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Does Multilevel Lumbar Stenosis Lead to Poorer Outcomes? A Subanalysis of the SPORT Lumbar Stenosis Study

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Introduction

Lumbar spinal stenosis (SpS) is defined as narrowing or stricture of the spinal canal. In some patients, this compression becomes symptomatic; the classic presentation is that of bilateral neurogenic claudication defined as intermittent pain radiating to the buttocks/thigh and/or leg that is worse with prolonged standing, walking, or lumbar extension. However, many individuals remain asymptomatic, and radiographic findings do not necessarily correlate with clinical symptoms.[1,2] Lumbar SpS occurs with normal vertebral alignment; however, some patients also suffer from concomitant degenerative spondylolisthesis (DS). DS is defined as the forward slipping of one lumbar vertebra on another with an intact neural arch. Most DS affects the L4-5 level.[3,4] It commonly occurs in patients over the age of 50 and affects females 6 to 1.[5] DS is generally asymptomatic, but can be associated with symptomatic SpS and radiculopathy.[4]

When patients suffer from symptomatic SpS, irrespective of concomitant DS, treatment options include either surgical or non-operative measures. Outcome studies comparing surgical treatment to non-operative measures have been performed. The Maine Lumbar Spine Study demonstrated superior surgical outcomes at one and four years. At eight to ten year follow-up, low back pain relief, predominant symptom improvement, and satisfaction with current state were similar between the two groups. Leg pain relief and greater back-related functional status, however, favored surgical intervention.[6-8] Amundsen et al also reported a prospective study where after four years, excellent or fair results were found in 50% of the non-operative patients while excellent or fair results were found in 80% of surgical patients.[9] More importantly, predictors of who would benefit from surgery or non-operative measures have been elusive.

One potential predictive factor may be the number of stenotic levels. To date, no study has thoroughly compared the results of non-operative versus surgical options in patients with

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isolated one level SpS compared to multilevel SpS. Furthermore, no study has compared systematically if surgery and non-operative outcomes are superior for one level SpS with DS compared to multiple levels.

Recently, a multicenter randomized and observational trial, the Spine Patient Outcomes Research Trial (SPORT), compared surgical versus non-operative treatment for SpS without spondylolisthesis or scoliosis.[10] Although there was a high level of non-adherence in the randomized groups, this study demonstrated significantly more improvement with operative treatment in all primary outcomes than non-operative treatment when an as-treated analysis was performed. This benefit appeared at three months and remained significant out to two years.[10] In a separate study arm, the SPORT trial also examined patients with SpS and associated DS.[11] Similar to the SpS group, a high level of crossover was found. In an as-treated analysis, surgical treatment substantially demonstrated greater improvement in pain and function during the 2-year collecting period.[11]

In the current study, sub-analyses of SPORT for isolated SpS with normal vertebral alignment and SpS with associated DS were performed to determine the impact of multilevel SpS compared to single level disease on patients' baseline symptoms and clinical outcomes over time. These analyses represent the first clinical study comparing the presentation and treatment outcomes of one, two, and multilevel lumbar SpS in patients with and without associated DS.

Methods

Patient Population

Spinal Stenosis Group—At 13 spine clinics in the United States, 289 patients were enrolled in a randomized cohort, and 365 patients were enrolled in the observational cohort out of a total of 1091 patients eligible for enrollment. Each patient demonstrated a history of at least 12 weeks of symptoms and radiographically had confirmed SpS without DS or associated scoliosis. Treatment was either decompressive surgery or usual non-operative care defined by each institution. In total, 400 patients received surgery, and 254 remained in non-operative management. There was a total of 634 patients, each having had at least one follow-up through 2 years. Of these, 15 were excluded as they did not have data on the number of moderate/severe levels, leaving 619 patients in the current analysis.

Degenerative Spondylolisthesis Group—Patients who also had at least 12 weeks of symptoms and radiographic confirmation of SpS and with the addition of an associated DS were offered enrollment into the separate degenerative spondylolisthesis arm of SPORT. DS was diagnosed on standing lateral radiographs. Patients with isthmic spondylolisthesis were excluded. Patients with only one level of spondylolithesis were included. Treatment was either decompressive surgery with or without fusion or usual non-operative care. Overall, 607 of 892 eligible patients were enrolled; 304 patients were placed in the randomized cohort and 303 patients in the observational cohort.

Outcome Measures

The primary outcomes measures were the Bodily Pain and Physical Function scales of the Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36) and the modified Oswestry Disability Index at six weeks, three months, six months, one year, and two years. Secondary outcome measures included the SpS bothersomeness index, leg pain bothersomeness, low back pain bothersomeness, and patient satisfaction.

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Statistical Analysis

Primary analyses compared surgical and non-operative treatments 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. Because of the crossover, analyses were based on treatments actually received in the combined randomized and observational cohorts. In these as-treated analyses, the treatment indicator was a time-varying covariate, allowing for variable times of surgery. Times are measured from the beginning of treatment, i.e. the time of surgery for the surgical group and the time of enrollment for the non-operative group. Therefore, all changes from baseline prior to surgery were included in the estimates of the non-operative treatment effect. After surgery, changes were assigned to the surgical group with follow-up measured from the date of surgery. Repeated measures of outcomes were used as the dependent variables, and treatment received was included as a time-varying covariate. Adjustments were made for the time of surgery with respect to the original enrollment date so as to approximate the designated follow-up times. To adjust for potential confounding, baseline variables associated with missing data or treatment received were included as adjusting covariates in longitudinal regression models.[12] The outcomes were stratified by the number of stenotic levels and outcomes between these sub-groups were compared using a Wald test. Computations were done using SAS procedures PROC MIXED for continuous data and PROC GENMOD for binary and non-normal secondary outcomes (SAS version 9.1 Windows XP Pro, 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

Spinal Stenosis Group—Analysis of the demographics of patients with one, two, or three or more levels of SpS, demonstrated several differences (Table 1). Patients with three or more levels of SpS were significantly older and more likely to be male. They were somewhat more likely to report co-morbid hypertension and joint problems; they were more likely to report neurogenic claudication and less likely to have a radicular distribution of their pain. Single level SpS patients were more likely to smoke and suffer from depression. Work status did not differ between the groups nor did patient preference for mode of treatment. Radiographically, with increasing number of SpS levels, the likelihood that at least one level would be rated severe increased. The majority of patients with one level SpS had the L4-5 level involved, two levels L3-5, and three levels L2-5.

Degenerative Spondylolisthesis Group—Similar to the SpS group, patients with multilevel SpS and DS were older, somewhat more likely to be male, less likely to smoke, and demonstrated more evidence of pseudoclaudication and less radiating pain. In contrast, however, in the DS cohort, multilevel SpS patients were more likely to be retired and clinically demonstrate asymmetric reflexes. Furthermore, no differences were found in medical comorbidities. Radiographically, the most common level of SpS was at L4-5; multilevel SpS patients demonstrated severe radiographic signs of SpS similar to the SpS cohort (Table 1).

Baseline Symptoms

Spinal Stenosis Group—Patients with three or more levels of SpS had somewhat less severe pain at baseline on the SF-36 bodily pain scale compared to one and two levels. (Table 1). Patients with single level SpS were less likely to present with neurogenic claudication ($p<0.001$) and more likely to dermatomal pain radiation ($p=0.04$). Other baseline symptoms were similar across groups.

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Degenerative Spondylolisthesis Group—Patients did not demonstrate any statistical difference in baseline pain or disability scores (Table 1). Similar to the SpS group, those with single level stenosis were less likely to present with neurogenic claudication (p=0.03) and more likely to have dermatomal pain radiation (p=0.04). Patients with multilevel had a somewhat higher incidence of neurologic defects at baseline (p=0.04). Other baseline symptoms were similar across groups.

Surgical procedures

Spinal Stenosis Group—Overall, few patient underwent fusion in addition to their laminectomy and less so with increasing levels involved. With three or more levels of SpS, there were fewer instrumented fusions performed (2% compared to 9% for one level) and no multilevel fusions compared to 5% in those with one or two levels. Operative time and intra-operative blood loss increased with increasing levels involved. Complications however did not differ significantly nor did the rate of reoperations (Table 2). Mortality was extremely low and did not differ between subgroups.

Degenerative Spondylolisthesis Group—In comparison to the SpS group, the majority of patients in the spondylolisthesis group underwent a fusion with a trend toward non-instrumented fusion for increasing levels of SpS. Operative time did not differ significantly; however, blood loss increased with more levels. There was an overall trend towards more complications in the subgroup with multilevel stenosis as well (Table 2).

Outcomes

Spinal Stenosis group—For all outcome measures, there were no differences in non-operative outcomes when comparing one, two, or three or more level SpS at all time points except patient satisfaction at two years. More patients with one level SpS were satisfied with their symptoms than were patients with two or more levels. Interestingly, this difference was not seen at one year or in the percent of patients reporting major improvement at either one or two years (Table 3).

Surgical outcomes did not differ significantly at the various time points when comparing one, two, or three level isolated SpS. The SF-36 physical function score was significantly better in the multilevel SpS group only at the one year assessment. This difference was not seen at three months or two years, or in any of the other measures (Table 3).

When comparing surgical to non-operative treatments for one, two, or three level isolated SpS, there was a significant surgical treatment effect in most outcomes measures within each subgroup at each time point (Table 3). The only significant difference in treatment effects between subgroups was at two years for patient satisfaction with symptoms. Patients with single level SpS had a smaller difference in satisfaction between surgery and non-operative treatment (i.e. a smaller treatment effect) than the other two groups.

Degenerative Spondylolisthesis Group—For the majority of outcome measures, there was no difference in non-operative outcomes when comparing one or multiple level SpS with concomitant DS at the early time points. However, at two years, the SF-36 Bodily Pain and Physical Function scales, as well as the Oswestry Disability Index showed greater improvements in the single level patients compared to those with multilevel SpS. (Table 4).

The effect of multilevel involvement was even more pronounced in the surgical treatment group. The surgical outcomes were significantly better at 2 years in the single level patients compared to those with multilevel SpS for all primary outcome measures. Furthermore, SF-36

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bodily pain and Oswestry scores remained significant at all time points, and at one year the self rated progress was also greater in those with single level SpS (Table 4).

As in the SpS group, surgical treatments demonstrated significant treatment improvement over non-operative measures within each subgroup of DS patients (Table 4). The only significant difference in treatment effects between subgroups, however, was the low back pain bothersomeness at 2 years which showed a significantly greater advantage for surgery relative to non-operative treatment among patients with single level SpS compared with their multiple level counterparts. At three months, SF-36 bodily pain and Oswestry Disability Index showed a trend favoring a greater surgical treatment effect for single level patients compared to multilevel patients.

Discussion

SpS with and without associated degenerative spondylolisthesis is a common problem, and treatment choices are either non-operative modalities or surgical intervention. Various studies have compared these treatments choices,[6-9,13] the most recent being the SPORT study.[10,11] These studies demonstrated significant benefit from surgical intervention initially but a decline in benefit with time. In particular, the SPORT study demonstrated, in the as-treated analysis, the treatment effect for surgery was seen as early as 6 weeks, appeared to reach a maximum at 6 months, and persisted for 2 years. In comparison, the non-operative patients improved only moderately during the two-year period.[10,11] In this sub-analysis of SPORT data, multilevel SpS did not demonstrate worse baseline symptoms or worse treatment outcomes in isolated SpS; however, if concomitant DS existed, single level patients tended to improve more than multilevel patients, particularly with surgery.

Despite the hypothesis that multilevel SpS patients fair worse with non-operative treatment, this study did not find this to be true in patients with isolated SpS and normal alignment. Non-operative treatment ranged from bed rest, NSAIDS, analgesics, physical therapy, and oral corticosteroids. Non-operative treatment has been suggested to improve outcomes through improved lumbopelvic muscular stabilization enabling better maintenance of posterior pelvic tilt.[14] Improved cardiovascular conditioning has also been suggested as having a positive treatment effect.[14] If these theories are true, multilevel SpS should not inhibit a patient's ability to improve their symptomology. In Simotas et al, 49 patients underwent non-operative treatment.[14] At three years, nine of the 49 had surgical intervention and of the remaining 40 patients, two suffered significant motor deterioration, five worse, 12 no change, 11 mild improvement, and 12 sustained improvement. This study found a trend between worse outcomes and more levels of SpS using patient reported scales such as visual analog scales, Roland-Morris disability scale, and overall rating of anxiety and depression.[14] Importantly, the authors stated more patients needed to be analyzed to see if this conclusion is valid. Furthermore, this study population had a mixture of SpS cases with and without DS.[14] Those significant differences may have been due to the DS patients.

Contrary to Simotas et al, the other few studies that mention the effect of multilevel SpS and outcome do not demonstrate a difference in number of SpS levels and outcomes. These studies unfortunately included patients with and without DS. Amundsen et al stated patients with multilevel afflictions, treated surgically or non-operatively, did not have poorer outcome than those with single level SpS.[9] Yukawa et al demonstrated when operating in cases with single versus two level SpS, outcomes did not change as measured by the Oswestry disability index and a visual analog scale.[15] They suggest that multilevel SpS should not affect surgical outcome if each compressed level is adequately addressed at surgery.[15]

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Although this sub-analysis demonstrated no significant difference in surgical outcomes in patients with isolated SpS similar to previous published reports, patients with DS and multiple levels of SpS demonstrated worse outcomes for all primary and secondary outcome measurements at 2 years. This difference suggests that these two disease entities differ in clinically important ways. In the pathogenesis of DS, secondary degeneration of the facets, ligamentum flavum, and osteophytic spurs develop because of the subtle instability of the spondylolisthesis segment.[16,17] Compression of neural elements can be from both the slippage of the vertebral segment and secondary degeneration in contrast to only primary degenerative changes in isolated SpS patients. Previous reports may not have detected differences in DS patients as their studies were an admixture of isolated and DS patients.

In SPORT, clinical presentation of patients with varying levels of SpS did not differ substantially. It is known that many patients with radiographic SpS remain asymptomatic,[1,2] so it is not surprising that multilevel SpS irrespective of the presence or absence of DS does not predict a worse baseline score. Mariconda et al have reported, however, a correlation with higher levels of SpS and higher psychosocial occupational discomfort.[18] It is likely that patients present to the physicians office once a threshold of symptoms is met irrespectively of SpS degree. The correlation between severity of SpS and clinical symptoms awaits further study, but it is known there are many asymptomatic people with images consistent with SpS.[2]

The advantages of the SPORT study have been described in the original SPORT lumbar SpS study. In brief, the advantages include a multi-centered study, a large sample size, strict enrollment criteria, and use of multiple validated outcome scores. Although this study is a sub-group analysis of the original data, it is the first we are aware of that systematically compared independently outcomes for one, two, or multilevel SpS in patients with and without DS, which could influence patient outcome. Other studies included a mixed population.[6-8,13,15,19]

Limitations of this study include this being a secondary analysis and not the a priori hypothesis for which SPORT was designed and heterogeneity of nonsurgical treatments. The flexible non-operative treatments allowed individualization of the treatment protocol, and more accurately reflects the treatment in most community practices.

In summary, this study demonstrates that patients with SpS without associated DS or scoliosis can be managed non-operatively irrespective of the number of levels involved. If surgery is performed, the number of levels treated does not predict outcome. Overall, patients with multiple levels do as well as those with single level disease. Patients should be reassured that despite the severity of their SpS, they should not fear that they will get worse without surgery. In contrast, patients with DS and single level SpS do better surgically than their counterparts with additional stenotic levels. Non-operative treatment outcomes were also somewhat better in the single level patients with spondylolisthesis as compared to multilevel. This study emphasizes the importance of shared decision-making approach between the physician and patient when considering treatment for SpS.

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Table 1

Baseline demographic characteristics and comorbidities accroding to stenosis level

Baseline demographic characteristics, comorbidities and outcomes scores according to stenosis level for patients with isolated spinal stenosis and degenerative spondylolisthesis with stenosis.

	SPS				DS		
Characteristic	**1 level (n=234)**	**2 levels (n=241)**	**3/3+ levels (n=144)**	**p-value**	**1 level (n=351)**	**2/2+ levels (n=170)**	**p-value**
Mean Age (SD)	61.7 (12)	65.5 (10.8)	67.9 (11.4)	<0.001	64.5 (10.2)	70.2 (9.5)	<0.001
Female	115 (49%)	89 (37%)	40 (28%)	<0.001	252 (72%)	103 (61%)	0.013
Ethnicity - Not Hispanic†	223 (95%)	229 (95%)	139 (97%)	0.78	341 (97%)	166 (98%)	0.97
Race - White†	196 (84%)	199 (83%)	125 (87%)	0.54	292 (83%)	146 (86%)	0.51
Education - At least some college	148 (63%)	148 (61%)	94 (65%)	0.75	235 (67%)	104 (61%)	0.23
Marital Status - Married	168 (72%)	166 (69%)	100 (69%)	0.77	237 (68%)	109 (64%)	0.50
Work Status				0.25			0.022
Full or part time	92 (39%)	81 (34%)	38 (26%)		139 (40%)	46 (27%)	
Disabled	23 (10%)	22 (9%)	13 (9%)		30 (9%)	12 (7%)	
Retired	96 (41%)	114 (47%)	78 (54%)		142 (40%)	90 (53%)	
Other	23 (10%)	24 (10%)	15 (10%)		40 (11%)	22 (13%)	
Compensation - Any‡	17 (7%)	20 (8%)	9 (6%)	0.75	24 (7%)	10 (6%)	0.82
BMI(Mean Body Mass Index), (SD)§	29.1 (6)	29.7 (5.5)	30 (5.4)	0.29	29.2 (6)	29.3 (6.9)	0.90
Current Smoker	31 (13%)	20 (8%)	10 (7%)	0.08	37 (11%)	9 (5%)	0.07
Comorbidities							
Hypertension	93 (40%)	113 (47%)	75 (52%)	0.054	162 (46%)	81 (48%)	0.82
Diabetes	34 (15%)	34 (14%)	27 (19%)	0.43	47 (13%)	25 (15%)	0.79
Osteoporosis	24 (10%)	22 (9%)	14 (10%)	0.92	46 (13%)	15 (9%)	0.20
Heart Problem	54 (23%)	70 (29%)	39 (27%)	0.33	63 (18%)	42 (25%)	0.092
Stomach Problem	59 (25%)	47 (20%)	30 (21%)	0.30	78 (22%)	36 (21%)	0.87
Bowel or Intestinal Problem	30 (13%)	26 (11%)	26 (18%)	0.12	20 (6%)	16 (9%)	0.17
Depression	38 (16%)	17 (7%)	13 (9%)	0.004	64 (18%)	24 (14%)	0.29
Joint Problem	112 (48%)	133 (55%)	93 (65%)	0.006	198 (56%)	101 (59%)	0.58
Other¶	87 (37%)	78 (32%)	51 (35%)	0.54	138 (39%)	63 (37%)	0.69

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	SPS				DS		
Characteristic	**1 level (n=234)**	**2 levels (n=241)**	**3/3+ levels (n=144)**	**p-value**	**1 level (n=351)**	**2/2+ levels (n=170)**	**p-value**
Sympton Duration > 6 months	128 (55%)	139 (58%)	91 (63%)	0.27	209 (60%)	99 (58%)	0.85
SF-36 Bodily Pain (BP) (SD) //	30.7 (19.5)	34.2 (20.6)	36.7 (18.6)	0.012	33.7 (19.3)	33.5 (18.8)	0.91
SF-36 Physical Functioning (PF) (SD)//	33.7 (23.9)	35.2 (23.8)	35.6 (21.9)	0.68	35.3 (22.3)	32.5 (22.2)	0.18
Mental Component Summary (MCS) (SD)//	49.1 (12.3)	49.1 (11.7)	50 (11.9)	0.70	49.6 (11.5)	50.6 (11.2)	0.36
Oswestry Disability Index (ODI) (SD)**	43.5 (18.9)	42.6 (19.6)	40.8 (16)	0.39	41.1 (18)	41.6 (17.3)	0.80
Stenosis Frequency Index (0-24) (SD)††	13.7 (5.8)	14.1 (6.1)	14.1 (5.4)	0.70	13.9 (5.5)	14.4 (5.6)	0.31
Stenosis Bothersome Index (0-24) (SD)‡‡	14 (5.7)	14.7 (6)	14.5 (5.5)	0.43	14.5 (5.5)	15.1 (5.5)	0.25
Back Pain Bothersomeness (0-6) (SD)§§	4.1 (1.9)	4.2 (1.8)	3.9 (1.7)	0.17	4.2 (1.8)	4.2 (1.8)	0.85
Leg Pain Bothersomeness (0-6) (SD)¶¶	4.4 (1.7)	4.4 (1.7)	4.2 (1.6)	0.52	4.6 (1.6)	4.5 (1.7)	0.42
Very dissatisfied with symptoms	170 (73%)	160 (66%)	95 (66%)	0.25	245 (70%)	115 (68%)	0.69
Patient self-assessed health trend				0.67			0.67
Problem getting better	15 (6%)	20 (8%)	8 (6%)		23 (7%)	8 (5%)	
Problem staying about the same	72 (31%)	80 (33%)	44 (31%)		117 (33%)	53 (31%)	
Problem getting worse	146 (62%)	136 (56%)	91 (63%)		209 (60%)	104 (61%)	
Treatment preference				0.35			0.88
Definitely prefer non-surg	42 (18%)	50 (21%)	27 (19%)		75 (21%)	37 (22%)	
Probably prefer non-surg	37 (16%)	47 (20%)	17 (12%)		57 (16%)	28 (16%)	
Not sure	51 (22%)	39 (16%)	28 (19%)		85 (24%)	35 (21%)	
Probably prefer surgery	29 (12%)	37 (15%)	19 (13%)		36 (10%)	21 (12%)	
Definitely prefer surgery	75 (32%)	67 (28%)	53 (37%)		97 (28%)	49 (29%)	
Pseudoclaudication - Any	168 (72%)	206 (85%)	124 (86%)	<0.001	291 (83%)	154 (91%)	0.028
SLR or Femoral Tension Sign	58 (25%)	41 (17%)	25 (17%)	0.07	59 (17%)	19 (11%)	0.12
Pain radiation - any	191 (82%)	192 (80%)	102 (71%)	0.038	287 (82%)	125 (74%)	0.04
Any Neurological Deficit	130 (56%)	128 (53%)	82 (57%)	0.74	182 (52%)	105 (62%)	0.041
Reflexes - Asymmetric Depressed	59 (25%)	66 (27%)	38 (26%)	0.87	77 (22%)	51 (30%)	0.058
Sensory - Asymmetric Decrease	69 (29%)	68 (28%)	42 (29%)	0.95	102 (29%)	51 (30%)	0.91
Motor - Asymmetric Weakness	64 (27%)	71 (29%)	39 (27%)	0.84	78 (22%)	50 (29%)	0.093

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	SPS				DS		
Characteristic	**1 level (n=234)**	**2 levels (n=241)**	**3/3+ levels (n=144)**	**p-value**	**1 level (n=351)**	**2/2+ levels (n=170)**	**p-value**
Stenosis Levels							
L2-L3	12 (5%)	50 (21%)	114 (79%)	<0.001	4 (1%)	28 (16%)	<0.001
L3-L4	74 (32%)	197 (82%)	144 (100%)	<0.001	31 (9%)	148 (87%)	<0.001
L4-L5	197 (84%)	226 (94%)	144 (100%)	<0.001	349 (99%)	170 (100%)	0.82
L5-S1	37 (16%)	58 (24%)	75 (52%)	<0.001	10 (3%)	44 (26%)	<0.001
Stenosis Locations Central	184 (79%)	218 (90%)	137 (95%)	<0.001	324 (92%)	159 (94%)	0.75
Lateral Recess	170 (73%)	196 (81%)	126 (88%)	0.002	314 (89%)	159 (94%)	0.18
Neuroforamen	70 (30%)	81 (34%)	53 (37%)	0.37	138 (39%)	80 (47%)	0.11
Stenosis Severity				<0.001			<0.001
Moderate	152 (65%)	90 (37%)	40 (28%)		154 (44%)	35 (21%)	
Severe	82 (35%)	151 (63%)	104 (72%)		197 (56%)	135 (79%)	
Instability	0(0%)	0(0%)	0(0%)		25 (7%)	16 (9%)	0.46

† 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, 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, lung, fibromyalgia, chronic fatigue syndrome, post traumatic stress disorder, alcohol, drug dependency, liver, kidney, blood vessel, nervous system, migraine, anxiety.

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

** The Oswestry Disability Index ranges from 1 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 Bothersomness ranges from 0 to 6, with lower scores indicating less severe symptoms.

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

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Table 2

Operative treatments, complications and events accroding to stenosis level

Surgical data, complications, and events according to stenosis level for the isolated spinal stenosis and degenerative spondylolisthesis cohorts.

	SPS				DS		
Characteristic	**1 level (n=139)**	**2 levels (n=154)**	**3/3+ levels (n=95)**	**p-value**	**1 level (n=224)**	**2/2+ levels (n=104)**	**p-value**
Specific procedures				0.046			0.092
Decompression only	121 (88%)	134 (89%)	86 (91%)		9 (4%)	7 (7%)	
Non-instrumented fusion	3 (2%)	10 (7%)	7 (7%)		43 (19%)	29 (28%)	
Instrumented fusion	13 (9%)	7 (5%)	2 (2%)		172 (77%)	68 (65%)	
Multi-level fusion	7 (5%)	8 (5%)	0 (0%)	0.079	45 (20%)	30 (29%)	0.11
Decompression Level							
L2-L3	14 (10%)	54 (35%)	75 (79%)	<0.001	6 (3%)	26 (25%)	<0.001
L3-L4	55 (41%)	124 (81%)	91 (96%)	<0.001	61 (28%)	83 (80%)	<0.001
L4-L5	119 (89%)	143 (93%)	91 (96%)	0.12	223 (100%)	102 (98%)	0.49
L5-S1	39 (29%)	62 (41%)	48 (51%)	0.004	53 (24%)	42 (40%)	0.004
Levels decompresssed				<0.001			<0.001
None	5 (4%)	1 (1%)	0 (0%)		0 (0%)	0 (0%)	
One	68 (49%)	14 (9%)	3 (3%)		131 (58%)	12 (12%)	
Two	45 (32%)	65 (42%)	11 (12%)		69 (31%)	48 (46%)	
Three+	21 (15%)	74 (48%)	81 (85%)		24 (11%)	44 (42%)	
Operation time, minutes (SD)	114.9 (71.7)	128.8 (57.1)	146.2 (63.9)	0.001	208.4 (86.7)	204.8 (78)	0.72
Blood loss, cc(SD)	221 (444.1)	338.1 (384.6)	415.3 (381.3)	0.001	532.3 (393.7)	732.4 (605.6)	<0.001
Blood Replacement							
Intraoperative replacement	12 (9%)	19 (12%)	6 (6%)	0.25	74 (33%)	42 (40%)	0.26
Post-operative transfusion	7 (5%)	7 (5%)	5 (5%)	0.97	43 (19%)	24 (23%)	0.53
Length of hospital stay (SD)	2.8 (2.5)	5.7 (30)	3.6 (3)	0.40	6.4 (24.9)	4.8 (3.2)	0.52
Intraoperative complications[§]							
Dural tear/spinal fluid leak	8 (6%)	19 (12%)	9 (9%)	0.15	19 (8%)	14 (13%)	0.23
Vascular injury	0 (0%)	0 (0%)	0 (0%)		0 (0%)	1 (1%)	0.69
Other	1 (1%)	1 (1%)	1 (1%)	0.94	7 (3%)	2 (2%)	0.80

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	SPS				DS		
Characteristic	**1 level (n=139)**	**2 levels (n=154)**	**3/3+ levels (n=95)**	**p-value**	**1 level (n=224)**	**2/2+ levels (n=104)**	**p-value**
None	130 (94%)	133 (87%)	85 (89%)	0.17	199 (89%)	88 (85%)	0.37
Postoperative complications/events[¶]							
Nerve root injury	0 (0%)	0 (0%)	0 (0%)		0 (0%)	1 (1%)	0.70
Wound dehiscence	0 (0%)	0 (0%)	0 (0%)		1 (0%)	0 (0%)	0.70
Wound hematoma	1 (1%)	1 (1%)	2 (2%)	0.50	1 (0%)	0 (0%)	0.70
Wound Infection	4 (3%)	2 (1%)	1 (1%)	0.49	10 (5%)	1 (1%)	0.19
Other	5 (4%)	10 (7%)	6 (6%)	0.49	16 (7%)	15 (14%)	0.062
None	122 (88%)	134 (88%)	82 (86%)	0.88	157 (71%)	68 (65%)	0.40
Post-operative mortality (death within 6 weeks of surgery)	1‡ (0.7%)	0 (0%)	0 (0%)	0.41	1 (0.4%)	0 (0%)	0.69
Post-operative mortality (death within 3 months of surgery)	1‡ (0.7%)	0 (0%)	0 (0%)	0.41	1 (0.4%)	1 (1%)	0.84
Additional surgeries (1-year rate)[//]	6 (4%)	11 (7%)	3 (3%)	0.316	16 (7%)	5 (5%)	0.41
Additional surgeries (2-year rate)[//]	10 (7%)	15 (10%)	5 (5%)	0.402	24 (11%)	18 (17%)	0.127
Recurrent stenosis / progressive listhesis	4 (2.8%)	4 (2.6%)	2(2.1%)		4 (1.8%)	7 (6.8%)	
Pseudarthrosis / fusion exploration	0 (0%)	0 (0%)	0 (0%)		2 (0.9%)	1 (1%)	
Complication or Other	5 (3.5%)	9 (5.9%)	0 (0%)		17 (7.6%)	5 (4.9%)	
New condition	1 (0.7%)	3 (2%)	2(2.1%)		2 (0.9%)	3 (2.9%)	

[§]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, pseudarthrosis.

[//]One- and two year post-surgical re-operation rates are Kaplan Meier estimates and p-values are based on log-rank test.

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Table 3

Subgroup results from common adjusting covariates* as-treated outcome analysis by number of levels with moderate or severe stenosis for the randomized and observational SPS cohorts combined

Analysis results from adjusted as-treated outcome analysis by number of levels with moderate or severe stenosis for the randomized and observational cohort for patients with isolated spinal stenosis.

SPS cohort		3-Months			1-Year			2-Year		
Outcomes	**Stenosis Level**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**
SF-36 Bodily Pain (BP) (0-100) (SE)†	One	31 (2)	13.2 (2.1)	17.8 (12.8, 22.9)	29.6 (2.2)	16.8 (2.4)	12.8 (7, 18.6)	28.6 (2.1)	17.3 (2.5)	11.2 (5.2, 17.3)
	Two	27.9 (1.9)	12 (2)	15.9 (11, 20.8)	27.6 (2.1)	11.5 (2.4)	16.1 (10.3, 21.9)	27.9 (2.1)	12.8 (2.5)	15.1 (9, 21.1)
	Three+	30.5 (2.5)	15 (2.9)	15.5 (8.8, 22.3)	33.8 (2.5)	16.4 (3.2)	17.4 (9.8, 25.1)	28.7 (2.5)	13.9 (3.4)	14.7 (6.9, 22.6)
	pvalue	*0.49*	*0.69*	*0.81*	*0.16*	*0.23*	*0.58*	*0.96*	*0.43*	*0.63*
SF-36 Physical Function (PF) (0-100) (SE)†	One	25.3 (1.9)	11.7 (2)	13.7 (9, 18.3)	26.4 (2.1)	12.9 (2.2)	13.5 (8.1, 18.9)	23 (2)	13.7 (2.4)	9.3 (3.7, 15)
	Two	22.7 (1.8)	8.1 (1.9)	14.6 (10, 19.1)	23.2 (2)	9.3 (2.2)	13.9 (8.6, 19.3)	21.5 (2)	10.5 (2.4)	11 (5.4, 16.6)
	Three+	26.8 (2.4)	10.5 (2.7)	16.4 (10.1, 22.6)	30.6 (2.4)	9.4 (3.1)	21.3 (14.1, 28.4)	25.2 (2.4)	10.4 (3.2)	14.7 (7.4, 22.1)
	pvalue	*0.34*	*0.42*	*0.79*	*0.057*	*0.47*	*0.18*	*0.48*	*0.59*	*0.51*
Mental Component Summary (MCS) (0-100) (SE)†	One	3.9 (0.8)	2.2 (0.9)	1.7 (-0.5, 3.8)	2.8 (0.9)	2.6 (1)	0.2 (-2.2, 2.7)	2.8 (0.9)	1.5 (1)	1.3 (-1.3, 3.9)
	Two	4 (0.8)	1.5 (0.8)	2.5 (0.4, 4.6)	3.6 (0.9)	1.2 (1)	2.4 (-0.1, 4.8)	4 (0.9)	1.7 (1)	2.2 (-0.3, 4.8)
	Three+	4.2 (1)	2.4 (1.2)	1.8 (-1.1, 4.6)	5.1 (1)	3.5 (1.3)	1.6 (-1.6, 4.8)	4.7 (1)	-0.4 (1.4)	5.1 (1.8, 8.4)
	pvalue	*0.98*	*0.79*	*0.84*	*0.27*	*0.34*	*0.46*	*0.35*	*0.43*	*0.19*
Oswestry Disability Index (ODI) (0-100) (SE)‡	One	-20.6 (1.6)	-8.9 (1.6)	-11.7 (-15.5, -7.9)	-19.9 (1.7)	-10.6 (1.8)	-9.3 (-13.7, -4.9)	-19.8 (1.6)	-10.4 (1.9)	-9.4 (-14, -4.8)
	Two	-21.3 (1.5)	-5.1 (1.6)	-16.2 (-19.9, -12.5)	-20.6 (1.6)	-7.4 (1.8)	-13.2 (-17.6, -8.8)	-20.2 (1.6)	-9.4 (1.9)	-10.7 (-15.3, -6.2)
	Three+	-22.4 (1.9)	-9.6 (2.2)	-12.8 (-17.9, -7.7)	-24.4 (2)	-8.4 (2.5)	-16 (-21.8, -10.2)	-21.9 (1.9)	-6.3 (2.6)	-15.7 (-21.6, -9.7)
	pvalue	*0.78*	*0.12*	*0.21*	*0.19*	*0.46*	*0.17*	*0.68*	*0.45*	*0.25*
Stenosis Frequency Index (0-24) (SE)§	One	-7.7 (0.7)	-3.3 (0.6)	-4.4 (-6, -2.8)	-7.3 (0.6)	-3.8 (0.6)	-3.4 (-5, -1.8)	-6.9 (0.6)	-4.4 (0.7)	-2.6 (-4.3, -0.9)
	Two	-7.5 (0.7)	-2 (0.6)	-5.5 (-7.2, -3.8)	-7 (0.6)	-2.9 (0.6)	-4.1 (-5.7, -2.5)	-7.3 (0.6)	-3.9 (0.7)	-3.3 (-5.1, -1.6)
	Three+	-8.6 (0.8)	-3.5 (0.8)	-5 (-7.2, -2.9)	-8.3 (0.7)	-4.1 (0.9)	-4.2 (-6.3, -2.1)	-7.4 (0.7)	-2.8 (0.9)	-4.6 (-6.8, -2.4)
	pvalue	*0.60*	*0.13*	*0.65*	*0.30*	*0.43*	*0.79*	*0.85*	*0.43*	*0.35*

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SPS cohort		3-Months			1-Year			2-Year		
Outcomes	**Stenosis Level**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**
Stenosis Bothersomeness Index (0-24) (SE) §	One	-8.4 (0.7)	-3.4 (0.6)	-4.9 (-6.6, -3.3)	-8.2 (0.6)	-4 (0.6)	-4.2 (-5.8, -2.6)	-7.4 (0.6)	-4.5 (0.7)	-2.8 (-4.5,-1.1)
	Two	-8.5 (0.7)	-2.2 (0.6)	-6.3 (-8, -4.5)	-7.7 (0.6)	-3.7 (0.7)	-4.1 (-5.7, -2.4)	-8.1 (0.6)	-4.3 (0.7)	-3.7 (-5.5, -2)
	Three+	-8.9 (0.8)	-3.2 (0.8)	-5.7 (-7.8, -3.5)	-9 (0.7)	-3.9 (0.9)	-5.2 (-7.3, -3)	-8 (0.7)	-4.1 (0.9)	-3.9 (-6.1, -1.7)
	pvalue	*0.89*	*0.27*	*0.53*	*0.33*	*0.95*	*0.68*	*0.66*	*0.92*	*0.66*
Low Back Pain Bothersomeness (0-6) (SE)¶	One	-1.8 (0.2)	-0.8 (0.2)	-1 (-1.5, -0.5)	-2 (0.2)	-1 (0.2)	-1 (-1.5, -0.5)	-2.1 (0.2)	-1.3 (0.2)	-0.8 (-1.3, -0.3)
	Two	-2.2 (0.2)	-0.8 (0.2)	-1.4 (-1.9, -0.9)	-1.9 (0.2)	-1.1 (0.2)	-0.8 (-1.3, -0.3)	-1.9 (0.2)	-1.1 (0.2)	-0.8 (-1.3, -0.3)
	Three+	-2 (0.2)	-1 (0.2)	-1 (-1.6, -0.4)	-2.2 (0.2)	-1 (0.3)	-1.2 (-1.8, -0.6)	-2.1 (0.2)	-0.8 (0.3)	-1.3 (-1.9, -0.7)
	pvalue	*0.42*	*0.64*	*0.43*	*0.39*	*0.94*	*0.58*	*0.75*	*0.28*	*0.35*
Very/somewhat satisfied with symptoms (%)	One	62.1	24.7	37.4 (26.1, 48.7)	67.3	28.9	38.4 (25.4, 51.4)	63.8	44.7	19.1 (4.3, 33.9)
	Two	63.2	21.7	41.5 (30.8, 52.2)	62.3	29.7	32.6 (19.3, 45.8)	71.5	22	49.5 (37, 62)
	Three+	56.1	24.9	31.2 (16.3, 46.1)	75.3	32.1	43.2 (26.7, 59.7)	69	21.2	47.8 (32, 63.6)
	pvalue	*0.59*	*0.83*	*0.57*	*0.19*	*0.93*	*0.61*	*0.48*	*0.01*	*0.005*
Self-rated progress major improvement (%)	One	72.4	23.9	48.4 (38, 58.9)	65.9	27.6	38.3 (25.6, 51)	62.3	36.2	26.1 (12.1, 40.2)
	Two	70.4	17.6	52.8 (43.2, 62.4)	66.1	24.8	41.3 (29, 53.7)	64.7	25.2	39.5 (26.5, 52.5)
	Three+	71.6	17.3	54.2 (41.4, 67.1)	74.6	26.4	48.2 (32.7, 63.8)	59.4	24.5	34.9 (18.2, 51.6)
	pvalue	*0.95*	*0.43*	*0.70*	*0.39*	*0.92*	*0.63*	*0.77*	*0.30*	*0.42*

* Adjusted for age, gender, stomach comorbidity, SLR or femoral tension sign, smoking status, joint comorbidity, patient self assessed health trend, income, compensation, bmi, 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 1 to 100, with lower scores indicating less severe symptoms.

§ The Stenosis Bothersomeness Index and the Stenosis Frequency Index range from 0 to 24, with lower scores indicating less severe symptoms.

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

** Treatment effect is the difference between the surgical and non-operative mean change from baseline. Analysis is done using a mixed model with a random subject intercept term. Treatment is a time-varying covariate where a patients' experience prior to surgery is attributed to the non-operative arm and time is measured from enrollment and his/her post-surgery outcomes are attributed to the surgical arm and time is measured from time of surgery.

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Table 4

Subgroup results from common adjusting covariates* as-treated outcome analysis by number of levels with moderate or severe stenosis for the randomized and observational cohorts combined DS Cohort with Listhesis Level of L4-L5

Analysis results from adjusted as-treated outcome analysis by number of levels with moderate or severe stenosis for the randomized and observational cohort for patients with degenerative spondylolisthesis.

DS cohort		3-Months			1-Year			2-Year		
Outcomes	**Stenosis Level**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**
SF-36 Bodily Pain (BP) (0-100) (SE)†	One	32.7 (1.5)	11.6 (1.7)	21.2 (17.2, 25.1)	34.9 (1.6)	13.9 (1.9)	21 (16.5, 25.6)	34.9 (1.6)	16 (2)	18.8 (14.1, 23.6)
	Two/three+	24.4 (2.2)	9.5 (2.4)	14.9 (9.3, 20.5)	27 (2.4)	9.8 (2.7)	17.2 (10.6, 23.9)	22.8 (2.4)	8.9 (2.9)	13.9 (6.9, 20.9)
	pvalue	0.002	0.48	0.066	0.008	0.22	0.35	<0.001	0.045	0.24
SF-36 Physical Function (PF) (0-100) (SE)†	One	23.1 (1.5)	7.4 (1.6)	15.7 (12, 19.5)	29.7 (1.5)	9 (1.8)	20.7 (16.4, 25.1)	28.5 (1.5)	10.8 (1.9)	17.7 (13.1, 22.2)
	Two/three+	19.3 (2.1)	9 (2.3)	10.3 (5, 15.6)	28.3 (2.4)	8.3 (2.6)	19.9 (13.6, 26.2)	21.3 (2.3)	2.6 (2.8)	18.7 (12, 25.3)
	pvalue	0.14	0.56	0.092	0.62	0.84	0.84	0.007	0.016	0.80
Mental Component Summary (MCS) (0-100) (SE)†	One	4.4 (0.6)	2.1 (0.7)	2.3 (0.6, 4)	3.4 (0.7)	0.8 (0.8)	2.5 (0.6, 4.5)	3.3 (0.7)	1.1 (0.9)	2.1 (0.1, 4.2)
	Two/three+	3.2 (0.9)	0.3 (1)	2.9 (0.5, 5.3)	2.9 (1)	2.4 (1.1)	0.5 (-2.4, 3.4)	1.7 (1)	-0.3 (1.2)	2 (-1, 5.1)
	pvalue	0.27	0.13	0.68	0.73	0.25	0.25	0.20	0.35	0.96
Oswestry Disability Index (ODI) (0-100) (SE)‡	One	-22 (1.2)	-5.8 (1.3)	-16.2 (-19.1, -13.2)	-26.4 (1.2)	-7.8 (1.4)	-18.5 (-21.9, -15.1)	-25.6 (1.2)	-9.1 (1.5)	-16.5 (-20.1, -12.9)
	Two/three+	-18.4 (1.7)	-6.6 (1.8)	-11.8 (-16, -7.7)	-22.1 (1.9)	-3.9 (2.1)	-18.2 (-23.2, -13.2)	-19.5 (1.8)	-2.7 (2.3)	-16.7 (-22, -11.4)
	pvalue	0.085	0.72	0.088	0.062	0.13	0.91	0.005	0.021	0.94
Stenosis Frequency Index (0-24) (SE)§	One	-9.5 (0.6)	-1.9 (0.4)	-7.6 (-8.9, -6.2)	-9.2 (0.4)	-2.9 (0.5)	-6.3 (-7.5, -5.1)	-8.7 (0.4)	-3.8 (0.6)	-4.9 (-6.2, -3.6)
	Two/three+	-9.1 (0.9)	-3.4 (0.6)	-5.7 (-7.7, -3.7)	-7.9 (0.7)	-2.6 (0.7)	-5.3 (-7.1, -3.4)	-6.6 (0.7)	-2.8 (0.8)	-3.8 (-5.7, -1.9)
	pvalue	0.71	0.059	0.12	0.10	0.76	0.35	0.006	0.33	0.32
Stenosis Bothersomeness Index (0-24) (SE)§	One	-10.7 (0.6)	-2.6 (0.5)	-8.1 (-9.5, -6.7)	-9.9 (0.4)	-3.3 (0.5)	-6.6 (-7.9, -5.3)	-9.5 (0.4)	-4 (0.6)	-5.5 (-6.9, -4.2)
	Two/three+	-9.6 (0.9)	-3.5 (0.7)	-6.2 (-8.2, -4.1)	-8.7 (0.7)	-3.7 (0.8)	-4.9 (-6.8, -3)	-8 (0.7)	-3.6 (0.8)	-4.4 (-6.4, -2.4)
	pvalue	0.32	0.29	0.13	0.13	0.65	0.15	0.059	0.74	0.34
Low Back Pain Bothersomeness (0-6) (SE)¶	One	-2.3 (0.2)	-1 (0.1)	-1.3 (-1.7, -0.9)	-2.5 (0.1)	-0.9 (0.1)	-1.5 (-1.9, -1.1)	-2.2 (0.1)	-1.1 (0.2)	-1.2 (-1.6, -0.8)
	Two/three+	-2.2 (0.3)	-1.2 (0.2)	-1 (-1.6, -0.4)	-2.2 (0.2)	-1.2 (0.2)	-1 (-1.5, -0.5)	-1.7 (0.2)	-1.3 (0.2)	-0.5 (-1.1, 0.1)

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DS cohort		3-Months			1-Year			2-Year		
Outcomes	**Stenosis Level**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**	**Surgical**	**Non-operative**	**Treatment Effect** ** **(95% CI)**
	pvalue	0.76	0.41	0.46	0.20	0.31	0.11	0.027	0.45	0.043
Very/somewhat satisfied with symptoms (%)	One	72.2	24.9	47.3 (38.8, 55.9)	75.3	29.3	46 (36, 56.1)	72.3	37.2	35.2 (24, 46.3)
	Two/three+	64.7	25.1	39.6 (27, 52.1)	66.2	21.2	45 (30.6, 59.3)	52.3	30.3	22.1 (5.3, 38.8)
	pvalue	0.23	0.97	0.35	0.17	0.23	0.98	0.003	0.44	0.25
Self-rated progress major improvement (%)	One	79.6	21.3	58.3 (50.4, 66.1)	80.5	26.2	54.4 (45.1, 63.7)	77.1	27.9	49.2 (39.1, 59.4)
	Two/three+	71.9	22	49.9 (38.2, 61.7)	66.8	22.7	44.1 (29.7, 58.4)	59.6	20.3	39.3 (24.3, 54.3)
	pvalue	0.17	0.91	0.28	0.024	0.62	0.25	0.005	0.35	0.43

* Adjusted for age, gender, stomach comorbidity, SLR or femoral tension sign, smoking status, joint comorbidity, patient self assessed health trend, income, compensation, bmi, 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 1 to 100, with lower scores indicating less severe symptoms.

§ The Stenosis Bothersomeness Index and the Stenosis Frequency Index range from 0 to 24, with lower scores indicating less severe symptoms.

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

** Treatment effect is the difference between the surgical and non-operative mean change from baseline. Analysis is done using a mixed model with a random subject intercept term. Treatment is a time-varying covariate where a patients' experience prior to surgery is attributed to the non-operative arm and time is measured from enrollment and his/her post-surgery outcomes are attributed to the surgical arm and time is measured from time of surgery.

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