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Predominant Leg Pain Is Associated With Better Surgical Outcomes in Degenerative Spondylolisthesis and Spinal Stenosis: Results from the Spine Patient Outcomes Research Trial (SPORT)

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Abstract

Study Design—As-treated analysis of the Spine Patient Outcomes Research Trial (SPORT).

Objective—To compare baseline characteristics and surgical and nonoperative outcomes in degenerative spondylolisthesis (DS) and spinal stenosis (SpS) patients stratified by predominant pain location (i.e. leg vs. back).

Summary of Background Data—Evidence suggests that degenerative spondylolisthesis (DS) and spinal stenosis (SpS) patients with predominant leg pain may have better surgical outcomes than patients with predominant low back pain (LBP).

Methods—The DS cohort included 591 patients (62% underwent surgery), and the SpS cohort included 615 patients (62% underwent surgery). Patients were classified as leg pain predominant, LBP predominant or having equal pain according to baseline pain scores. Baseline characteristics were compared between the three predominant pain location groups within each diagnostic category, and changes in surgical and nonoperative outcome scores were compared through two years. Longitudinal regression models including baseline covariates were used to control for confounders.

Results—Among DS patients at baseline, 34% had predominant leg pain, 26% had predominant LBP, and 40% had equal pain. Similarly, 32% of SpS patients had predominant leg pain, 26% had predominant LBP, and 42% had equal pain. DS and SpS patients with predominant leg pain had baseline scores indicative of less severe symptoms. Leg pain predominant DS and SpS patients treated surgically improved significantly more than LBP predominant patients on all primary outcome measures at one and two years. Surgical outcomes for the equal pain groups were intermediate to those of the predominant leg pain and LBP groups. The differences in nonoperative outcomes were less consistent.

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Conclusions—Predominant leg pain patients improved significantly more with surgery than predominant LBP patients. However, predominant LBP patients still improved significantly more with surgery than with nonoperative treatment.

Keywords

Degenerative Spondylolisthesis; Spinal Stenosis; SPORT; Leg Pain; Back Pain

INTRODUCTION

Spine surgeons have long assumed that degenerative spondylolisthesis (DS) and spinal stenosis (SpS) patients whose leg pain is more severe than their back pain have better outcomes than those with predominant low back pain (LBP). Surprisingly, there is not much data in the literature supporting this view. Using results from the Spine Tango registry, Kleinstuck et al. recently reported that patients with predominant LBP were less likely to have a “good” outcome and that the magnitude of difference between leg pain and LBP was the strongest predictor of 12 month outcomes.[1] Similarly, the Maine Lumbar Spine Study (MLSS) reported that the presence of predominant LBP decreased the odds of patient satisfaction at 4 years by 70% compared to patients with predominant leg pain.[2] Both of these studies support the hypothesis that predominant leg pain is associated with better outcomes in SpS. However, both of these studies also combined DS and SpS patients, so it is not possible to determine if the effect of predominant pain location on outcomes varied with diagnosis. In addition, the Spine Tango study did not evaluate nonoperative outcomes, and the MLSS combined surgery and nonoperative patients in its evaluation of predominant pain location on outcomes.

The Spine Patient Outcomes Research Trial (SPORT) demonstrated that DS and SpS patients improved more with surgery compared to nonoperative treatment, and DS patients improved more with surgery than SpS patients.[3–5] Given the differences in outcomes across treatments and diagnoses, the effect of predominant pain location on outcomes should be evaluated separately for the two diagnoses and treatments. As such, the goals of this study were to 1) determine if baseline characteristics varied with predominant pain location in DS and SpS, and 2) determine if predominant pain location predicted surgical and nonoperative outcomes.

METHODS

Study Design

The initial design of SPORT consisted of a randomized controlled trial with a concurrent observational cohort study conducted in 11 states at 13 institutions with multidisciplinary spine practices.[6] The human subject committees at each participating institution approved a standardized protocol for the study.

Patient Population

Patients were considered for inclusion in the DS or SpS cohort of SPORT if they were over 18 years old, considered surgical candidates by their treating physicians, and had neurogenic claudication or radicular pain with associated neurologic signs for at least 12 weeks and spinal stenosis on cross-sectional imaging.[3,6] Patients with listhesis on the lateral x-ray were assigned to the DS cohort, while patients without listhesis were assigned to the SpS cohort. Exclusion criteria for both diagnoses included: cauda equina syndrome; malignancy; significant deformity; prior back surgery; and other established medical contra-indications to elective surgery.[6] In addition, patients with “instability” (defined as greater than 4 mm of anterior-posterior translation or 10 degrees of intervertebral rotation on lateral flexion-extension x-rays) were excluded from the SpS group, and patients with spondylolysis were excluded from the DS group.

Study Interventions

All surgically treated patients in both diagnostic cohorts had a decompressive laminectomy. If fusion was performed, it consisted of bone grafting with or without instrumentation based on the surgeon's preferences.[6] The nonoperative treatment group received "usual care", recommended to include at least physical therapy, education and counseling with home exercise instruction, and non-steroidal anti-inflammatory drugs if tolerated. Details are reported elsewhere.[3,4]

Study Measures

Data utilized in this study were obtained from patient questionnaires completed at baseline, one and two years after enrollment or surgery that included the SF-36,7 ODI, [8] Stenosis Bothersomeness Index (SBI),[9,10] Leg Pain Bothersomeness Score, and Low Back Pain Bothersomeness Score.11 The SF-36 scales and the ODI range from 0–100, the Stenosis Bothersomeness Index from 0–24, and the Leg and Low Back Pain Bothersomeness Scores from 0–6. Higher scores indicated more severe symptoms on the ODI, Stenosis Bothersomenss Index, and Leg and Low Back Pain Bothersomeness Scores, while higher scores indicated less severe symptoms on the SF-36.

Imaging

All patients underwent standing lateral x-rays and cross-sectional imaging. The treating physician determined if listhesis was present on the lateral x-ray. In addition, the cross-sectional imaging was evaluated to determine which levels were stenotic and the severity of the stenosis (mild, moderate or severe).[12] The kappa scores for intra-rater reliability of the severity classification have been reported to range from 0.75 to 0.82, while inter-rater reliability ranged from 0.49 to 0.73.12

Predominant Pain Location

Patients with baseline Leg Pain Bothersomeness Scores higher than their LBP Bothersomeness Scores were classified as Leg Pain Predominant, those with LBP Bothersomenss Scores higher than their Leg Pain Bothersomeness Scores as LBP Predominant, and those with equal Leg Pain and LBP Bothersomeness Scores as having Equal Pain.

Statistical Considerations

The initial design of SPORT included both a randomized and an observational cohort. In the first two years of surveillance of the DS randomized trial, 36% of patients assigned to surgery did not have that intervention, and 49% of patients assigned to nonoperative treatment underwent surgery.3 A similar trend was observed in the SpS randomized trial, where 33% of patients assigned to surgery did not have that intervention, and 43% of patients assigned to non-operative treatment did have surgery.4 We previously reported comparisons of the baseline characteristics and outcomes between the randomized and observational cohorts for DS and SpS.3[,4] Given the high rate of protocol non-adherence (crossover between treatment groups) and the consistency of the baseline characteristics between the randomized and the observational cohorts for both diagnostic groups, the data from the randomized and observational trials (DS and SpS) were combined in an as-treated analysis. The detailed statistical rationale for this strategy has been presented elsewhere.[13]

Within each diagnostic category (i.e. DS or SpS), differences in baseline characteristics between the leg pain predominant, LBP predominant, and equal pain groups were compared using chi square tests for categorical data and ANOVA for continuous data. The primary analyses compared changes in the clinical outcome measures from baseline among the three predominant pain location groups, within each treatment group (i.e. surgery or nonoperative). In addition, the treatment effect of surgery was also compared among the three predominant pain location groups (i.e. leg pain predominant treatment effect vs. LBP predominant treatment effect vs. equal pain treatment effect). The treatment effect of surgery was defined as:

Treatment Effect = Change in Outcome Measure$_{surgery}$ - Change in Outcome Measure$_{nonoperative}$—Positive treatment effects for SF-36 scores and negative treatment effects for ODI, Stenosis Bothersomeness Index, and Leg and Low Back Pain Bothersomeness Scores indicated that surgery was more effective than nonoperative treatment. In these analyses, the treatment indicator (surgery or nonoperative) was assigned according to the actual treatment received at each time point. For surgery patients, all changes from baseline prior to surgery were included in the estimates of the effect of nonoperative treatment. Following surgery, follow-up times were measured from the date of surgery.[13]

Longitudinal regression models were created for each diagnostic group (DS and SpS). To adjust for potential confounding, baseline variables associated with missing data or treatment received (baseline outcome score, age, gender, medical center, body mass index, baseline Stenosis Bothersomeness Index, presence of joint or stomach problems, self-rated health trend, insurance status, number of moderate or severe levels, stenosis severity, income, smoking status, and diabetes) were included as adjusting covariates in longitudinal regression models.[14] A random individual effect was specified to account for the repeated measurements of individual patients. Statistical analysis was performed on SAS Software (SAS Institute Inc, Cary, NC) using PROC MIXED for continuous data with normal random effects (SF-36 bodily pain and physical function, ODI, Sciatica Bothersomeness) and PROC GENMOD for non-normal outcomes (Leg and Low Back Pain Bothersomeness). At each time point, adjusted mean scores were estimated, and differences among the three predominant pain location groups were compared using a Wald test. Statistical significance was defined as $p<0.05$ on the basis of a two-sided hypothesis test.

RESULTS

Patients

The DS cohort enrolled 607 of 892 eligible patients.3 Of those enrolled, 591 patients responded to the baseline leg and LBP bothersomeness questions and completed at least one follow-up visit and were included in the analysis. Sixty-two percent (n=364) of patients underwent surgery within two years of enrollment, while the other 38% (n=227) were treated nonoperatively. Ninety-three percent of analyzed patients completed their one year follow-up, and 89% completed two year follow-up. Of 1,696 patients screened for inclusion in the SpS cohort, 1,091 were eligible, and 654 were enrolled.[4] Six hundred fifteen patients responded to the baseline leg and LBP bothersomeness questions and completed at least one follow-up visit within the first two years and were included in the study. Three hundred seventy four (61%) underwent surgery within two years, while the remaining 241 received exclusively nonoperative care. Ninety-two percent of analyzed patients completed their one year follow-up, and 86% completed two year follow-up.

Predominant Pain Location

Among the 591 DS patients, 199 (34%) were classified as leg pain predominant, 154 (26%) as LBP predominant, and 238 (40%) as having equal pain (Figure 1). Similarly, 196 (32%) of the 615 SpS patients were leg pain predominant, 159 (26%) were LBP predominant, and 260 (42%) had equal pain. The differences in these distributions across the diagnoses (i.e. DS vs. SpS) were not significantly different.

Comparison of Baseline Characteristics

Among DS patients, there were no significant age or gender differences across the predominant pain location groups (Table 1). Leg pain and LBP predominant patients were more likely to have completed at least some college as compared to equal pain patients (72% leg pain predominant, 71% LBP predominant vs. 58% equal pain, p=0.002), and LBP predominant patients were more likely to report other joint problems (68% LBP predominant vs. 54% leg pain predominant and 56% equal pain, p=0.022). Equal pain patients had the worst baseline symptoms as measured on the SF-36 bodily pain (BP) and physical function (PF) scales, ODI, and SBI (p<0.01 on all measures, Table 1). Leg pain predominant patients had scores indicative of the least severe symptoms on those measures other than the SBI, on which the LBP predominant patients had the least severe symptoms. The equal pain patients had LBP Bothersomeness scores similar to the LBP predominant patients (5.2 vs. 5.0), while their Leg Pain Bothersomeness scores were identical to the leg pain predominant patients (5.2 for both groups). The equal pain patients were also most likely to report that their problem was getting worse (66% equal pain vs. 55% leg pain predominant and 60% LBP predominant, p=0.049). These data suggest that the DS equal pain group had the worst baseline symptoms of the three pain location groups.

Similar baseline patterns across predominant pain location groups were seen among the SpS patients. Demographic characteristics were similar across the predominant pain location groups with the exception of the leg pain predominant group including a higher proportion of married patients (78% leg pain predominant vs. 67% LBP predominant and 67% equal pain, p=0.028) and the equal pain group including more patients receiving worker's compensation (11% equal pain vs. 5% leg pain predominant and 6% LBP predominant, p=0.027). The equal pain patients had scores indicative of the most severe baseline symptoms on BP, PF, ODI, and SBI (p<0.03 on all measures, Table 1).

Comparison of Imaging Findings

There were no significant differences among the predominant pain location groups on the intervertebral levels affected by stenosis, severity of stenosis, number of levels graded as stenotic or the location of stenosis within the spinal canal (i.e. central, lateral recess or foraminal) for either the DS or SpS cohort. Among the DS patients, there was no association between predominant pain location and level of listhesis (i.e. L3-4 vs. L4-5) or the presence of "instability" (present in 7% leg pain predominant, 9% LBP predominant, and 8% equal pain, p=0.67).

Comparison of Treatment Received

Predominant pain location was not associated with treatment type for DS patients, with 61% of leg pain predominant, 59% of LBP predominant, and 63% of equal pain patients undergoing surgery within two years (p=0.68). Overall, 94% of DS surgical patients underwent fusion, and there were no significant differences in the rate of fusion (93% leg pain predominant, 94% LBP predominant, and 96% equal pain, p=0.44) or type of fusion (instrumented fusion: 83% leg pain predominant, 81% LBP predominant, and 72% equal pain, p=0.08) across predominant pain location groups. Among SpS patients, the rate of surgery was not significantly different across the predominant pain location groups, with 66% of leg pain predominant, 55% of LBP predominant, and 64% of equal pain patients undergoing surgery (p=0.069). Only 11% of SpS patients underwent fusion, and the rates of fusion (9% predominant leg pain, 17% predominant LBP, and 10% equal pain, p=0.21) and type of fusion (instrumented fusion: 45% predominant leg pain, 53% predominant LBP, and 59% equal pain, p=0.93) did not vary significantly across the predominant pain location groups.

Comparison of Outcomes

Among DS patients treated surgically, predominant pain location was significantly associated with improvement on all outcomes other than Back Pain Bothersomeness at both one and two years, with the leg pain predominant group improving the most and the LBP predominant group improving the least (Table 2, Figure 2). The equal pain group tended to have intermediate levels of improvement. Such marked differences in nonoperative outcomes were not observed, though predominant pain location was significantly associated with improvement on PF at one year and ODI at one and two years, with the leg pain predominant group improving the most (Table 2). The leg pain predominant group had a significantly higher treatment effect of surgery on BP and PF at one year (BP: 25.7 leg pain predominant vs. 15.8 LBP predominant vs. 17.2 equal pain, p=0.031; PF: 26.8 leg pain predominant vs. 18.1 LBP predominant vs. 15.4 equal pain, p=0.011), though these differences were no longer significant at two years.

Among SpS patients treated surgically, predominant pain location was significantly associated with improvement all outcomes other than the LBP Bothersomeness score at one year and the Leg Pain Bothersomeness score at one and two years, with the leg pain predominant group improving the most and the LBP predominant group improving the least (Table 3, Figure 3). The equal pain group tended to have intermediate surgical outcomes. There were no significant differences in nonoperative outcomes among the predominant pain location groups other than on the Leg Pain Bothersomeness score at one year, on which the leg pain preodominant group improved the most. The only significant difference in treatment effect was observed at two years on the LBP Bothersomeness score, with the leg pain predominant group having the greatest treatment effect (−1.5 leg pain predominant vs. −0.6 LBP predominant and −0.7 equal pain, p=0.04).

DISCUSSION

The current study confirmed the commonly held belief that DS and SpS patients with predominant leg pain improved more with surgery than patients with predominant LBP. However, the predominant LBP patients improved significantly more with surgery than with nonoperative treatment on nearly all outcome measures at one and two years. Contrary to anecdotal evidence that suggested DS patients were more likely to have predominant LBP than SpS patients,[15–19] the pattern of predominant pain location was remarkably similar for the two diagnostic groups, with approximately one third of patients presenting with predominant leg pain, one quarter with predominant LBP, and the remaining 40% with equal leg and low back pain. Nonoperative outcomes were generally not associated with predominant pain location, though leg pain predominant DS patients treated nonoperatively improved more on PF and ODI than LBP predominant patients.

While many studies have evaluated predictors of outcomes in SpS, the association between predominant pain location and outcomes has not been extensively studied.[2,20–25] Kleinstuck et al. analyzed the Spine Tango registry of SpS patients treated surgically and reported that baseline LBP score was the strongest predictor of the 12 month Core Outcome Measure Index (COMI) and the difference between baseline leg pain and LBP was the strongest predictor of global outcome at 12 months.[1] Previous studies had identified gender and medical comorbidities as significant predictors of outcomes,[20,22] and while these remained significant in the Spine Tango model, they were not as powerful as the severity of baseline LBP in predicting outcomes. The Maine Lumbar Spine Study (MLSS) also demonstrated that predominant LBP was strongly associated with a lower rate of patient satisfaction four years after treatment for SpS, with the odds of satisfaction decreasing by 70% for LBP predominant patients.[2] Katz et al. also reported that predominant leg pain was associated with better walking capacity, symptom severity, and patient satisfaction two years after surgery for SpS, though predominant pain location did not remain a significant predictor in their multivariate model.[22]

The results of the current study support the findings of these prior studies that suggested predominant leg pain was associated with better surgical outcomes in SpS. These previous studies analyzed predominant pain location as a predictor in multivariate analysis and did not directly compare outcomes among the predominant pain location groups.[1,2] Unlike those studies, the current study reported the magnitude of the difference in surgical outcomes between the predominant leg pain and predominant LBP groups, which was up to 13 points on the SF-36 bodily pain and physical function scales. To our knowledge, the present study was the first to report nonoperative outcomes stratified by predominant pain location, which allowed for comparison of surgical and nonoperative outcomes within each predominant pain location group (i.e. surgical vs. nonoperative outcomes for LBP predominant patients). While prior studies questioned if surgery resulted in better outcomes than nonoperative treatment in LBP predominant patients, they were unable to answer this question with the available data. The current study demonstrated that LBP predominant patients with neurogenic claudication still had better outcomes with surgery. In addition, the present study was unique in its separate analyses for DS and SpS patients.

There are important limitations to this study that must be considered when evaluating its findings. Because of the high rate of protocol non-adherence, the data were analyzed on an as-treated basis, with loss of the benefits of randomization. As such, the potential for confounding by unmeasured variables exists. We have detailed the rationale behind these analyses elsewhere.[13] In addition, SPORT was not initially powered to make comparisons among the predominant pain location subgroups.[6] As such, the possibility of Type II error exists. However, the differences in surgical outcomes among the predominant pain location groups tended to be significant. The inability to consistently detect the smaller differences in nonoperative outcomes may have been related to the decreased power inherent in subgroup analyses. Another issue is the lack of a pre-defined intervention in the non-operative group; patients received individualized treatment based on current knowledge and patterns of practice.[3,4,6,26] Thus while the non-operative outcomes represent the likely results of non-operative treatment that a patient could expect at a multi-disciplinary spine center today, it may not necessarily represent optimal treatment if future research reveals a significantly better non-operative approach for spinal stenosis. Future studies should compare the efficacy of specific nonoperative programs to surgery. Finally, patients were not forced to choose a predominant pain location, and approximately 40% of patients were classified as having equal pain. These patients had the worst baseline symptoms, and the equivalence of their leg and back pain may have represented a ceiling effect on the 7 point Leg Pain and LBP Bothersomeness scales in some cases. However, the equal pain group tended to have intermediate outcomes compared to the leg pain and LBP predominant groups, indicating that there may be a “dose-response” relationship between the magnitude of difference between leg pain and LBP and surgical outcomes.

While the current study convincingly demonstrated that predominant leg pain is associated with better surgical outcomes in DS and SpS, it does not explain the etiology of this difference. Traditional teaching has suggested that patients with predominant LBP may benefit from fusion to address their LBP.[17] As such, one might expect a wider difference in outcomes between the predominant leg and predominant LBP patients in SpS compared to DS since the SpS patients underwent fusion at a much lower rate. However, the outcome differences between the predominant leg pain and predominant LBP patients were nearly identical for the DS and SpS cohorts. One possible explanation is that surgery resulted in more consistent relief of leg pain than LBP whether fusion was performed or not.[27,28] Due to the small number of SpS patients who underwent fusion, we were unable to determine if fusion improved outcomes in SpS patients with predominant LBP.

The current study demonstrated that DS and SpS patients with predominant leg pain improved significantly more with surgery than patients with predominant LBP. However, predominant LBP patients still improved significantly more with surgery compared to nonoperative treatment. While predominant pain location is not a modifiable patient factor, patients with predominant LBP should have realistic expectations about the results of surgery, which may be inferior to those with predominant leg pain. Future studies should evaluate the role of fusion in predominant pain location subgroups in order to determine if the effect of fusion varies with predominant pain location.

Key Points

- The proportion of patients presenting with predominant leg pain, predominant back pain, and equal leg and back pain were very similar for degenerative spondylolisthesis (DS) and spinal stenosis (SpS).
- Patients with predominant leg pain had less severe symptoms at baseline compared to those with predominant back pain or equal leg and back pain.
- Patients with predominant leg pain improved significantly more with surgery than patients with predominant back pain, while patients with equal leg and back pain had intermediate outcomes.
- Patients improved significantly more with surgery than with nonoperative treatment regardless of the predominant pain location.

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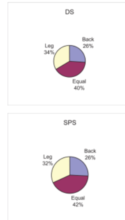
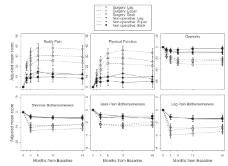


Figure 1.


Surgery: Leg
Surgery: Equal
Surgery: Back
Non-operative: Leg
Non-operative: Equal
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Bodily Pain
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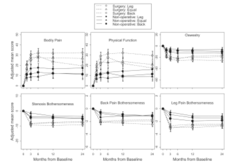
Back Pain Bothersomeness
Leg Pain Bothersomeness
Adjusted mean score
Months from Baseline

Figure 2.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Adjusted mean score
Months from Baseline

Figure 3.

Table 1

Baseline characteristics among DS and SPS cohorts stratified by predominant pain location.

	DS				SPS			
	Predominant Leg Pain (n = 199)	Predominant Back Pain (n = 154)	Equal Pain (n = 238)	p-value	Predominant Leg Pain (n = 196)	Predominant Back Pain (n = 159)	Equal Pain (n = 260)	p-value
Mean Age (stdev)	66.6 (10.2)	66 (10.8)	65.9 (10.1)	0.77	65.5 (11.8)	65 (11.8)	63.8 (11.6)	0.27
Female	125 (63%)	112 (73%)	169 (71%)	0.084	71 (36%)	62 (39%)	110 (42%)	0.42
Race - White	175 (88%)	128 (83%)	194 (82%)	0.17	168 (86%)	135 (85%)	217 (83%)	0.80
Education - At least some college	144 (72%)	109 (71%)	138 (58%)	0.002	126 (64%)	106 (67%)	156 (60%)	0.36
Marital Status - Married	135 (68%)	94 (61%)	161 (68%)	0.32	153 (78%)	107 (67%)	176 (68%)	0.028
Work Status				0.79				0.12
Full or part time	69 (35%)	61 (40%)	85 (36%)		70 (36%)	45 (28%)	98 (38%)	
Disabled	13 (7%)	13 (8%)	24 (10%)		14 (7%)	15 (9%)	26 (10%)	
Retired	91 (46%)	63 (41%)	99 (42%)		94 (48%)	87 (55%)	105 (40%)	
Other	26 (13%)	17 (11%)	30 (13%)		18 (9%)	12 (8%)	31 (12%)	
Compensation - Any	11 (6%)	12 (8%)	17 (7%)	0.67	9 (5%)	9 (6%)	28 (11%)	0.027
Mean Body Mass Index (BMI), (SD)	28.6 (6.5)	29.6 (6.3)	29.5 (5.8)	0.26	28.8 (5.4)	29.8 (6.3)	29.7 (5.3)	0.13
Smoker	15 (8%)	17 (11%)	19 (8%)	0.46	16 (8%)	17 (11%)	28 (11%)	0.61
Comorbidities								
Hypertension	84 (42%)	68 (44%)	121 (51%)	0.17	82 (42%)	83 (52%)	117 (45%)	0.14
Diabetes	18 (9%)	25 (16%)	37 (16%)	0.074	20 (10%)	28 (18%)	44 (17%)	0.076
Osteoporosis	23 (12%)	18 (12%)	28 (12%)	1	19 (10%)	12 (8%)	28 (11%)	0.55
Heart Problem	38 (19%)	36 (23%)	47 (20%)	0.58	49 (25%)	43 (27%)	67 (26%)	0.91
Stomach Problem	41 (21%)	38 (25%)	54 (23%)	0.66	39 (20%)	40 (25%)	57 (22%)	0.49
Bowel or Intestinal Problem	12 (6%)	15 (10%)	16 (7%)	0.38	32 (16%)	21 (13%)	30 (12%)	0.33

	DS				SPS			
	Predominant Leg Pain (n = 199)	Predominant Back Pain (n = 154)	Equal Pain (n = 238)	p-value	Predominant Leg Pain (n = 196)	Predominant Back Pain (n = 159)	Equal Pain (n = 260)	p-value
Depression	27 (14%)	33 (21%)	37 (16%)	0.13	19 (10%)	17 (11%)	33 (13%)	0.59
Joint Problem	107 (54%)	104 (68%)	133 (56%)	0.022	107 (55%)	96 (60%)	137 (53%)	0.30
Other	72 (36%)	65 (42%)	95 (40%)	0.50	68 (35%)	51 (32%)	99 (38%)	0.44
Bodily Pain (BP) Score	33.6 (16.1)	32.2 (16.9)	27.9 (16.5)	[lt]0.001	32.7 (16.3)	33.3 (17)	29.1 (17.7)	0.02
Physical Functioning (PF) Score	39 (21.4)	33.8 (22.6)	30.2 (21.9)	[lt]0.001	37.9 (21.6)	35.1 (23.1)	31.8 (23.9)	0.02
Mental Component Summary (MCS) Score	51.1 (11.3)	49.4 (11)	49.7 (12.2)	0.34	50.7 (11.8)	49.6 (11.2)	48.4 (12.4)	0.14
Oswestry (ODI)	38.7 (16.4)	42.4 (17.7)	44 (18.2)	0.006	38.1 (16.1)	42.8 (17.7)	45.8 (19.7)	[lt]0.001
Stenosis Bothersome Index (0--24)	15.6 (4.7)	11.4 (5.1)	16.3 (5.5)	[lt]0.001	15.5 (4.5)	11.3 (5.9)	15.7 (5.5)	[lt]0.001
Back Pain Bothersomeness	2.7 (1.7)	5 (1.3)	5.2 (1.1)	[lt]0.001	2.6 (1.6)	5 (1.3)	4.8 (1.3)	[lt]0.001
Leg Pain Bothersomeness	5.2 (0.9)	2.8 (1.7)	5.2 (1.1)	[lt]0.001	5.1 (1.1)	2.8 (1.7)	4.8 (1.3)	[lt]0.001
Satisfaction with symptoms - very dissatisfied	134 (67%)	106 (69%)	172 (72%)	0.52	134 (68%)	103 (65%)	183 (70%)	0.49

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Table 2

Change from baseline scores for degenerative spondylolisthesis predominant pain location groups (adjusted*, as-treated analysis).

	Predominant Pain Location	1Y Surgical	1Y Non-operative	1Y Treatment Effect	2Y Surgical	2Y Non-operative	2Y Treatment Effect
Bodily Pain	Leg	38 (2.1)	12.3 (2.2)	25.7 (20.1 ,31.3)	37 (2)	12.7 (2.4)	24.3 (18.6 ,30)
	Back	25.6 (2.4)	9.9 (2.5)	15.8 (9.5 ,22)	23.6 (2.3)	8.4 (2.8)	15.2 (8.6 ,21.8)
	Equal	30.9 (1.8)	13.7 (2.2)	17.2 (11.9 ,22.5)	29.6 (1.8)	12.3 (2.4)	17.3 (11.7 ,22.9)
	p-value	[lt]0.001	0.51	0.031	[lt]0.001	0.45	0.08
Physical Function	Leg	35.9 (2.1)	9.1 (2.3)	26.8 (21.2 ,32.5)	33.5 (2)	10.1 (2.4)	23.4 (17.7 ,29.1)
	Back	22.7 (2.4)	4.6 (2.6)	18.1 (11.9 ,24.3)	20.8 (2.3)	5.4 (2.8)	15.4(8.8 ,22)
	Equal	28.8 (1.9)	13.4 (2.2)	15.4 (10.1 ,20.7)	25.2 (1.8)	7.9 (2.4)	17.3 (11.7 ,22.9)
	p-value	[lt]0.001	0.034	0.011	[lt]0.001	0.45	0.15
Oswestry Disability Index	Leg	−30 (1.7)	−9.7 (1.8)	−20.3 ([minus]24.7 ,−15.8)	−29.6 (1.6)	−9.6 (1.9)	−20 ([minus]24.6 ,−15.5)
	Back	−22.2 (1.9)	−2.6 (2)	−19.6 ([minus]24.5 ,−14.7)	−20.3 (1.8)	−2 (2.2)	−18.4 ([minus]23.5 ,−13.2)
	Equal	−24.4 (1.5)	−8.4 (1.7)	−16 ([minus]20.2 ,−11.9)	−23.1 (1.5)	−8.5 (1.9)	−14.6 ([minus]19 ,−10.1)
	p-value	0.006	0.025	0.34	[lt]0.001	0.024	0.21
Stenosis Bothersomeness Index	Leg	−11.3 (0.6)	−3.8 (0.6)	−7.5 ([minus]9.1 ,−5.8)	−11 (0.6)	−4.3 (0.7)	−6.6 ([minus]8.3 ,−4.9)
	Back	−8.8 (0.7)	−3.5 (0.7)	−5.3 ([minus]7.1 ,−3.4)	−7.9 (0.7)	−3.3 (0.8)	−4.6 ([minus]6.6 ,−2.6)
	Equal	−8.9 (0.5)	−3.8 (0.6)	−5.1 ([minus]6.7 ,−3.6)	−8.4 (0.5)	−3.5 (0.7)	−4.9 ([minus]6.6 ,−3.2)
	p-value	0.004	0.96	0.083	[lt]0.001	0.59	0.21
Back Pain Bothersomeness	Leg	−2.6 (0.2)	−1 (0.2)	−1.5 ([minus]2 ,−1)	−2.4 (0.2)	−1.4 (0.2)	−1 ([minus]1.5 ,−0.5)
	Back	−2.3 (0.2)	−1 (0.2)	−1.3 ([minus]1.8 ,−0.8)	−1.9 (0.2)	−1 (0.2)	−1 ([minus]1.6 ,−0.4)
	Equal	−2.4 (0.2)	−1.3 (0.2)	−1.2 ([minus]1.7 ,−0.7)	−2.3 (0.2)	−1.2 (0.2)	−1.1 ([minus]1.6 ,−0.6)
	p-value	0.59	0.51	0.55	0.22	0.42	0.95

	Predominant Pain	1Y			2Y		
	Location	Surgical	Non-operative	Treatment Effect	Surgical	Non-operative	Treatment Effect
Leg Pain Bothersomeness	Leg	−3.7 (0.2)	−1.4 (0.2)	−2.3 ([minus]2.8 ,−1.8)	−3.4 (0.2)	−1.4 (0.2)	−2 ([minus]2.5 ,−1.5)
	Back	−2.9 (0.2)	−1.3 (0.2)	−1.5 ([minus]2.1 ,−0.9)	−2.6 (0.2)	−1.3 (0.3)	−1.3 ([minus]1.9 ,−0.7)
	Equal	−2.8 (0.2)	−1.4 (0.2)	−1.4 ([minus]1.9 ,−0.9)	−2.8 (0.2)	−1.4 (0.2)	−1.4 ([minus]1.9 ,−0.9)
	p-value	[lt]0.001	0.99	0.081	0.009	0.94	0.20

*Adjusted for age, gender, site, baseline score, bmi, baseline Sciatica Bothersomeness, joint comorbidities, self-rated health trend, insurance coverage, no. of moderate/severe levels, stenosis severity, stomach comorbidities, income, smoking status, diabetes.

Table 3

Change from baseline scores for spinal stenosis predominant pain location groups (adjusted*, as-treated analysis).

	Predominant Pain	1Y			2Y		
	Location	**Surgical**	**Non-operative**	**Treatment Effect**	**Surgical**	**Non-operative**	**Treatment Effect**
Bodily Pain	Leg	31.8 (2.1)	16.5 (2.4)	15.3 (9.4 ,21.1)	32.4 (2.1)	17.4 (2.6)	14.9 (8.8 ,21.1)
	Back	23.5 (2.5)	12.2 (2.6)	11.3 (4.7 ,17.9)	19.4 (2.4)	11.3 (2.7)	8.2 (1.5 ,14.8)
	Equal	27.1 (1.8)	12 (2.2)	15.1 (9.8 ,20.4)	26.8 (1.8)	11.9(2.4)	14.9 (9.3 ,20.5)
	p-value	0.033	0.31	0.61	[lt]0.001	0.18	0.22
Physical Function	Leg	32.2 (2.1)	14.3 (2.4)	17.9 (12.1 ,23.6)	29.6 (2.1)	16 (2.6)	13.7 (7.6 ,19.7)
	Back	21.8 (2.5)	9.6 (2.6)	12.2 (5.7 ,18.8)	17.4 (2.5)	11.5 (2.7)	5.9 ([minus]0.7 ,12.5)
	Equal	23.8 (1.9)	8.9 (2.2)	14.9 (9.6 ,20.1)	20.7 (1.8)	9.2(2.3)	11.5(6.1 ,17)
	p-value	0.002	0.21	0.43	[lt]0.001	0.15	0.20
Oswestry Disability Index	Leg	−24.7 (1.7)	−12.1 (2)	−12.5 ([minus]17.2 ,−7.8)	−25.4 (1.7)	−12.8(2.1)	−12.7 ([minus]17.6 ,−7.7)
	Back	−18 (2)	−8.9 (2.1)	−9.1 ([minus]14.4 ,−3.8)	−16.4 (2)	−10 (2.2)	−6.4 ([minus]11.8 ,−1.1)
	Equal	−20.5 (1.5)	−6.4 (1.8)	−14.1 ([minus]18.4 ,−9.8)	−18.9 (1.5)	−6.2(1.9)	−12.7 ([minus]17.2 ,−8.3)
	p-value	0.035	0.094	0.35	[lt]0.001	0.066	0.14
Stenosis Bothersomeness Index	Leg	−9.6 (0.6)	−4 (0.7)	−5.6 ([minus]7.3 ,−3.9)	−9.1 (0.6)	−4.8 (0.8)	−4.3 ([minus]6.1 ,−2.5)
	Back	−7.9 (0.7)	−4.7 (0.8)	−3.2 ([minus]5.2 ,−1.2)	−7.7 (0.7)	−5.2 (0.8)	−2.5 ([minus]4.5 ,−0.5)
	Equal	−7.5 (0.5)	−3.4 (0.6)	−4.2 ([minus]5.7 ,−2.6)	−7 (0.5)	−3.6 (0.7)	−3.4 ([minus]5 ,−1.7)
	p-value	0.023	0.43	0.18	0.02	0.27	0.40
Back Pain Bothersomeness	Leg	−2.3 (0.2)	−1.1 (0.2)	−1.1 ([minus]1.6 ,−0.6)	−2.5 (0.2)	−1 (0.2)	−1.5 ([minus]2 ,−1)
	Back	−1.8 (0.2)	−0.9 (0.2)	−0.9 ([minus]1.5 ,−0.3)	−1.7 (0.2)	−1.1 (0.2)	−0.6 ([minus]1.2 ,0)
	Equal	−2 (0.2)	−1.1 (0.2)	−0.9 ([minus]1.4 ,−0.4)	−1.9 (0.2)	−1.2 (0.2)	−0.7 ([minus]1.2 ,−0.2)
	p-value	0.34	0.60	0.75	0.014	0.80	0.043
Leg Pain Bothersomeness	Leg	−2.9 (0.2)	−1.4 (0.2)	−1.5 ([minus]2.1 ,−0.9)	−2.7 (0.2)	−1.5 (0.2)	−1.2 ([minus]1.8 ,−0.6)
	Back	−2.6 (0.2)	−1.9 (0.2)	−0.7 ([minus]1.3 ,−0.1)	−2.6 (0.2)	−1.8 (0.2)	−0.8 ([minus]1.4 ,−0.2)
	Equal	−2.4 (0.2)	−1.1 (0.2)	−1.3 ([minus]1.8 ,−0.8)	−2.4 (0.2)	−1.2 (0.2)	−1.2 ([minus]1.7 ,−0.7)
	p-value	0.13	0.027	0.16	0.46	0.076	0.38

* Adjusted for age, gender, site, baseline score, bmi, baseline Sciatica Bothersomeness, joint comorbidities, self-rated health trend, insurance coverage, no. of moderate/severe levels, stenosis severity, stomach comorbidities, income, smoking status, diabetes.