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Prospective outcomes evaluation after decompression with or without instrumented fusion for lumbar stenosis and degenerative Grade I spondylolisthesis

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Object. There is considerable debate among spine surgeons regarding whether fusion should be used to augment decompressive surgery in patients with symptomatic lumbar spinal stenosis involving Grade I degenerative spondylolisthesis. The authors prospectively evaluated the outcomes of patients treated between 2000 and 2002 at two institutions to determine whether fusion improves functional outcome 1 year after surgery.

Methods. Patients ranged in age from 50 to 81 years. They presented with degenerative Grade I (3- to 14-mm) spondylolisthesis and lumbar stenosis without gross instability (< 3 mm of motion at the level of subluxation). Those in whom previous surgery had been performed at the level of subluxation were excluded. Each patient completed Oswestry Disability Index (ODI) and Short Form–36 (SF-36) questionnaires preoperatively and at 6 to 12 months postoperatively. Some patients underwent decompression alone (20 cases), whereas others underwent decompression and posterolateral instrumentation-assisted fusion (14 cases), at the treating surgeon's discretion. Baseline demographic data, radiographic features, and ODI and SF-36 scores were similar in both groups. The 1-year fusion rate was 93%.

Both forms of surgery independently improved outcome compared with baseline status, based on ODI and SF-36 physical component summary (PCS) results ($p < 0.001$). Decompression combined with fusion led to an improvement in ODI scores of 27.5 points, whereas decompression alone was associated with a 13.6-point increase ($p = 0.02$). Analysis of the SF-36 PCS data also demonstrated a significant intergroup difference ($p = 0.003$).

Conclusions. Surgery substantially improved 1-year outcomes based on established outcomes instruments in patients with Grade I spondylolisthesis and stenosis. Fusion was associated with greater functional improvement.

Key Words • lumbar spine • decompression • fusion • spondylolisthesis • stenosis • prospective clinical trial

Degenerative spondylolisthesis with symptomatic spinal stenosis is a common source of low-back pain and radiculopathy. There is considerable debate among spine surgeons regarding whether instrumented pedicle screw fixation and fusion should also be undertaken when a decompressive laminectomy is performed to relieve neural compression. Evaluation of small prospective studies indicates that the addition of fusion may improve outcomes.[2,11] In a 1994 metaanalysis of the literature,[21] the authors found support for the use of fusion. With the dramatic increase in lumbar fusion surgery since 1980, however, many surgeons have criticized the undertaking of fusion in older patients with degenerative spondylolisthesis and spinal stenosis. A less invasive approach might be appropriate in certain patients in whom hypermobility is absent on flexion–extension radiographs.[17] Lumbar fusion for stenosis and spondylolisthesis is associated with higher postoperative mortality, complication,[20] and cost rates.[18] The striking variability in rates of fusion in patients with spinal stenosis and degenerative spondylolisthesis, even among surgeons within single institutions, further underscores the importance of identifying the indications for fusion in patients.[15]

To determine the outcomes after surgery for degenerative spondylolisthesis and symptomatic spinal stenosis, we studied patients treated surgically for Grade I spondylolisthesis at two institutions. Preoperative and postoperative outcomes data were prospectively obtained. This study was intended to provide pilot data to lay the foundation

Abbreviations used in this paper: CT = computerized tomography; DSH = disc space height; MCS = mental component summary; ODI = Oswestry Disability Index; PCS = physical component summary; SF-36 = Short Form–36.

for a prospective, randomized multicenter trial, in which the following three questions would be addressed. 1) Do significant differences exist in outcome between patients who undergo fusion and those who do not? 2) For patients who undergo laminectomy, are there radiographic features that predict outcome? 3) Does the extent of facet joint removal affect functional outcome?

Clinical Material and Methods

A database was constructed using preoperative and 1-year outcome data supplied by two surgeons (Z.G. and E.C.B.) at different institutions. All patients underwent surgery for degenerative nonisthmic Grade I spondylolisthesis and symptomatic lumbar spinal stenosis. Patients with a history of laminectomy at the level of the spondylolisthesis were excluded. Cases involving gross instability (> 3 mm on flexion–extension radiographs of the lumbar spine) were also excluded. Data were collected by nurse coordinators who reviewed the operative notes from both surgeons performing the procedures between 2000 and 2002. Both surgeons routinely collected ODI and SF-36 data before and after spinal stenosis surgery during this period. Institutional review board approval was obtained from both institutions.

The surgical strategy was at the discretion of each surgeon. Two surgeons performed all operations. All decompressive laminectomies involved an aggressive facet-sparing technique. All fusion operations were performed with laminectomy and dorsolateral pedicle screw fixation. Iliac crest autograft was supplemented with allograft, or in some cases, with allograft supplemented with locally harvested autograft. The radiographic data were analyzed by an independent radiologist or reviewer who had no knowledge of the clinical status of any of the patients. Preoperative magnetic resonance and CT images were used to determine the anatomy of the facet joints and other anatomical features. Plain flexion–extension radiographs were reviewed as well to determine the degree of vertebral instability (measured in millimeters) and to calculate the sagittal rotation angle as defined by Iguchi, et al.[12] The extent of facet joint removal was estimated by measuring the length of the facet before and after surgery on axial CT or magnetic resonance images (Fig. 1).

Outcomes were assessed by comparing preoperative and 6- to 12-month postoperative ODI and SF-36 scores. The ODI and SF-36 instruments were either completed by the patients in the office or were mailed to patients and returned to the office. The ODI scores were calculated as described by Fairbank, et al.,[5] (0–20 representing minimal disability, 20–40 moderate disability, 40–60 severe disability, 60–80 crippled status, and 80–100 bedridden status). For the SF-36, raw scores for eight categories (physical functioning, role [physical], bodily pain, general health, vitality, social functioning, role [emotional], and mental health) were linearly transformed using standard scoring algorithms yielding scores between 0 and 100.[30] The PCS and MCS scores were then calculated using 1998 US population-adjusted norms to generate normalized scores with a mean of 50 ± 10 (standard deviation).[29] Any discrepancies on the questionnaires were addressed by a nurse coordinator not directly involved in a patient's care to avoid observer bias.

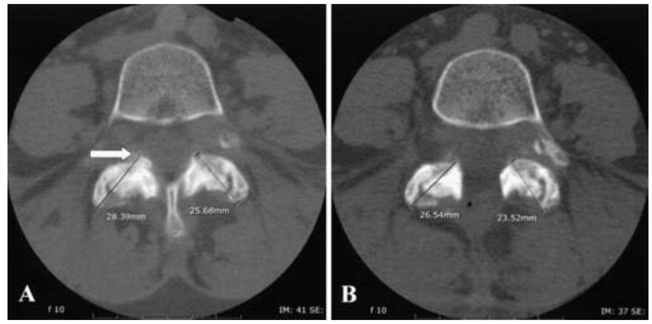

FIG. 1. Preoperative (A) and postoperative (B) axial CT scans demonstrating the facet joint at the level of spondylolisthesis. The first axial image (3-mm cuts) below the pedicle was selected in each case and the superior facet (from the vertebral body below the spondylolisthesis) was measured. The *arrow* indicates an osteophyte removed during decompression. The extent of facet removal was expressed as a percentage based on the following formula: postoperative facet length/preoperative facet length.

The data were analyzed using commercially available software (Stata for Windows; Stata Corp., College Station, TX). Statistical analysis was performed using the chi-square test, Student t-test, and uni- and multivariate regression analysis. A probability value of less than 0.05 was considered statistically significant.

Results

Patient Population

Data were obtained in 34 patients with Grade I spondylolisthesis and symptomatic lumbar spinal stenosis. Patients with a history of laminectomy or gross vertebral instability (> 3 mm motion on flexion–extension lumbar spine x-ray films) at the level of spondylolisthesis were not included. Fourteen of the patients underwent laminectomy and a fusion procedure and 20 laminectomy alone. The demographic and radiographic characteristics are summarized in Table 1. The mean age was 69 years, and approximately two thirds of the population was female. The extent of facet removal was calculated by subtracting the preoperative from the postoperative facet lengths (Fig. 1). There were no significant intergroup differences in the preoperative variables (Table 1), including the SF-36 mean transformed scores, and PCS and MCS scores (Fig. 2).

Predictors of Outcome

To determine whether demographic or radiographic features independently predict 1-year outcome, a univariate regression analysis of each factor was performed, adjusting for preoperative ODI or SF-36 PCS scores (Table 2). The ODI and the SF-36 PCS scores were used as the primary measures of 1-year outcome. Older age was shown to be a predictor of outcome on univariate analysis. Loss of DSH was a negative predictor of SF-36 PCS outcome when laminectomy alone was performed ($p = 0.036$). The degree of facet removal was approximately 15% in both groups. This variable was not associated with outcome. A multivariate regression analysis demonstrated that older age remained a strong independent predictor of poorer 1-year

TABLE 1

Demographic and radiographic features of patients with Grade I spondylolisthesis and stenosis treated with surgery

Characteristic	Value
mean age (yrs)*	68.8 ± 8.0
female sex (%)	68
L4–5 slippage (%)	82
extent of slippage (mm)*	8.5 ± 3.6
sagittal rotation angle (°)*	4.7 ± 2.8
motion at dislocation (flexion–extension)*	1.5 ± 1.2
DSH (mm)*	8.0 ± 3.1
>15° lat scoliosis (%)	12
>15° rotational scoliosis (%)	24
facet angle (°)*	48.0 ± 10.7
extent of facet removal (%)	15

* Value represents the mean ± standard deviation.

outcomes in both groups even after adjustment for preoperative ODI and SF-36 PCS scores and DSH (Table 3).

Postoperative Complications

One patient (7%) in the fusion-treated group was readmitted to the hospital within 30 days of surgery, suffering from community-acquired pneumonia. There was one major wound infection (7%) in the fusion-treated group and none in the laminectomy-alone group. One patient (5%) in the laminectomy-alone group experienced worsening of a preexisting radiculopathy. No cerebrospinal fluid leaks occurred in either group, and there were no apparent instrumentation-associated complications in this study. Because of the low overall incidence of complications, statistical comparison of the complication rates in the two groups was not possible.

Fusion was achieved in 13 patients for a 1-year rate of 93% with no repeated operations performed in the decompression/fusion group. In the laminectomy-alone group three (15%) of 20 patients underwent a second operation at 1 year to fuse the level of the spondylolisthesis for delayed-onset instability.

One-Year Surgery-Related Outcomes

Table 4 provides a summary of the 1-year outcomes data for the 34 cases, categorized by the surgical strategy with pre- and postoperative ODI and SF-36 PCS scores. A negative difference in ODI score represents improvement. The converse is true for the SF-36 PCS score. Both surgical strategies significantly improved patient outcome at 1 year. Moreover, surgery improved scores significantly in seven of eight of the SF-36 categories as well as the PCS and MCS scores (Fig. 3). Based on 1-year ODI and SF-36 PCS scores, the postoperative outcomes were significantly better in the fusion group compared with the laminectomy-alone group, adjusting for older age and preoperative score (ODI, $p = 0.02$; SF-36 PCS, $p = 0.003$) (Fig. 4).

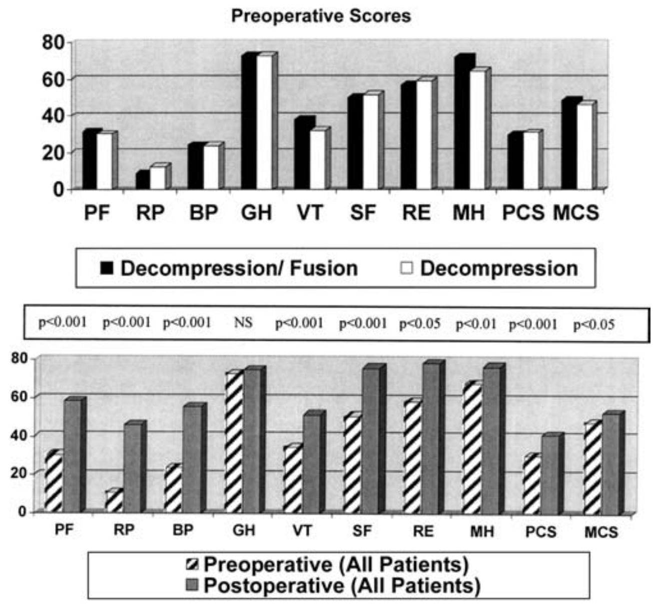

FIG. 2. Bar graphs. *Upper:* The mean preoperative SF-36 transformed scores for both groups. None of the differences in the SF-36 scores is significantly different. BP = bodily pain; GH = general health; MH = mental health; PF = physical functioning; RE = role (emotional); RP = role (physical); SF = social functioning; VT = vitality. *Lower:* The mean pre- and postoperative SF-36 transformed scores for both groups combined. The probability values are depicted above the bar graph for each category.

Discussion

The use of well-established outcomes instruments for evaluating the results of medical intervention is increasing. Particularly in spinal surgery, such reliable and valid instruments are valuable in helping clinicians determine how intervention affects quality of life.[7–9,16,23] In this study, both surgical treatments resulted in significant improvement in the SF-36 PCS and ODI scores compared with preoperative scores. When both groups are considered, the overall reduction in ODI score was 19.5 points and the improvement in SF36-PCS score was 10.4 points, which compares favorably with other conditions reported in the literature. A successful hip replacement, for example, is associated with a 9.6-point SF-36 PCS improvement.[14,29] Heart valve replacement is associated with a 7.6-point SF-36 PCS score improvement.[25,29] In the Spinal Patient Outcomes Research Trial, Birkmeyer and colleagues[1] have suggested that a 10-point difference on the ODI represents a meaningful clinical difference upon which sample size calculations are based. Differences of at least 3 to 5 points in the SF-36 scores are thought to be clinically relevant.[27] Overall, the differences between surgical treatments observed in the present study appear not only to be statistically significant but also clinically meaningful.

Considerable attention has been given to the preoperative demographic radiographic features observed in patients with spinal stenosis and spondylolisthesis in an effort to identify a subgroup in which favorable outcomes might result from decompression alone. Age, facet joint orientation, extent of decompression, degree of spondylolisthesis, and degenerative status of disc are thought to influence the outcome of patients undergoing a decompression without fusion. Disc height has been the subject of several reports. Lombardi, et al.,[19] found that a DSH of greater than 6 mm is associated with progression of vertebral slippage after laminectomy. In work published by Bridwell and colleagues[2] it is suggested that progression

TABLE 2

*Demographic and radiographic predictors outcome at 1 year**

Characteristic	p Value					
	Both Groups		Decompression Alone		Decompression & Fusion	
	ODI	SF-36 PCS	ODI	SF-36 PCS	ODI	SF-36 PCS
age	0.019	0.001	0.036	0.007	NS	0.043
female sex	NS†	NS	NS	NS	NS	NS
% L4–5 slippage	NS	NS	NS	NS	NS	NS
extent of slippage	NS	NS	NS	NS	NS	NS
sagittal rotation angle	NS	NS	NS	NS	NS	NS
motion at dislocation	NS	NS	NS	NS	NS	NS
DSH	NS	NS	NS	0.036	NS	NS
>15° lat scoliosis	NS	NS	NS	NS	NS	NS
>15° rotational scoliosis	NS	NS	NS	NS	NS	NS
facet angle	NS	NS	NS	NS	NS	NS
facet decompression	NS	NS	NS	NS	NS	NS

* Based on univariate analysis of each characteristic adjusted for preoperative score. NS = not significant ($p > 0.05$).

of the dislocation might be associated with worse outcomes. Johnsson, et al.,[13] however, did not find DSH to be a predictor of outcome after laminectomy. Matsunaga, et al.,[22] studied 145 patients with degenerative spondylolisthesis in whom no surgery was performed and who were followed for a minimum of 10 years. They found that progression of vertebral slippage was associated with DSH and that patients in whom this was reduced did not, in general, suffer from progression of the lesion. Of interest, neurological symptoms did not progress when the slippage increased, although most patients experienced a reduction in back pain during a 10-year period when DSH was reduced. In our study, a decrease in DSH was associated with poorer SF-36 PCS outcome scores in patients treated with laminectomy alone. This correlation was not statistically significant with respect to ODI scores. Further studies might help clarify the importance of DSH as a predictor of outcome after laminectomy, especially in the younger patient.

Many surgeons believe that the extent of facet removal is a significant determinant of outcome after laminectomy. Shenkin and Hash[28] have reported the development of slippage in 10% of patients with lumbar stenosis who underwent aggressive laminectomy and facetectomy during a 6-year follow-up period. The extent of facet excision has not been rigorously studied. The use of an undercutting technique to preserve facet joint integrity has been shown to be effective. Recently, facet-sparing laminectomy and a more aggressive technique involving extensive facet removal were compared biomechanically.[3] Support for the use of a facet-sparing approach was established. The authors estimated that 85% of the joint was preserved in both groups. The extent of decompression, as measured in our study, was not a predictor of outcome. This finding may be related to the uniformity in surgical technique, of which the aim was to preserve the facet joints. It is possible that a more critical digital assessment of facet anatomy and an analysis of facet volume would reveal differences that could be correlated with outcome.

In the present study, age was a significant feature associated with outcome in both groups. Older age has been cited as a reason for a less extensive lumbar surgery.[17] Older age, however, was not found to be predictive of poorer long-term outcome in one retrospective study of 68 patients who underwent lumbar stenosis surgery.[10] Analysis of findings in our study indicates that although age may be a factor that limits the effectiveness of lumbar surgery in general, it is not associated with poorer outcomes when fusion is used to supplement laminectomy compared with laminectomy alone. As the US population ages, with octogenarians currently comprising the fastest-growing segment of the population,[26] it is important to determine if the apparent benefits of decompression and fusion observed in this study apply specifically to patients older than 75 years of age.

In a prospective study of 50 patients with Grade I spondylolisthesis and spinal stenosis, Herkowitz and Kurz[11] demonstrated that intertransverse process arthrodesis and decompression resulted in greater decrease in back and leg

TABLE 3

*Summary of factors affecting 1-year outcome after surgery**

Characteristic	p Value					
	Both Groups		Decompression Alone		Decompression & Fusion	
	ODI	SF-36 PCS	ODI	SF-36 PCS	ODI	SF-36 PCS
preop outcome score	NS	0.022	NS	0.001	NS	NS
age	0.015	0.002	0.028	0.008	NS	0.05
DSH	NS	NS	NS	0.036	NS	NS

* Multivariate analyses were adjusted for preoperative outcome score, age, and/or DSH as appropriate.

TABLE 4
*Clinical 1-year ODI and SF-36 PCS outcomes after surgery for Grade I spondylolisthesis and symptomatic spinal stenosis**

Op Strategy	ODI Score Preop	ODI Score Postop	ODI Score Diff	ODI Score p Value	SF-36 PCS Score Preop	SF-36 PCS Score Postop	SF-36 PCS Score Diff	SF-36 PCS Score p Value
decompression & fusion	41.5	14.0	−27.5	<0.001	29.8	45.7	+15.9	<0.001
decompression alone	41.0	27.4	−13.6	0.003	30.9	37.4	+6.5	0.005
both groups	41.2	21.7	−19.5	<0.001	30.4	40.8	+10.4	<0.001

* Improvement is denoted by a negative difference for ODI scores and a positive difference for SF-36 PCS scores. Diff = difference in post- from preoperative score.

pain than decompression alone. In a prospective study of 44 patients, Bridwell, et al.,[2] found no significant difference between the results of decompression alone and decompression and fusion. Favorable outcomes were reported in three of nine patients who underwent decompression alone and three of 10 who underwent decompression and uninstrumented fusion. In contrast, 20 of 24 patients who underwent decompression and instrumentation-assisted fusion experienced favorable outcomes. Bridwell, et al., reported the fusion rates 30 and 87.5% in the noninstrumented and instrumented-assisted fusion group, respectively. In a prospective randomized study, Fischgrund and colleagues[6] later demonstrated that the fusion rate was higher in patients in whom instrumentation was used. It was not, however, associated with improved outcome. This finding is in contrast to those of Bridwell and colleagues. In these three studies investigators did not use established outcomes instruments; rather, outcomes were judged by the treating surgeons or by patients themselves. In a metaanalysis of the literature some authors found that 69% of patients treated with decompression alone experienced a satisfactory outcome, whereas 90% of those treated with decompression and fusion experienced a satisfactory outcome.[21] Without randomization, these published data are subject to a selection bias because most surgeons will not include debilitated patients in poorer health for lumbar fusion. We found in the present study that fusion might result in improved outcomes, although it was also subject to a similar selection bias. This surgery-related selection bias might have had a significant effect on the outcomes in this study. Moreover, differences in the two surgeons' techniques may also have affected the observed outcomes. Although there were no significant intergroup differences in age or preoperative SF-36 PCS and ODI scores, other significant, but unapparent, underlying differences may have affected the 1-year outcome. Long-term outcome studies would be helpful in determining if the differences observed in the present study persist beyond 1 year. A randomized prospective study would help to determine if decompression combined with fusion is superior to decompression alone for all patients with symptomatic lumbar stenosis and degenerative spondylolisthesis.[24]

In recent studies the costs, complications, and recovery time have been compared between lumbar pedicle screw fixation and fusion in patients who have undergone surgery for spinal stenosis. Deyo and colleagues[4] reported that lumbar fusion is associated with a higher rate of postoperative complications. The incidence of permanent nerve root injury has been reported to be 60% less common in patients in whom decompression is not combined with fusion.[31] Furthermore, the incidence of major medical complications is estimated to be 3.7% in patients treated with fusion and decompression, whereas it is 2.2% in those treated with decompression alone. These data raise provocative questions regarding the role of fusion surgery, particularly in older patients. Based on the data accrued in this study, fusion was not associated with a significantly greater morbidity rate. In 1997, Katz, et al.,[15] reported that the direct hospital costs for laminectomy were $14,700 compared with $30,200 for a lumbar instrumentation-augmented fusion and laminectomy. In their cost-effectiveness study of instrumentation-assisted fusion in patients with lumbar spinal stenosis and degenerative spondylolisthesis, Kuntz, et al.,[18] concluded that a randomized clinical trial was necessary to assess surgical outcomes accurately.

Conclusions

The results of prospectively evaluated ODI- and SF-36

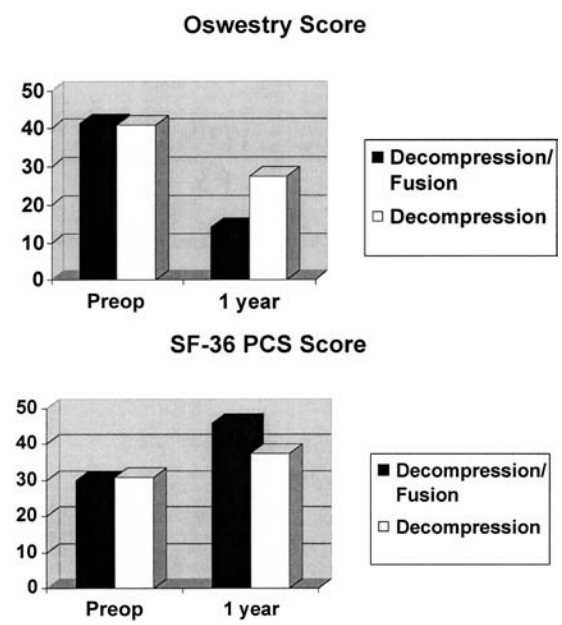

FIG. 3. Bar graphs depicting ODI *(left)* and SF-36 PCS *(right)* 1-year outcomes data for surgically treated patients with symptomatic lumbar spinal stenosis and Grade I spondylolisthesis. Preoperative scores were not significantly different. Fusion was associated with significantly improved 1-year outcome based on ODI (p = 0.02) and SF-36 PCS (p = 0.003) scores.

PCS–based outcomes indicated that surgery for symptomatic lumbar spinal stenosis and Grade I spondylolisthesis dramatically improved 1-year outcomes regardless of the applied surgical strategy. Preoperative radiographic features did not predict failure of laminectomy management, with the possible exception of loss of DSH. Preoperatively, reduced DSH was associated with poorer postoperative outcomes based on SF-36 PCS scores; however, loss of DSH was not a significant predictor of postoperative ODI score. Moreover, the extent of facet removal was not predictive of outcome. Older age was associated with poorer outcomes in both treatment groups. The choice of surgical strategy remains a challenge for spine surgeons, especially older patients. Our surgery-related results indicated that outcomes were significantly improved after surgery, and these data support the need for a prospective randomized multicenter trial to determine the most effective surgical strategy for patients with degenerative spondylolisthesis and symptomatic lumbar spinal stenosis.

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