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Risks Factors For Reoperation in Patients Treated Surgically for Degenerative Spondylolisthesis: A subanalysis of the 8 year data from the SPORT trial

Michael C. Gerling, MD¹, Dante Leven, DO^{1,2}, Peter G. Passias, MD¹, Virgnie Lafage, PhD¹, Kristina Bianco, BA¹, Alexandra Lee, BSN¹, Tamara S. Morgan, MA^{3,4}, Jon D. Lurie, MD, MS^{3,4}, Tor D. Tosteson, ScD^{3,4}, Wenyan Zhao, PhD^{3,4}, Kevin F. Spratt, PhD^{3,4}, Kristen Radcliff, MD⁵, and Thomas J. Errico, MD¹

¹Department of Orthopaedic Surgery, New York University Langone Medical Center, New York, NY

²State University of New York, Downstate Medical Center, Brooklyn, NY

³Geisel School of Medicine at Dartmouth, Dartmouth College, Hanover, NH

⁴The Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College, Lebanon, NH

⁵Rothman Institute of Thomas Jefferson University, Philadelphia, PA

Abstract

Study Design—Retrospective analysis of prospective data from the degenerative spondylolisthesis (DS) arm of the Spine Patient Outcomes Research Trial.

Objective—To identify risk factors for reoperation in patients treated surgically for DS and compare outcomes between patients who underwent reoperation with non-reoperative patients.

Summary of Background Data—Several studies have examined outcomes following surgery for DS, but few have identified risk factors for reoperation.

Method—Analysis included patients with neurogenic claudication (>12 weeks), clinical neurological signs, spinal stenosis, and DS on standing lateral x-rays. Univariate and multivariate analyses were used to investigate patient characteristics and risk factors. Treatment effects (TE) were calculated and compared between study groups.

Results—Of 406 patients, 72% underwent instrumented fusion, 21% non-instrumented fusion, and 7% decompression alone. At 8 years, the reoperation rate was 22%, of which 28% occurred within one year, 54% within 2 years, 70% within 4 years, and 86% within 6 years. The reasons for reoperation included recurrent stenosis or progressive spondylolisthesis (45%), complications such as hematoma, dehiscence, or infection (36%), or new condition (14%). Re-operative patients were younger (62.2 vs 65.3, $p=0.008$). Significant risk factors were use of antidepressants ($p=0.008$, HR 2.08) or having no neurogenic claudication upon enrollment ($p=0.02$, HR 1.82). Patients who were smokers, diabetics, obese, or on workman's compensation were not at greater risk for reoperation.

At eight year follow-up, scores for SF-36 bodily pain (BP), ODI, and stenosis frequency index were better in non-re-operative patients. TE favored non-re-operative patients for SF-36 BP, physical function, ODI, stenosis bothersomeness index and satisfaction with symptoms ($p<0.001$).

Conclusion—The incidence of reoperation for patients with DS was 22% eight years following surgery. Patients with a history of no neurogenic claudication and patients taking antidepressants were more likely to undergo reoperation. Outcomes scores and TE were more favorable in non-re-operative patients.

Keywords

Lumbar; degenerative spondylolisthesis; Spine patient outcomes research trial (SPORT); reoperation; surgery

INTRODUCTION

Degenerative spondylolisthesis (DS) is an acquired anterior displacement of one vertebrae over another most commonly occurring in patients over 50 years old. [1–3] This vertebral slip may produce various symptoms including back pain and neurogenic claudication. [1, 2, 4, 5] Several well-designed, prospective studies support surgical intervention for patients with severe, unremitting symptoms after conservative treatment. [1, 2, 4–7] In the early 1990's, Herkowitz showed significantly favorable outcomes in patients undergoing decompression with arthrodesis versus decompression alone.[8] Surgical decompression with arthrodesis has now become the mainstay of treatment for patients with symptomatic DS. [1, 2, 4–6] Several high quality studies have examined patient outcomes, complications and costs following DS surgery, but few have identified consistent risk factors for reoperation. [1, 2, 4–6]

Although there are several known patient factors, including obesity, depression, and diabetes, which are predictors of poor outcome of treatment of degenerative spondylolisthesis, risk factors for reoperation are less well studied. The current literature shows a marked variance in reoperation rates for the treatment of DS, ranging from 5%–35%.[1, 6, 9] Several factors contribute to the variability in reoperation rates: hospital and geographic variables; surgeon experience; surgical technique; and patient risk factors. [2, 4, 5, 10, 11] There are many potential risk factors, though few have been supported by a large prospective study.

The Spine Patient Outcomes Research Trial (SPORT) is a large, multicenter, prospective study with strict inclusion criteria across three arms: intervertebral disc herniation, degenerative spondylolisthesis (DS) and spinal stenosis. The purpose of this study was to perform a sub-analysis of the eight-year SPORT data to determine baseline risk factors for and outcomes of reoperation in patients treated surgically for DS.

METHODS

This study was a sub-group analysis of data from the SPORT trial. Enrollment began in March of 2000 and ended in February 2005.

Patient Population

The SPORT trial is a multicenter study carried out among 13 institutions in 11 states across the United States. Patients diagnosed with DS were enrolled in the observational or randomized groups and underwent either surgical or nonsurgical treatment. Data was collected at 6 weeks, 3, 6, and 12 months, and then yearly to 8 years post enrollment.

Inclusion criteria were symptoms of spinal stenosis for at least 12 weeks plus a confirmatory imaging study (CT or MRI) showing spinal stenosis on cross-sectional imaging, and DS on standing lateral radiographs of L3/4 or L4/5. Exclusion criteria were prior lumbar spine surgery; isthmic spondylolisthesis; cauda equina syndrome; scoliosis greater than 15 degrees; vertebral fractures; infection or tumor; inflammatory spondyloarthropathy; pregnancy; or medical contraindications for surgery.

Study Intervention

The protocol surgery was a standard posterior decompressive laminectomy, with or without bilateral single-level fusion with or without posterior pedicle-screw instrumentation. Nonsurgical protocol included at least active physical therapy, education or counseling, home exercises, and NSAIDs if tolerated with additional treatments individualized to patient need. "Reoperation" included any surgical treatment performed in the lumbar spine either at or adjacent to the level of the index procedure.

Study Measures

Primary endpoints were the Medical Outcomes Study 36-Item Short-Form General Health Survey bodily pain and physical function scores (SF 36 BP and PF), as well as Oswestry Disability Index, American Academy of Orthopaedic Surgeons/Modems version (ODI). Secondary outcomes included patient reported self-improvement, Stenosis Bothersomeness Index (SBI), satisfaction with current symptoms and care, and work status.

Patient characteristics included age, gender, work lift demand, race, education, marital status, work status, compensation, body mass index (BMI), and smoking status. Assessed co-morbidities included hypertension, diabetes, osteoporosis, depression, heart problems, stomach problems, bowel or intestinal problems, depression, joint problems, and "other". Additional candidate variables included duration of symptoms, patient's self-assessment of health, patient satisfaction with symptoms, expectation of being pain-free with surgery or non-operative treatment, opioid use, injections, physical therapy, antidepressant use, NSAID's, missed work, and low back pain severity.

Operative outcomes included procedure (decompression only, non-instrumented fusion, instrumented fusion), multi-level fusion, levels decompressed, operative time, blood loss, blood replacement, length of hospital stay, and complications. Intraoperative complications included dural tear or spinal fluid leak, nerve root injury, or other. Post-operative complications were measured up to 8 weeks post-operatively and included nerve root injury, wound hematoma, or other post-operative complications. Reasons for reoperation were defined by categories including progressive spondylolisthesis, recurrent stenosis, complications, or other. The operative outcomes were analyzed for the reoperation versus no

reoperation group, as well as for the non-instrumented fusion versus instrumented fusion groups.

Statistical Considerations

We performed a subgroup analysis of surgically treated patients, including both randomized and observational cohorts, stratified into two groups: reoperation or no reoperation. Baseline characteristics, operative factors, complications, and medical events were compared between the two groups using chi-square tests for categorical variables and t-tests for continuous variables. A Cox's proportional hazards model was used to analyze the risk factors for reoperation. Variables that were significant at the $p < 0.10$ level were candidates for inclusion in the final multivariable regression model. Final selection for the model was done using the stepwise method, removing variables that did not maintain $p < 0.05$. Age and gender were forced into the model. Primary outcomes analyses compared the reoperation and no reoperation groups using changes from baseline at each follow-up, with a mixed-effects longitudinal regression model including a random individual effect to account for correlation between repeated measurements within individuals. The analyses were adjusted for age, sex, race, work status, body mass index, neuroforaminal involvement, depression, joint problem, stomach problem, reflex deficit, number of moderately or severely stenotic levels, other comorbidities, baseline scores (for SF-36, ODI, SBI), and center. Across the eight years of follow-up, overall comparisons of "area under the curve" between groups were performed using a Wald test. Computations were performed using SAS procedure PROC MIXED for continuous data and PROC GENMOD for binary outcome (SAS version 9.2, SAS Institute Inc., Cary, NC). Statistical significance was defined as $p < 0.05$ based on a two-sided hypothesis test with no adjustments made for multiple comparisons.

RESULTS

Patient characteristics

Overall, 607 of 892 eligible participants were enrolled into the study; 304 in the randomized cohort and 303 in the observational cohort (Figure 1). Of these, 601 completed at least one follow-up visit. A total of 406 surgery patients were available at 8 years post enrollment, constituting 69% of the randomized and 57% of the observational participants.

Univariate analysis revealed patients who had undergone a reoperation by 8 years were younger than those without a reoperation (62.2 vs. 65.3 years, $p=0.008$). Patients who had a reoperation were less likely to have neurogenic claudication at baseline (73% vs. 89%, $p<0.002$). There were no significant differences in other demographic variables or specific comorbidities (Table 1). Patients who underwent a reoperation had worse SF-36 BP (28.1 vs. 32.6, $p=0.044$), ODI (47.0 vs. 43.1, $p=0.048$), and Stenosis Frequency Index scores (15.8 vs. 14.3, $p=0.021$) at baseline.

Operative outcomes

Univariate analysis revealed patients in the reoperation group had a higher incidence of total post-operative complications following the index surgery (39% vs. 27%, $p=0.036$). However, there were no significant differences in wound hematoma rate, infection rate, neurological

injury, or dural tear between the reoperation and non-reoperation groups. There were no significant differences in other operative outcomes measures including type of operation, operative time, blood loss, length of hospital stay, or incidence of intra-operative complications (Table 2).

When comparing all patients included in the study, the non-instrumented fusion group had a higher rate of decompression at L2-L3 (20% vs. 10%, $p=0.014$) and L3-L4 (61% vs. 46%, $p=0.022$) than the instrumented fusion group. The non-instrumented fusion group had a significantly shorter operative time (157.6 vs. 226.6 min., $p<0.001$), less blood loss (506.5 vs. 632.2, $p=0.031$), and a lower rate of intra-operative blood replacement (27% vs. 38%, $p=0.062$) than the instrumented fusion group (Table 3). There was no significant difference in the rate of wound hematoma, neurological injury, or infection between instrumented and non-instrumented cases.

Surgical treatment

Of the 406 surgery patients, 72% underwent instrumented fusion, 21% non-instrumented fusion, and 7% underwent decompression alone; 97 underwent a multi-level fusion (24%). At eight-year follow-up, 91/406 (22%) had a reoperation. Of these patients, 25 occurred within the first year (28%), 49 within 2 years (54%), 64 within 4 years (70%), and 78 within 6 years (86%) (Table 1; Figure 1). The reasons for reoperation included recurrent stenosis or progressive spondylolisthesis (45%), complications such as hematoma, dehiscence, or infection (Complete list in Table 3) (36%), and the development of a new condition (14%).

Patient reported outcomes

Patient reported outcomes at 8 years were compared between the reoperation and no reoperation groups. For both primary and secondary outcomes (including SF-36 BP, SF-36 PF, ODI, SBI, and satisfaction with symptoms), patients in the reoperation group had significantly less improvement, represented by mean change in scores from baseline to eight-year follow up, (Table 4; Figure 2).

Risk Factors for reoperation

Multivariate regression analysis using all of the baseline demographic variables in Table 1 showed that age ($p=0.018$, HR 0.97); patients with 2/3 moderate or severe stenotic levels ($p=0.02$, HR 1.71); predominant back pain ($p=0.023$, HR 2.09); no physical therapy ($p=0.017$, HR 1.74); absence of neurogenic claudication ($p=0.019$, HR 1.89); and greater leg pain score at baseline ($p=0.003$, HR 1.39) predicted higher reoperation rates (Table 5). Factors that did not affect the risk for reoperation included: smoking, diabetes, obesity, longer duration of symptoms, or workman's compensation.

Of the patients who underwent reoperation, 80 of 91 patients had complete information available on reoperation levels. 18/80 (22.5%) had a reoperation at the same level as the index operation, 40/80 (50%) had a reoperation at at least one different level than the index operation, and 37/80 (46%) had levels unspecified. Of these 80 patients, 13 patients had two reoperations and one had three reoperations (data not shown).

Multivariate analysis was used to further investigate the demographic risk factors for reoperation for patients who received non-instrumented fusion or instrumented fusion. Using all of the demographic factors in Table 1, in the non-instrumented fusion group, patients without neurogenic claudication were more likely to undergo reoperation ($p=0.0034$, HR 7.12), as were patients of older age ($p=0.009$, HR 0.92). In the instrumented fusion group, patients without neurogenic claudication ($p=0.0098$, HR 2.16) and those with a higher baseline SBI score ($p=0.0161$, HR 1.06) were more likely to undergo reoperation (data not shown).

DISCUSSION

This study performed a sub-analysis of the eight-year SPORT data to determine baseline risk factors for reoperation in patients treated surgically for DS, and compare outcomes with patients that did not undergo reoperation. Several similar studies have been limited by small demographic groups, homogenous cohorts, or by retrospective analysis. [7, 10–13] This is the first subanalysis of its kind using SPORT data.

The incidence of reoperation for patients treated surgically for DS was 22% at eight years, with 54% of these occurring in the first two years. The most common indication for reoperation was progressive spondylolisthesis or recurrent stenosis (45%). These findings are consistent with several reports in the literature with similar patient demographics. [1–3, 5, 7, 10, 11, 13]

Previously reported risk factors for adjacent segment disease and radiographic degeneration after lumbar fusion include age, [10, 11, 13] number of levels fused, [9, 10, 12] preexisting disc degeneration, [14, 15] smoking, [16] body mass index, [11] and preexisting facet degeneration. [8] The strongest baseline positive predictors for reoperation in this study were lack of neurogenic claudication and back pain predominant symptoms (HR = 1.89, HR = 2.09, respectively). Interestingly, demographic factors including smoking, obesity, diabetes, duration of symptoms, and workman's compensation were not associated with an increased risk of reoperation.[10] Similarly, surgical factors such as the type of surgery performed, blood loss, time of operation, intraoperative complications, level of fusion, and multi-level laminectomy were not associated with an increased risk for reoperation.

Compared to patients with neurogenic claudication, patients without neurogenic claudication who underwent fusion showed a higher risk for reoperation. They were seven times as likely to undergo reoperation with non-instrumented fusion and twice as likely to undergo reoperation after instrumented fusion. Further studies are needed to address this question but the findings suggest that fusion with instrumentation may result in fewer reoperations in patients without neurogenic claudication.

Patients who had a reoperation were more likely to have a history of antidepressant use (11% vs. 4%, $p<0.014$). However, depression itself was not a significant risk factor. Though other studies have identified the correlation between inferior outcomes and depression for patients undergoing lumbar spine surgery, they have not reported on outcomes in patients taking antidepressants without underlying depression. [1, 2, 8, 16, 17] This may indicate that

patients with DS on antidepressants for treatment of chronic pain are predisposed to worse clinical outcomes.

Contrary to prior studies, the overall use of instrumentation showed no significant difference in reoperation rates at 8 year follow up (21% versus 24%, $p = 0.51$) [1, 2, 5, 7, 11, 17] Also, rates of late complications requiring reoperation, (progressive spondylolisthesis, recurrent stenosis, pseudoarthrosis, wound exploration, or other complications) were not significantly different between these two groups ($p = 0.60$). This is contrary to several reports that suggest instrumented fusion may facilitate the development of complications such as adjacent segment disease that may require a reoperation. [9, 13, 17–20] [deletion]

In this analysis, there was a surprisingly low pseudoarthrosis reoperation rate (1–2%, Table 2) among the entire SPORT degenerative spondylolisthesis cohort who underwent fusion. However, patients in the SPORT trial were not routinely imaged during follow up, thus, pseudoarthrosis rates, particularly those that were asymptomatic, may be underreported. Kornblum et al noted that patients with a solid fusion have significantly better outcomes than patients who develop a pseudoarthrosis. [18] Subsequent papers have established no difference in outcome due to fusion technique or use of instrumentation. [17, 19] The discrepancy between the current study pseudoarthrosis rate and the historical pseudoarthrosis rate may lie in the fact that this represents the symptomatic pseudoarthrosis rate, which may be different from the radiographic pseudoarthrosis rate which was evaluated in previous studies. Similar to other studies, number of levels fused was not associated with increased risk of reoperation. [21]

The SF-36 BP and PF, ODI, SBI, and satisfaction with symptoms showed significantly greater improvement in the no reoperation group. These findings are consistent with other reports showing worse outcomes in patients requiring a reoperation.[7, 10, 11, 13] Although both groups of patients improved from baseline, our data indicate that reoperation may not be able to “rescue” the symptoms of an unsuccessful initial surgery.

Martin et al studied reoperation rates in a large retrospective study ($n = 24,882$) and found patients with spondylolisthesis had a lower reoperation rate after fusion surgery than after decompression alone (17.1% vs 28%, $p = 0.002$) [7, 13] In a similar study, Lad et al[14] found higher complication rates in patients undergoing arthrodesis compared with decompression alone (8.3% vs 4.8%; $p < 0.0001$). These findings were similar to our study, though both of these studies included heterogenous patient groups.

Limitations of our study: The drop-out rate with any long term study can also confound the study findings. Patients with worse outcomes may seek treatment elsewhere or not at all, and patients doing well following surgical or nonsurgical intervention may also be less likely to follow-up. Reasons for reoperation are unknown other than broad categories such as recurrent stenosis, progressive spondylolisthesis, infection, or pseudoarthrosis. We do not have information on the specific symptoms or findings that prompted reoperation. Another possible limitation of this study is limited sample size for sub-group analyses, which could limit the ability to identify a significant factor associated with reoperation. However, this study comprises one of the largest series in the literature on a pure population with

degenerative spondylolisthesis with good follow-up. Finally, radiographic parameters such as sagittal alignment and pseudarthrosis may influence the rate of adjacent and same segment disease,[21, 22] yet the limited available radiographic data precluded our ability to include these radiographic analyses.

CONCLUSION

Overall, this study demonstrated a modest reoperation rate of 22% at the 8-year follow-up for patients treated surgically in the DS arm of the SPORT trial. Reoperations were most commonly due to recurrent stenosis or progressive spondylolisthesis. The strongest predictors for reoperation were patients with predominant back pain symptoms and patients without neurogenic claudication at enrollment. As patients are guided through the shared decision making process, these risk factors and the understanding of patient specific outcomes can facilitate making the best decisions between physicians and patients. Future studies should involve larger prospective studies of patient subgroups with DS to improve the individualization of treatment in the clinical setting.

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Figure 1. Exclusion, Enrollment, Randomization and Follow-up of Trial Participants

The values for surgery, withdrawal, and death are cumulative over eight years. For example, a total of 8 patients died during the follow-up period. [Data set 09/03/13]

Table 1

Univariate analysis of baseline demographics, comorbidities, and health status measures for reoperation and no reoperation groups within the SPORT DS study.

	Had Reoperation (n=90)*	No Reoperation (n=319)	P Value
Mean Age (SD)	62.2 (10)	65.3 (10)	0.008
Female - no. (%)	66 (73%)	212 (66%)	0.27
Ethnicity: Not Hispanic [†]	88 (98%)	312 (98%)	0.70
Race - White	78 (87%)	274 (86%)	0.99
Education - At least some college	61 (68%)	217 (68%)	0.93
Marital Status - Married	59 (66%)	218 (68%)	0.71
Work Status			0.083
Full or part time	36 (40%)	115 (36%)	
Disabled	13 (14%)	24 (8%)	
Retired	29 (32%)	142 (45%)	
Other	12 (13%)	38 (12%)	
Compensation - Any [‡]	12 (13%)	24 (8%)	0.13
Mean Body Mass Index (BMI), (SD) [§]	29.8 (5.8)	29.2 (6.5)	0.37
Smoker	7 (8%)	28 (9%)	0.93
Comorbidities			
Hypertension	33 (37%)	146 (46%)	0.16
Diabetes	14 (16%)	39 (12%)	0.51
Osteoporosis	10 (11%)	35 (11%)	0.88
Heart Problem	12 (13%)	63 (20%)	0.22
Stomach Problem	22 (24%)	68 (21%)	0.63
Bowel or Intestinal Problem	9 (10%)	22 (7%)	0.45
Depression	19 (21%)	54 (17%)	0.45
Joint Problem	52 (58%)	178 (56%)	0.83
Other [¶]	43 (48%)	123 (39%)	0.15
Time since most recent episode > 2 years	17 (19%)	57 (18%)	0.95

	Had Reoperation (n=90)*	No Reoperation (n=319)	P Value
SF-36 scores, mean(SD)//			
Bodily Pain (BP)	28.1 (17.4)	32.6 (19.2)	0.044
Physical Functioning (PF)	29.3 (20.2)	32.7 (21.8)	0.19
Physical Component Summary (PCS)	28.2 (7.2)	29.1 (8.2)	0.40
Mental Component Summary (MCS)	48 (12.8)	50 (11.5)	0.17
Oswestry (ODI) **	47 (16)	43.1 (17)	0.048
Stenosis Frequency Index (0–24) ††	15.8 (5.3)	14.3 (5.5)	0.021
Stenosis Bothersome Index (0–24) ‡‡	16.1 (5.5)	15.1 (5.6)	0.16
Back Pain Bothersomeness scale §§	4.6 (1.7)	4.3 (1.8)	0.21
Leg Pain Bothersomeness scale ¶¶	4.9 (1.6)	4.6 (1.6)	0.11
Satisfaction with symptoms - very dissatisfied	73 (81%)	238 (75%)	0.26
Problem getting better or worse			0.59
Getting better	6 (7%)	16 (5%)	
Staying about the same	20 (22%)	85 (27%)	
Getting worse	64 (71%)	213 (67%)	
Treatment preference			0.49
Preference for non-surg	22 (24%)	76 (24%)	
Not sure	25 (28%)	71 (22%)	
Preference for surgery	43 (48%)	172 (54%)	
Neurogenic claudication - Any	68 (76%)	284 (89%)	0.002
SLR or Femoral Tension	15 (17%)	37 (12%)	0.27
Pain radiation - any	69 (77%)	250 (78%)	0.84
Any Neurological Deficit	41 (46%)	178 (56%)	0.11
Reflexes - Asymmetric Depressed	17 (19%)	90 (28%)	0.10
Sensory - Asymmetric Decrease	20 (22%)	95 (30%)	0.20
Motor - Asymmetric Weakness	19 (21%)	76 (24%)	0.69
Listhesis Level			0.92

	Had Reoperation (n=90)*	No Reoperation (n=319)	P Value
L3-L4	10 (11%)	32 (10%)	
L4-L5	80 (89%)	287 (90%)	
Stenosis Levels			
L2-L3	7 (8%)	28 (9%)	0.93
L3-L4	42 (47%)	121 (38%)	0.17
L4-L5	87 (97%)	307 (96%)	0.90
L5-S1	8 (9%)	26 (8%)	0.99
Stenotic Levels (Mod/Severe)			0.30
None	4 (4%)	9 (3%)	
One	51 (57%)	205 (64%)	
Two	31 (34%)	83 (26%)	
Three+	4 (4%)	22 (7%)	
Stenosis Locations			
Central	80 (89%)	296 (93%)	0.33
Lateral Recess	81 (90%)	294 (92%)	0.66
Neuroforamen	38 (42%)	131 (41%)	0.94
Stenosis Severity			0.39
Mild	4 (4%)	9 (3%)	
Moderate	36 (40%)	109 (34%)	
Severe	50 (56%)	201 (63%)	
Instability	11 (12%)	26 (8%)	0.33
Taking antidepressants	10 (11%)	12 (4%)	0.014

* Ninty one patients underwent reoperation within 8 years of index surgery. Of the 91 reoperation patients, 90 had at least one follow-up through 8 years and were included in the analysis along with the 319 no reoperation patients.

† Race or ethnic group was self-assessed. Whites and blacks could be either Hispanic or non-Hispanic.

‡ This category includes patients who were receiving or had applications pending for workers compensation, Social Security compensation, or other compensation.

§ The body-mass index is the weight in kilograms divided by the square of the height in meters.

¶ Other = problems related to stroke, cancer, fibromyalgia, CFS, PTSD, alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine or anxiety.

// The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.

*** The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms.

†† The Stenosis Frequency Index ranges from 0 to 24, with lower scores indicating less severe symptoms.

†† The Stenosis Bothersomeness Index ranges from 0 to 24, with lower scores indicating less severe symptoms.

§§ The Low Back Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms

¶¶ The Leg Pain Bothersomeness Scale ranges from 0 to 6, with lower scores indicating less severe symptoms.

Table 2

Operative treatments, complications, and events for reoperation versus no reoperation groups within the SPORT DS study.

	Had Reoperation (n=89)[*]	No Reoperation (n=317)	P Value
Procedure			0.38
Decompression only	9 (10%)	20 (6%)	
Non-instrumented fusion	20 (22%)	64 (20%)	
Instrumented fusion	60 (67%)	233 (74%)	
Multi-level fusion	26 (29%)	71 (22%)	0.23
Decompression level			
L2-L3	10 (11%)	39 (13%)	0.91
L3-L4	49 (56%)	149 (48%)	0.28
L4-L5	83 (94%)	306 (97%)	0.26
L5-S1	28 (32%)	89 (29%)	0.67
Levels decompressed			0.82
0	1 (1%)	3 (1%)	
1	33 (37%)	134 (42%)	
2	32 (36%)	110 (35%)	
3+	23 (26%)	70 (22%)	
Operation time, minutes (SD)	208.9 (86)	205.6 (82.8)	0.75
Blood loss, cc (SD)	570.2 (498.1)	577.8 (461.3)	0.89
Blood Replacement			
Intraoperative replacement	26 (30%)	108 (35%)	0.50
Post-operative transfusion	20 (23%)	62 (20%)	0.61
Length of hospital stay, days (SD)	4.9 (4.4)	4.6 (2.5)	0.35
Intraoperative complications [§]			
Dural tear/spinal fluid leak	6 (7%)	36 (11%)	0.29
Vascular injury	0 (0%)	1 (0%)	0.50
Other	2 (2%)	7 (2%)	0.70
None	81 (91%)	275 (87%)	0.37
Postoperative complications/events [¶]			
Nerve root injury	0 (0%)	1 (0%)	0.49
Wound dehiscence	1 (1%)	0 (0%)	0.49
Wound hematoma	0 (0%)	1 (0%)	0.49
Wound infection	3 (3%)	8 (3%)	0.93
Other	14 (16%)	23 (7%)	0.022
None	53 (61%)	230 (73%)	0.036

^{*} In total, 413 (195 RCT and 218 OBS) patients had surgery, surgical information was available for 89 reoperation patients and 317 no reoperation patients.

[§]None of the following were reported: aspiration, nerve root injury, operation at wrong level.

[¶]Any reported complications up to 8 weeks post operation. None of the following were reported: bone graft complication, CSF leak, paralysis, cauda equina injury, wound dehiscence, pseudarthrosis.

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Table 3

Operative outcomes for patients who received non-instrumented fusion versus instrumented fusion in the SPORT DS study.

	Non-Instrumented Fusion (n=84)	Instrumented Fusion (n=293)	P Value
Multi-level fusion	16 (19%)	81 (28%)	0.15
Decompression level			
L2-L3	17 (20%)	27 (10%)	0.014
L3-L4	51 (61%)	130 (46%)	0.022
L4-L5	81 (96%)	281 (97%)	0.89
L5-S1	31 (37%)	79 (28%)	0.13
Levels decompressed			0.015
0	0 (0%)	3 (1%)	
1	27 (32%)	129 (44%)	
2	28 (33%)	106 (36%)	
3+	29 (35%)	55 (19%)	
Operation time, minutes (SD)	157.6 (58.7)	226.6 (81.9)	<0.001
Blood loss, cc (SD)	506.5 (390.7)	632.2 (489.4)	0.031
Blood Replacement			
Intraoperative replacement	22 (27%)	111 (38%)	0.062
Post-operative transfusion	12 (14%)	68 (23%)	0.11
Length of hospital stay, days (SD)	4.3 (3.4)	5 (2.9)	0.06
Intraoperative complications [§]			
Dural tear/spinal fluid leak	9 (11%)	26 (9%)	0.76
Vascular injury	0 (0%)	1 (0%)	0.50
Other	3 (4%)	5 (2%)	0.54
None	72 (86%)	262 (89%)	0.45
Postoperative complications/events [¶]			
Nerve root injury	0 (0%)	1 (0%)	0.50
Wound dehiscence	0 (0%)	1 (0%)	0.50
Wound hematoma	0 (0%)	1 (0%)	0.50
Wound infection	5 (6%)	6 (2%)	0.13
Other	4 (5%)	31 (11%)	0.16
None	64 (77%)	194 (67%)	0.10
Additional spine surgeries within:			
1 yr	5 (6%)	17 (6%)	0.98
2 yr	12 (14%)	30 (10%)	0.33
3 yr	14 (17%)	37 (13%)	0.36
4 yr	15 (18%)	40 (14%)	0.36
5 yr	16 (19%)	43 (15%)	0.35

	Non-Instrumented Fusion (n=84)	Instrumented Fusion (n=293)	P Value
6 yr	18 (21%)	49 (17%)	0.34
7 yr	19 (23%)	56 (19%)	0.48
8 yr	20 (24%)	60 (21%)	0.51
Recurrent stenosis/progressive listhesis	9 (11%)	27 (10%)	
Pseudarthrosis/fusion exploration	1 (NE) *	5 (2%)	
Complication	10 (12%)	21 (7%)	
New condition	5 (6%)	7 (2%)	

[§]None of the following were reported: aspiration, nerve root injury, operation at wrong level.

[¶]Any reported complications up to 8 weeks post operation. None of the following were reported: bone graft complication, CSF leak, paralysis, cauda equina injury, wound dehiscence, pseudarthrosis.

* Not estimable

Table 4

Adjusted change in score and treatment effects over 8 years for primary and secondary outcomes for reoperation and no reoperation groups.

	Mean change in score compared with baseline		Treatment effect (95% CI)	P-value
	Had Reoperation (n=90)	No Reoperation (n=319)		
SF-36 Bodily Pain (BP) (SE) ^{††}	20.3 (1.9)	31.1 (1)	-10.8 (-15.1, -6.5)	<0.001
SF-36 Physical Function (PF) (SE) ^{††}	14.9 (2)	25.6 (1)	-10.7 (-15.2, -6.2)	<0.001
Oswestry Disability Index (ODI) (SE) [‡]	-15.3 (1.6)	-22.8 (0.8)	7.5 (3.9, 11.1)	<0.001
Sciatica Bothersomeness Index (SE) [§]	-7.2 (0.6)	-9 (0.3)	1.9 (0.6, 3.2)	0.004
Very/somewhat satisfied with symptoms	51.5%	62.9%	-11.5 (-20.3, -2.7)	0.01

Scores are adjusted for age, gender, race, work status, depression, BMI, any neuroforamen L or R, joint problem, stomach problem, reflex deficit, number of moderate/severe stenotic levels, other** comorbidity, baseline stenosis bothersomeness, baseline score (for SF-36 and ODI), and center.

^{††}The SF-36 scores range from 0 to 100, with higher score indicating less severe symptoms.

[‡]The Oswestry Disability Index ranges from 0 to 100, with lower scores indicating less severe symptoms.

[§]The Sciatica Bothersomeness index range from 0 to 24, with lower scores indicating less severe symptoms.

** Other comorbidities include: stroke, cancer, fibromyalgia, chronic fatigue syndrome (CFS), post-traumatic stress disorder (PTSD), alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, anxiety.

Table 5

Results of Cox proportional hazards model for variables predicting time to reoperation.

Variable	Estimate	P Value	Hazard Ratio (95% Confidence Interval)
Age	−0.026	0.018	0.97 (0.95–1)
Gender (Female vs Male)	0.194	0.430	1.21 (0.75–1.96)
Moderate or severe stenotic levels			
Two/Three+ vs None/One	0.538	0.020	1.71 (1.09–2.69)
Predominant back pain (Yes vs No)	0.738	0.023	2.09 (1.11–3.94)
Physical Therapy (No vs Yes)	0.552	0.017	1.74 (1.11–2.73)
Neurogenic claudication (None vs Any)	0.638	0.019	1.89 (1.11–3.23)
Leg pain bothersomeness scale	0.332	0.003	1.39 (1.12–1.73)

Candidate predictor variables:

age, gender, race, education, marital status, work status, BMI, smoking status, work lift demand, hypertension, diabetes, osteoporosis, depression, heart problem, joint problem, time since most recent episode, patient's self-assessment of health trend, patient dissatisfied with symptoms, expectation of free of pain with surgery, expectation of free of pain with nonoperative treatment, opioid use, injections, had physical therapy, taking antidepressants, taking NSAID, predominant back pain, low back pain bothersomeness scale, back pain bothersomeness scale, stenosis bothersomeness index, Oswestry disability index, bodily pain, physical function, mental component summary, physical component summary, neurogenic claudication, pain on straight-leg raising or femoral-nerve tension sign, dermatomal pain radiation, any neurologic deficit, asymmetric reflex depression, asymmetric sensory decrease, asymmetric motor weakness, moderate or severe stenotic levels, location of stenosis, and severity of stenosis, spinal instability