Patient-reported outcome improvements at 24-month follow-up after fusion added to decompression for grade I degenerative lumbar spondylolisthesis: a multicenter study using the Quality Outcomes Database

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OBJECTIVE The ideal surgical management of grade I lumbar spondylolisthesis has not been determined despite extensive prior investigations. In this cohort study, the authors used data from the large, multicenter, prospectively collected Quality Outcomes Database to bridge the gap between the findings in previous randomized trials and those in a more heterogeneous population treated in a typical practice. The objective was to assess the difference in patient-reported outcomes among patients undergoing decompression alone or decompression plus fusion.

METHODS The primary outcome measure was change in 24-month Oswestry Disability Index (ODI) scores. The minimal clinically important difference (MCID) in ODI score change and 30% change in ODI score at 24 months were also evaluated. After adjusting for patient-specific and clinical factors, multivariable linear and logistic regressions were employed to evaluate the impact of fusion on outcomes. To account for differences in age, sex, body mass index, and baseline listhesis, a sensitivity analysis was performed using propensity score analysis to match patients undergoing decompression only with those undergoing decompression and fusion.

RESULTS In total, 608 patients who had grade I lumbar spondylolisthesis were identified (85.5% with at least 24 months of follow-up); 140 (23.0%) underwent decompression alone and 468 (77.0%) underwent decompression and fusion. The 24-month change in ODI score was significantly greater in the fusion plus decompression group than in the decompression-only group (-25.8 ± 20.0 vs -15.2 ± 19.8 , $p < 0.001$). Fusion remained independently associated with 24-month ODI score change ($B = -7.05$, 95% CI -10.70 to -3.39 , $p \leq 0.001$) in multivariable regression analysis, as well as with achieving the MCID for the ODI score (OR 1.767, 95% CI 1.058–2.944, $p = 0.029$) and 30% change in ODI score

ABBREVIATIONS MCID = minimal clinically important difference; NASS = North American Spine Society; NRS = numeric rating scale; ODI = Oswestry Disability Index; PRO = patient-reported outcome; QOD = Quality Outcomes Database; SLIP = Spinal Laminectomy Versus Instrumented Pedicle Screw; SPORT = Spine Patient Outcomes Research Trial.

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(OR 2.371, 95% CI 1.286–4.371, $p = 0.005$). Propensity score analysis resulted in 94 patients in the decompression-only group matched 1 to 1 with 94 patients in the fusion group. The addition of fusion to decompression remained a significant predictor of 24-month change in the ODI score ($B = 2.796$, 95% CI 2.228–13.275, $p = 0.006$) and of achieving the 24-month MCID ODI score (OR 2.898, 95% CI 1.214–6.914, $p = 0.016$) and 24-month 30% change in ODI score (OR 2.300, 95% CI 1.014–5.216, $p = 0.046$).

CONCLUSIONS These results suggest that decompression plus fusion in patients with grade I lumbar spondylolisthesis may be associated with superior outcomes at 24 months compared with decompression alone, both in reduction of disability and in achieving clinically meaningful improvement. Longer-term follow-up is warranted to assess whether this effect is sustained.

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LUMBAR spondylolisthesis remains a significant source of disability, affecting millions of individuals worldwide.¹ Although hundreds of studies have been published on the optimal management of lumbar spondylolisthesis, significant attention has been captured by three randomized controlled trials with disparate conclusions. The first, published in 2007, the Spine Patient Outcomes Research Trial (SPORT), compared operative and nonoperative management for spondylolisthesis.² In the as-treated cohort, significantly greater benefits were found in patients undergoing surgical intervention compared with those managed nonsurgically,² a result that has remained durable well past the original 2-year follow-up.^{3,4} The vast majority of surgical patients in the SPORT study (> 90%) underwent fusion procedures, leaving unanswered the question of what is the optimal surgical approach for the management of spondylolisthesis.

Two papers, published simultaneously in 2016, attempted to resolve the debate regarding whether treatment with decompression alone or with decompression plus fusion is more effective for spondylolisthesis. In a study by Försth et al.,⁵ patients diagnosed with lumbar stenosis with or without spondylolisthesis were randomized to decompression alone or decompression plus fusion, and the investigators found no difference between groups at 2 and 5 years for the primary outcome, i.e., change in Oswestry Disability Index (ODI) scores. In contrast, in the Spinal Laminectomy Versus Instrumented Pedicle Screw (SLIP) study,⁶ patients with stable spondylolisthesis were randomized to decompression alone or decompression plus fusion. The investigators found a significantly greater improvement in SF-36 physical component scores at 3 and 4 years in the fusion group. Numerous editorials have posited explanations for these conflicting results,^{7–9} with particular focus on the populations studied, the heterogeneity of diagnoses and operative techniques, and the differences in primary outcome measures. Because of the highly focused inclusion criteria of these randomized studies, significant ambiguity remains when selecting an operative strategy for patients with spondylolisthesis.

In an effort to bridge the gap between the findings of these randomized trials and the more heterogeneous populations treated in typical practices, we used the Quality Outcomes Database (QOD) to analyze 24-month patient-reported outcome (PRO) measures for surgical decompression alone versus decompression plus fusion for pa-

tients with grade I spondylolisthesis at 12 sites. The QOD is an initiative to collect high-quality, prospective data across various neurosurgical conditions to allow for assessment and improvement of patient outcomes.

Methods

Institutional review board approval was obtained at each site for data gathering as part of the QOD, with a waiver of informed consent. Shared data from the QOD were de-identified by each site.

Patient Identification

The methodological framework for this study has previously been described in our group's analysis of 12-month outcomes.¹⁰ Briefly, the QOD lumbar spine module contains aggregated data from > 100 sites nationwide and includes > 80 demographic, surgical, clinical, and outcome variables for each patient. For this study, data from 12 of the highest-enrolling QOD sites were analyzed. Selected patients included all those undergoing surgical intervention between July 1, 2014, and June 30, 2016, for a diagnosis of Meyerding¹¹ grade I lumbar spondylolisthesis, which was confirmed at each site by preoperative imaging. All included patients underwent surgery at the level of spondylolisthesis. Decompression-only patients received intervention at the index disc level (e.g., L3 or L3–4 laminectomy), whereas patients in the fusion group also received a single-level fusion (e.g., L3–4 posterior fusion).

Demographic, Clinical, and Surgical Variables

QOD data were collected for the following demographic variables: age, sex, ethnicity, BMI, smoking status, insurance type, education level, employment status, and the presence or absence of various comorbid conditions. Clinical variables for which data were collected included each patient's dominant symptom, motor function, ambulation status, and symptom duration. Surgical variable data included surgery type (decompression alone versus decompression and fusion) and whether the surgery was performed in a minimally invasive fashion (defined as any operation involving minimally invasive laminectomy, pedicle screw placement, or interbody graft placement).

Outcomes

Outcome data are also included in the QOD lumbar

spine module. The primary outcome selected for this study was the 24-month change in ODI scores compared with baseline values. For the patients who lacked 24-month follow-up but had 36-month follow-up, the values obtained at that time were used instead. Secondary outcomes included 24-month change in EQ-5D and changes in numeric rating scale (NRS) back and leg pain scores compared with baseline values. Patient satisfaction values at 24 months were also assessed using the North American Spine Society (NASS) satisfaction questionnaire, which grades satisfaction from 1 (surgery met my expectations) to 4 (I am the same or worse as compared with before surgery). In addition, the number of patients who reached a minimal clinically important difference (MCID) of improvement in ODI score was analyzed, with MCID defined as an improvement of 12.8.¹⁰ Finally, we also analyzed factors associated with 30% change in ODI score at 24 months to account for baseline differences in ODI scores.^{11,12} PRO data included in the QOD were obtained through the use of validated questionnaires, and final scores were audited for accuracy before analysis. Select perioperative outcomes were also recorded from the QOD, including intraoperative blood loss, operative time, length of stay, and discharge disposition.

Rates of reoperation were assessed for all patients at 24 months. The reason for reoperation was recorded in each instance and evaluated by the authors to assess whether the reoperation was related to the index surgery (e.g., repositioning of hardware placed during index operation) or not (e.g., abdominal hernia repair). Readmission and reason for readmission within 90 days were also tracked, with determination by the authors regarding whether each readmission was related to the index surgery or not. Finally, complications within 30 days, defined as the occurrence of deep venous thrombosis/pulmonary embolism, new neurological deficit, myocardial infarction, urinary tract infection, superficial surgical site infection, surgical hematoma, stroke, dural tear, or pneumonia, were documented for each patient. The data were audited to ensure accuracy.

Radiographic Follow-Up

Patients enrolled in the study had follow-up imaging at the discretion of the individual surgeon. Imaging obtained at baseline and the 12- and 24-month follow-ups was uploaded to a centralized database; images included MRI scans and static plain radiographs. Some patients also had flexion/extension plain radiographs and/or full 36-inch scoliosis films at the discretion of the treating surgeon. All images were evaluated by an independent radiologist not affiliated with any of the QOD sites enrolled for this study.

Statistical Analysis

Descriptive statistics are reported as mean values with standard deviations or as frequencies with percentages as appropriate. Statistical analyses were performed with the unpaired Student t-test for continuous variables and the Pearson chi-square test with Yates' correction as needed for categorical variables. Multivariable linear regression models were fitted for 24-month ODI score improvement and for factors associated with reaching the 24-month

MCID for the ODI score; for each model, all covariates with a $p < 0.20$ on univariate analysis were included. Sensitivity analyses were also performed by matching the two groups using propensity scoring on baseline listhesis (measured in millimeters). All probability values were 2-tailed, with $p < 0.05$ considered significant. Statistical analyses were performed using SPSS version 20.0 (IBM Corp.).

Results

Patient Population

During the study period, 608 patients across the 12 sites underwent surgical intervention for grade I spondylolisthesis. Of these, 140 (23.0%) underwent decompression alone (Fig. 1, illustrative case), whereas 468 (77.0%) underwent decompression and fusion (Fig. 2, illustrative case). At least 24 months of follow-up was achieved in 85.5% of patients, of which data for 67 patients were from the 36-month follow-up. Univariate analyses of demographic, clinical, surgical, and baseline PRO variables are presented in Table 1.

The decompression-only group tended to be older, to have more male patients and a lower BMI, and to have a higher likelihood of comorbid conditions, including diabetes and coronary artery disease. As well, they were more likely to have a motor deficit on presentation and longer symptom duration, yet they had less severe baseline pain, disability, and quality-of-life scores (Table 1). Over 50% of the patients in the cohort had spondylolisthesis at the L4–5 level. However, spondylolisthesis was more prevalent at L3–4 and L5–S1 in patients in the fusion group and at L4–5 in the decompression-alone group ($p = 0.000$; Table 2).

Operative-Perioperative Outcomes

Patients who underwent fusion plus decompression had higher estimated blood loss than patients who underwent decompression alone (224.5 ± 208.9 vs 57.5 ± 86.2 ml, $p < 0.001$; Table 3), as well as longer operative time (193.2 ± 83.1 vs 108.7 ± 57.8 minutes, $p < 0.001$). Patients in the fusion plus decompression group also had longer hospitalizations (3.2 ± 1.6 vs 1.2 ± 1.5 days, $p < 0.001$) but were equally likely to be discharged to home as those in the decompression-only group (90.0% vs 90.7%, $p = 0.793$).

Patient-Reported Outcomes

ODI Scores

Baseline ODI scores for the fusion group were significantly higher than those for the decompression-only group (48.8 ± 16.4 vs 39.7 ± 18.0 , $p < 0.001$), indicating that the fusion group was doing more poorly at baseline. At 24 months, both groups had large reductions in ODI scores, with similar scores between the two cohorts (22.4 ± 20.2 vs 22.9 ± 19.2 , $p = 0.828$). The reduction in ODI score for the fusion group was significantly larger at 24 months than that for the decompression-only group (-25.8 ± 20.0 vs -15.2 ± 19.8 , $p < 0.001$; Table 3). ODI score improvements reaching the MCID at 24 months occurred at a significantly higher rate in the fusion group than the decompression-only group (73.3% vs 56.0%, $p \leq 0.001$). Additionally, the

FIG. 1. Decompression-only case illustration. This 61-year-old man presented with several months of low-back and bilateral posterior leg pain. His legs were constantly numb, and the pain was aggravated by standing or walking. Sitting and lying down relieved the pain somewhat. Steroid medication helped relieve his symptoms. Dynamic radiographs (**A and B**) demonstrate grade I spondylolisthesis (L3–4). Sagittal (**C**) and axial (**D**) T2-weighted MRI scans demonstrate a right-sided synovial cyst resulting in severe central canal stenosis and neural foraminal narrowing.

percentage improvement in disability was higher in the fusion group (53.4% vs 34.5%, $p = 0.001$).

In our multivariable linear regression model for factors associated with achieving 24-month ODI score improvement (Table 4), fusion remained an independent predictor ($B = -7.046$, 95% CI -10.699 to -3.393 , $p \leq 0.001$). Other independent predictors of greater improvement in disability (ODI score) included older age, lower BMI, minimally invasive surgical approach, higher education level, active employment or on leave at the time of surgery, and higher baseline EQ-5D and ODI scores.

In our multivariable logistic regression model for factors associated with achieving the 24-month ODI MCID (Table 4), fusion was independently associated with a greater chance of reaching MCID (OR 1.767, 95% CI 1.058–2.944, $p = 0.029$). Other independent predictors of meeting MCID for the ODI score at 24 months includ-

ed active employment or on leave at the time of surgery, minimally invasive surgical approach, and higher baseline ODI score and EQ-5D.

In our multivariable logistic regression model for factors associated with achieving a 24-month 30% change in ODI score (Table 4), fusion was associated with significantly higher odds than decompression alone (OR 2.371, 95% CI 1.286–4.371, $p = 0.005$). Other independent factors included coronary artery disease (OR 3.627, 95% CI 1.223–10.752, $p = 0.020$), 4 years of college education (OR 1.65, 95% CI 1.001–2.710, $p = 0.049$), and higher baseline ODI score (OR 2.210, 95% CI 1.363–3.583, $p = 0.001$).

Sensitivity Analysis

We also performed sensitivity analysis in the form of a matched analysis of the two groups. Propensity score matching was performed using age, sex, BMI, and base-

FIG. 2. Decompression and fusion illustrative case. A 62-year-old woman presented with 2 years of progressively worsening leg pain and back pain that was worse with walking and standing but relieved with leaning forward. Sitting also initially helped the pain, but prolonged sitting made her right leg pain worse. She did not gain significant improvement with conservative management, including medication, physical therapy, or injections. Dynamic radiographs (**A and B**) demonstrate grade I spondylolisthesis (L4–5). Sagittal (**C**) and axial (**D**) T2-weighted MRI scans demonstrate bilateral facet arthropathy with right-sided synovial cyst resulting in severe central, right lateral recess and right foraminal stenosis.

line listhesis. A total of 94 patients in the decompression-only group were matched 1 to 1 with 94 patients in the fusion group (Table 5). Using the matched cohort, multivariable analysis revealed that fusion plus decompression remained a significant factor in predicting 24-month change in ODI score ($B = 2.796$, 95% CI 2.228–13.275, $p = 0.006$) and in achieving the 24-month MCID ODI score (OR 2.898, 95% CI 1.214–6.914, $p = 0.016$) and 24-month 30% change in ODI score (OR 2.300, 95% CI 1.014–5.216, $p = 0.046$).

NRS Back Pain Scores

Baseline NRS back pain scores for the fusion group were significantly higher than those for the decompression-only group (7.1 ± 2.5 vs 5.5 ± 3.3 , $p < 0.001$). At 24 months, the groups had similar NRS back pain scores (3.4

± 3.1 vs 3.3 ± 2.9 , $p = 0.901$), indicating a significantly higher degree of improvement in back pain for the fusion group (-3.8 ± 3.1 vs -1.8 ± 3.9 , $p < 0.001$).

NRS Leg Pain Scores

Baseline NRS leg pain scores for the fusion group were similar to those for the decompression-only group (6.6 ± 2.8 vs 6.3 ± 2.9 , $p = 0.244$). At 24 months, the groups had similar NRS leg pain scores (2.7 ± 3.2 vs 2.5 ± 3.1 , $p = 0.546$) and comparable degrees of improvement (-3.8 ± 3.9 vs -3.7 ± 3.6 , $p = 0.784$).

EQ-5D Scores

Baseline EQ-5D values for the fusion group were significantly lower than those for the decompression-only group (0.52 ± 0.23 vs 0.59 ± 0.21 , $p = 0.001$), whereas

TABLE 1. Characteristics of patients undergoing surgery for grade I lumbar spondylolisthesis

Characteristic	Decompression Alone	Decompression & Fusion	p Value
No. of patients	140 (23.0%)	468 (77.0%)	
Age, yrs	69.6 ± 11.5	59.9 ± 11.3	<0.001*
Female	66 (47.1%)	284 (60.7%)	0.004*
BMI	28.7 ± 5.4	30.9 ± 6.6	<0.001*
Active smoking	15 (10.7%)	56 (12.0%)	0.686
Diabetes mellitus	32 (22.9%)	69 (14.7%)	0.024*
Coronary artery disease	22 (15.7%)	46 (9.8%)	0.053
Anxiety	20 (14.3%)	88 (18.8%)	0.220
Depression	18 (12.9%)	105 (22.4%)	0.013*
Osteoporosis	9 (6.4%)	29 (6.2%)	0.921
Insurance type			<0.001*
Private	55 (39.3%)	264 (56.4%)	
Medicare/Medicaid/VA/uninsured	85 (60.7%)	204 (43.6%)	
Dominant symptom			<0.001*
Back pain dominant	36 (25.7%)	194 (41.5%)	
Leg pain dominant	66 (47.1%)	65 (13.9%)	
Back pain = leg pain	38 (27.1%)	209 (44.7%)	
Motor deficit at presentation	47 (33.6%)	92 (19.7%)	0.001*
Ambulation status			0.046*
Independent	117 (83.6%)	420 (89.7%)	
Symptom duration, mos			0.002*
<3	9 (6.4%)	6 (1.3%)	
≥3	128 (91.4%)	443 (94.7%)	
ASA grade			0.159
1 or 2	89 (63.6%)	257 (54.9%)	
3 or 4	49 (35.0%)	188 (40.2%)	
Ethnicity: Hispanic or Latino	3 (2.1%)	26 (5.6%)	0.096
Education level			0.002*
≥4 yrs college	68 (48.6%)	161 (34.4%)	
Employment status			0.003*
Employed & currently working or on leave	48 (34.3%)	227 (48.5%)	
MIS	72 (51.4%)	187 (40.0%)	0.016*
Baseline score measure			
ODI	39.7 ± 18.0	48.8 ± 16.4	<0.001*
NRS back pain	5.5 ± 3.3	7.1 ± 2.5	<0.001*
NRS leg pain	6.3 ± 2.9	6.6 ± 2.8	0.244
EQ-5D	0.59 ± 0.21	0.52 ± 0.23	0.001*

ASA = American Society of Anesthesiologists; MIS = minimally invasive surgery; VA = Veterans Affairs.

Values are presented as number (%) of patients or mean ± SD unless otherwise indicated. Values that do not add up to 100% indicate missing data/unknown response.

* Significant (p < 0.05).

24-month values were similar (0.75 ± 0.22 vs 0.78 ± 0.18 , $p = 0.178$). Although the 24-month improvement in EQ-5D appeared to be greater in the fusion group compared with the decompression-only group, the difference was not statistically significant (0.22 ± 0.24 vs 0.17 ± 0.25 , $p = 0.054$).

NASS Satisfaction Scores

The 24-month NASS satisfaction scores were similar between the fusion and decompression-only groups (over-

all $p = 0.338$; Table 3). Most patients in both groups felt that surgery met their expectations (63.4% and 55.4%, respectively), and of those who did not, a preponderance would still elect to have surgery again if given the choice (19.7% and 23.2%, respectively).

Reoperations, Readmissions, and Complications

Overall rates of reoperation were not significantly different between the fusion and decompression-only groups

TABLE 2. Level of listhesis by treatment strategy

Spine Level	Decompression Alone (n = 140)	Decompression & Fusion (n = 468)
L1–2	1 (0.7%)	2 (0.4%)
L2–3	2 (1.4%)	5 (1.1%)
L3–4	18 (12.9%)	37 (7.9%)
L4–5	102 (72.9%)	308 (65.8%)
L5–S1	15 (10.7%)	115 (24.6%)
L3–4, L4–5	2 (1.4%)	0 (0.0%)
L4–5, L5–S1	0 (0.0%)	1 (0.2%)

Values are presented as number (%) of patients.

(10.5% vs 10.0%, $p = 0.872$; Table 6), nor were rates of reoperation related to the index surgery (6.2% vs 9.3%, $p = 0.206$). Total 90-day readmission rates were also similar in each cohort (3.8% vs 3.6%, $p = 0.881$), as were 90-day readmission rates related to the index surgery (2.6% vs 2.1%, $p = 0.593$). The incidence of 30-day complications was also not significantly different between the two groups (7.1% vs 4.3%, $p = 0.241$). The reasons for readmission within 90 days for the decompression-only group were recurrent disc herniation ($n = 2$) or acute worsening of acute radiculopathy and dorsiflexion weakness ($n = 1$), whereas the reasons in the fusion group were wound infection ($n = 7$), radiculopathy ($n = 3$), CSF leak/pseudomeningocele (n

$= 1$), and endplate collapse ($n = 1$). Repeat decompression-only was the most common reoperation related to the index surgery in the decompression-only group ($n = 7$), with revision decompression with fusion occurring in nearly as many patients ($n = 6$). Revision for adjacent-segment disease was most commonly performed in the fusion group ($n = 9$); other reasons for reoperation in this group were incision and drainage for wound infection ($n = 6$), removal of instrumentation (with or without reinstrumentation; $n = 4$), and repeat surgery ($n = 4$), with 14 other less frequent causes. The most common complications within 30 days were urinary tract infection ($n = 3$) and durotomy ($n = 2$) in the decompression-only group and wound infection ($n = 10$) and durotomy ($n = 9$) in the fusion group.

Imaging Findings

Baseline imaging, including MRI, static radiographs, and dynamic radiographs, were available for 487, 391, and 281 patients, respectively. At the 12-month follow-up, static and dynamic radiographs were available for 21.4% and 13.6% of patients in the decompression-only group and 77.1% and 26.5% of patients in the fusion group, respectively. At the 24-month follow-up, static and dynamic radiographs were available for 37.1% and 30.7% of patients in the decompression-only group and 54.5% and 36.8% of those in the fusion group.

At baseline on static radiographs, patients in the decompression-only group had less anterolisthesis than those in the fusion group (5.3 vs 6.9 mm, $p = 0.001$). This differ-

TABLE 3. Perioperative and patient-reported outcomes for patients undergoing surgery for grade I lumbar spondylolisthesis

Outcome	Decompression Alone	Decompression & Fusion	p Value
Estimated blood loss, ml	57.5 ± 86.2	224.5 ± 208.9	<0.001*
Op time, mins	108.7 ± 57.8	193.2 ± 83.1	<0.001*
Length of hospitalization, days	1.2 ± 1.5	3.2 ± 1.6	<0.001*
Discharge disposition			0.793
Home/home health services	127 (90.7%)	421 (90.0%)	
Other	13 (9.3%)	47 (10.0%)	
24-mo outcome measure			
ODI score	22.9 ± 19.2	22.4 ± 20.2	0.828
ODI score change	-15.2 ± 19.8	-25.8 ± 20.0	<0.001*
NRS back pain score	3.3 ± 2.9	3.4 ± 3.1	0.901
NRS back pain score change	-1.8 ± 3.9	-3.8 ± 3.1	<0.001*
NRS leg pain score	2.5 ± 3.1	2.7 ± 3.2	0.546
NRS leg pain score change	-3.7 ± 3.6	-3.8 ± 3.9	0.784
EQ-5D score	0.78 ± 0.18	0.75 ± 0.22	0.178
EQ-5D score change	0.17 ± 0.25	0.22 ± 0.24	0.054
NASS satisfaction score	n = 112	n = 391	0.338
1 (surgery met my expectations)	62 (55.4%)	248 (63.4%)	
2 (I didn't improve as much as I had hoped, but would have same surgery for same results)	26 (23.2%)	77 (19.7%)	
3 (surgery helped but I wouldn't have same surgery for same results)	12 (10.7%)	26 (6.6%)	
4 (I am the same or worse after surgery)	12 (10.7%)	40 (10.2%)	

Values are presented as number (%) of patients or mean ± SD unless otherwise indicated.

* Significant ($p < 0.05$).

TABLE 4. Multivariable linear regression model for factors independently predictive of outcome

Variable	ODI Score at 24-Mo Outcome					
	Improvement		MCID		30% Change	
	B (95% CI)	p Value	OR (95% CI)	p Value	OR (95% CI)	p Value
Addition of fusion to procedure	-7.046 (-10.699 to -3.393)	<0.001	1.767 (1.058–2.944)	0.029	2.371 (1.286–4.371)	0.005
Age, yrs	-0.165 (-0.315 to -0.015)	0.031				
BMI	0.295 (0.054–0.535)	0.017				
MIS	-3.353 (-6.132 to -0.573)	0.018	1.700 (1.123–2.599)	0.013		
Education (≥4 yrs)	-4.328 (-7.267 to -1.389)	0.004			1.65 (1.001–2.710)	0.049
Employment (active or on leave)	-4.042 (-7.261 to -0.823)	0.014	1.747 (1.075–2.861)	0.025		
Baseline ODI score	-0.634 (-0.746 to -0.523)	<0.001	1.060 (1.042–1.080)	<0.001	2.210 (1.363–3.583)	0.001
Baseline EQ-5D score	-9.194 (-17.36 to -1.027)	0.027	3.820 (1.115–13.381)	0.034		
Coronary artery disease					3.627 (1.223–10.752)	0.020

Model adjusted for variables reaching $p < 0.20$ on univariate comparisons. These included the addition of fusion, age, sex, insurance type, ASA grade, diabetes mellitus, coronary artery disease, depression, dominant presenting symptom, motor deficit at presentation, ambulation status, symptom duration, BMI, ethnicity, education level, employment status, use of MIS techniques, and baseline NRS back pain, ODI, and EQ-5D scores.

ence was not seen at either follow-up time point (12-month follow-up: 4.8 vs 4.6 mm, $p = 0.811$; 24-month follow-up: 4.7 vs 4.5 mm, $p = 0.681$). As determined by motion on dynamic imaging, there was no difference in the rates of instability at baseline between the two groups (30% vs 33.5%, $p < 0.610$). Arthrodesis occurred in 199 patients in the fusion group at 12 months (95.2% of patients with sufficient imaging to determine arthrodesis in the fusion group vs 64.7% in the decompression-only group). By 24 months, 247 patients in the fusion group had achieved arthrodesis (96.1% of patients with sufficient imaging to determine arthrodesis vs 55.6% in the decompression-only group).

Discussion

In this prospectively collected cohort of over 600 patients undergoing surgery for grade I degenerative lumbar spondylolisthesis, participants in both cohorts experienced improvements in all surveyed PRO measures at 24 months of follow-up. Those who underwent fusion plus decompression had significantly greater improvements in ODI score and NRS back pain scores compared with those who received decompression alone. Our multivariable model suggests that the addition of fusion is independently as-

sociated with greater improvements in ODI scores at 24 months. The rate of achieving the MCID for ODI scores was significantly greater in patients who had fusion, with a rate of reaching the MCID at 24 months that was > 17% higher than the rate with decompression alone.

Our group has previously published the 12-month outcome data from the QOD lumbar spondylolisthesis initiative,¹³ and the present study represents a continuation of this ongoing study. The 24-month data demonstrate further separation between the decompression-only and fusion cohorts at the 2-year mark, with a greater magnitude of improvement in scores for both ODI and NRS back pain with the addition of fusion to decompression and a higher rate of achieving a clinically meaningful change in ODI score. This difference is likely multifactorial. The addition of nearly 200 patients to the study cohort with the expansion of our inclusion dates gave additional power to the study, providing the amount of data needed to evaluate more moderate outcome variations between the two groups. The 24-month follow-up duration is also likely more appropriate for our study questions, allowing time for differences in patient responses to interventions to emerge, especially given the differences in 1- and 2-year outcomes seen in prior investigations such as SLIP.⁶

Our study found more dramatic differences between

TABLE 5. Sensitivity analysis using propensity score to match the two groups

	Before Matching			After Matching		
	Decompression Alone (n = 140)	Decompression & Fusion (n = 468)	p Value	Decompression Alone (n = 94)	Decompression & Fusion (n = 94)	p Value
Age, yrs			<0.001			0.999
>65	97 (69.3%)	173 (37.0%)		63 (67.0%)	63 (67.0%)	
≤65	43 (30.7%)	295 (63.0%)		31 (33.0%)	31 (33.0%)	
BMI	28.735 ± 5.380	30.912 ± 6.551	<0.001	28.362 ± 5.194	27.618 ± 5.564	0.34
Female	66 (47.1%)	284 (60.7%)	0.004	43 (45.7%)	55 (58.5%)	0.08
Baseline listhesis, mm	5.107 ± 3.018	6.370 ± 3.134	<0.001	5.223 ± 2.963	5.415 ± 2.776	0.19

Values are presented as number (%) of patients or mean ± SD unless otherwise indicated. Boldface type indicates statistical significance.

TABLE 6. Rates of 2-year reoperation, 90-day readmission, and 30-day complications

Variable	Decompression Alone (n = 140)	Decompression & Fusion (n = 468)	p Value
2-yr return to operating room			
Any cause	14 (10.0%)	49 (10.5%)	0.872
Related to index surgery	13 (9.3%)	29 (6.2%)	0.206
90-day readmission			
Any cause	5 (3.6%)	18 (3.8%)	0.881
Related to index surgery	3 (2.1%)	12 (2.6%)	0.593
30-day complication	6 (4.3%)	33 (7.1%)	0.241

Values are presented as number (%) of patients unless otherwise indicated.

decompression alone and decompression and fusion than either the Swedish study by Försth et al.⁵ or the SLIP trial⁶ at 24 months. Although the registry-based design of our study is inevitably more vulnerable to selection bias than a well-designed randomized controlled trial, our protocol has several advantages. The first is the number of patients and centers available for inclusion in our analysis; our cohort contained nearly twice as many patients and as many centers, across a variety of geographic locations and practice types, as the SLIP and Swedish studies combined. In our study, the less stringent inclusion criteria (e.g., inclusion of mobile spondylolisthesis, higher American Society of Anesthesiologists physical classification status) also more closely mirror the average spondylolisthesis patient presenting to a surgeon in a clinic, thus expanding the generalizability of the results across real-world practices. It is for reasons such as these, in addition to the prohibitive cost and difficulty of conducting high-quality randomized studies, that prospective registry-based investigations are becoming more prevalent and vital to the comparison of interventions and continued evolution of defining value in healthcare.¹³

Our study has several limitations. As described above, the study design inherently increases its vulnerability to bias and, most importantly, our inability to control for unknown potential confounding variables. In particular, we did not assess the baseline images (MRI scans or radiographs) for additional potential confounding variables, including sagittal and coronal plane deformities. Although the breadth of our included practice types likely makes our study more generalizable, it also allows for heterogeneity in surgical technique and patient selection. Although this heterogeneity is accounted for in the adjusted analysis, the patients in our two groups were dissimilar in several ways, including age, BMI, and symptomatology, which must be taken into account in any interpretation of our results. Although baseline PRO values differed between the two patient groups, this is likely a reflection of experienced surgeons recognizing the need for a specific management strategy in certain subsets of patients on the basis of their clinical and radiographic presentation. Efforts such as the ongoing SLIP II study (clinicaltrials.gov identifier NCT03570801) are needed to better identify and codify these variables. As with any registry-based study, the possibility of data entry inaccuracy influencing our findings is present but is likely mitigated by the standardized nature

of data entry within the QOD and our independent auditing of the analyzed data set.

Conclusions

In this cohort of patients undergoing surgical intervention for grade I lumbar spondylolisthesis, those receiving fusion in addition to decompression had significantly greater improvements in ODI score and NRS back pain and were more likely to reach the MCID for the ODI score at 24 months than those receiving decompression alone. There was no statistical difference in complications, readmissions, or reoperations between groups.

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Author Contributions

Conception and design: all authors. Acquisition of data: all authors. Analysis and interpretation of data: all authors. Drafting the article: Bisson, Guan, Mummaneni. Critically revising the article: all authors. Reviewed submitted version of manuscript: Bisson, Guan, Mummaneni. Approved the final version of the manuscript on behalf of all authors: Bisson. Statistical analysis: Bisson, Guan, Mummaneni.

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