,25,27,28,30,33,34} These studies did not have a randomized control group receiving nonoperative treatment. Instead they compared different fusion techniques, compared fusion versus arthroplasty, or failed to include an adequate control group. As a result, they were classified as case series and only provided Level IV evidence supporting the utility of lumbar fusion for the treatment of patients with chronic back pain.

Summary

The results of this review reveal a lack of sufficient evidence to support a single treatment alternative in patients with intractable low-back pain without stenosis or spondylolisthesis. There is Level II evidence supporting the use of either intensive rehabilitation programs with a cognitive component or lumbar fusion. No significant clinical difference in outcomes were observed between these 2 options, but such rehabilitation programs are not generally available in most areas. There is Level II evidence to support lumbar fusion over traditional physical therapy alone, but that benefit is not present when fusion is compared with a more intensive physical therapy program with cognitive therapy. Numerous case series, constituting Level IV evidence, support the use of lumbar fusion in this patient population. These studies reported significant clinical improvements but failed to incorporate an adequate control group for comparison purposes.

Key Issues for Future Investigation

Treatment of intractable low-back pain in patients without stenosis or spondylolisthesis remains a difficult problem with many unanswered questions. Further investigation will be necessary to improve the diagnostic capabilities of identifying the origin of pain in this patient population. With improved diagnostic capabilities, intervention can be directed at the primary pathological process.

While there is currently a lack of high-quality Level I evidence to support the use of lumbar fusion for these patients, there are numerous studies that demonstrate a definitive clinical improvement following fusion. Future investigation will be necessary in an attempt to identify factors, both patient specific and surgery related, that are

predictive of outcome so that a subset of patients are defined who will respond favorably to fusion as compared with conservative management.

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