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## Does the duration of symptoms in patients with spinal stenosis and degenerative spondylolisthesis affect outcomes? Analysis of the Spine Outcomes Research Trial

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### Abstract

**Study Design**—Retrospective subgroup analysis of prospectively collected data according to treatment received.

**Objective**—The purpose of this study is to determine if the duration of symptoms affects outcomes following the treatment of spinal stenosis (SS) or degenerative spondylolisthesis (DS).

**Summary of Background Data**—The Spine Outcomes Research Trial (SPORT) study was designed to provide scientific evidence on the effectiveness of spinal surgery versus a variety of non-operative treatments.

**Methods**—An as-treated analysis was performed on patients enrolled in the Spine Patient Outcomes Research Trial (SPORT) for the treatment of SS or DS. A comparison was made between patients with SS with  $\leq 12$  months ( $n=405$ ) and those with  $>12$  months ( $n=227$ ) duration of symptoms. A comparison was also made between patients with DS with  $\leq 12$  months ( $n=397$ ) and those with  $>12$  months ( $n=204$ ) duration of symptoms. Baseline patient characteristics were documented. Primary and secondary outcomes were measured at baseline and at regular follow-up time intervals up to 4 years. The difference in improvement among patients whose surgical or nonsurgical treatment began less than or greater than 12 months after the onset of symptoms was measured. In addition, the difference in improvement with surgical versus nonsurgical treatment (treatment effect) was determined at each follow-period for each group.

**Results**—At final followup, there was significantly less improvement in primary outcome measures in SS patients with  $>12$  months symptom duration. Primary and secondary outcome measures within the DS group did not differ according to symptom duration. There were no statistically significant differences in treatment effect of surgery in SS or DS patients.

**Conclusions**—Patients with spinal stenosis with fewer than twelve months of symptoms experienced significantly better outcomes with surgical and nonsurgical treatment relative to those with symptom duration greater than twelve months. There was no difference in outcome of patients with degenerative spondylolisthesis according to symptom duration.

### Keywords

Surgery; Lumbar; Spinal Stenosis; Degenerative Spondylolisthesis; Outcomes

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## Introduction

The Spine Outcomes Research Trial (SPORT) study was designed to provide scientific evidence on the effectiveness of spinal surgery versus a variety of non-operative treatments. The prospective collection of data in the SPORT study provides a unique opportunity to correlate symptom duration with outcome. The purpose of this study was to assess the correlation between the duration of symptoms (DOS) prior to treatment and the outcome following the treatment of spinal stenosis (SS) and degenerative spondylolisthesis (DS).

The hypothesis of this study was that there exists a specific duration of symptoms of SS and DS beyond which clinical outcomes would be less favorable than with earlier intervention.

## Materials and Methods

### Study Design

SPORT was conducted at thirteen multidisciplinary spine practices in eleven states across the United States. The details of methods have been reported previously.<sup>19</sup>

### Patient Population

All patients had neurogenic claudication or radicular leg pain with associated neurological signs, SS seen on cross-sectional imaging, symptoms that had persisted for at least twelve weeks, and physician confirmation that they were a surgical candidate. Patients with DS seen on standing lateral radiographs were included in a separate analysis.

Patients with adjacent levels of stenosis were eligible, but those with spondylolysis and isthmic spondylolisthesis were not. Pre-enrollment nonoperative care was not specified but included physical therapy (68%), epidural injections (55%), chiropractic care (25%), anti-inflammatory medications (63%), and opioid analgesics (30%).

Enrollment began in March 2000 and ended in February 2005.

### Study Interventions

Patients were offered participation in either a randomized or observational cohort. Participants in the randomized cohort received computer-generated random treatment assignments blocked by center; those in the observational cohort chose their treatment with their physician. The protocol surgery consisted of a standard posterior decompressive laminectomy with or without bilateral single-level fusion (autogenous iliac crest bone-grafting with or without posterior pedicle screw instrumentation).

The non-operative protocol was “usual recommended care,” which includes, at least, active physical therapy, education and counseling with instructions regarding home exercise, and nonsteroidal anti-inflammatory drugs if the patient could tolerate them.

Because of extensive crossover in the randomized cohort (that is, some patients randomized to nonoperative care received operative care and vice versa) and similar baseline characteristics and outcomes between randomized and observational patients when analyzed by treatment, the two groups were combined in this “as-treated” analysis.

## Study Measures

Data used in this study were obtained from patient questionnaires completed at baseline, six weeks, three months, six months, one year, two years, and four years after enrollment or surgery.

Primary outcome measures included the bodily pain, physical function domains, and mental status domains of the SF-36 [22] and the American Academy of Orthopaedic Surgeons MODEMS (Musculoskeletal Outcomes Data Evaluation and Management System) version of the Oswestry Disability Index [23]. Secondary measures included patient self-reported improvement, work status, and satisfaction with current symptoms [1]. Symptom severity was measured by the low back pain bothersomeness scale, the sciatica bothersomeness index (SBI), and leg pain bothersomeness index [10] [24]. The SF-36 scales and the ODI range from 0 to 100, the SBI from 0 to 24, and the low back pain bothersomeness scale from 0 to 6. Higher scores indicated more severe symptoms on the ODI, SBI, and low back pain bothersomeness scale, whereas higher scores indicated less severe symptoms on the SF-36.

## Comparison

Differences in baseline characteristics were compared between patients with less than 12 months or greater than or equal to 12 months duration of symptoms prior to enrollment. The primary analyses compared changes in the clinical outcome measures from baseline as a function of the timing of surgery within each treatment arm (i.e., surgery or nonoperative). The treatment effect of surgery was defined to compare the improvement after surgical intervention. It was defined as the change in outcome measure after surgical treatment minus the change in outcome measure after nonoperative treatment [25]

## Statistical Analysis

Statistical modeling was performed with use of SAS software (version 9.1; SAS Institute, Cary, North Carolina), with the procedures PROC MIXED, and S-PLUS software (version 6.2; Insightful, Seattle, Washington) was used for all other calculations. Significance was defined as a p value of 0.05 on the basis of a two-sided hypothesis test.

## Results

Of the SS patients, there were four hundred and five patients with symptom duration < 12 months (SS <12 Months Patients). There were two hundred and twenty nine patients in the group with ≥12 months (SS >12 Months Patients). There was a significant baseline difference (Table 1) in unlisted comorbidities (SS <12 Months Patients 31% vs SS >12 Months Patients 41%,  $p=0.009$ ), patient self-assessed health trend getting worse (57% vs 64%, respectively,  $p=0.003$ ), and treatment preference for surgery at baseline (42% vs 49%,  $p=0.038$ ) favoring duration of symptoms < 12 months. There were significant differences in incidence of a positive straight leg raise (24% vs 16%,  $p=0.023$ ) and lateral recess stenosis (77% vs 84%,  $p=0.027$ ). At baseline, there was no instability or spondylolisthesis in the SS patient groups, as described in the methods (Table 1).

Operative details of the SS patients are described in Table 2. The majority of patients underwent decompression alone (90% SS <12 Months Patients and 85% SS >12 Months Patients). There were no statistically significant differences in types of fusion or use of instrumentation. There were no statistically significant differences in number of fusions. A higher percentage of patients in SS >12 Months Patients had decompression at L4-L5 (90% vs 97%,  $p=0.02$ ). There were no statistically significant differences in operative details or complications such as blood loss, dural tear, or wound complication.

There was an increased percentage of additional surgeries in SS >12 Months Patients at two (6% vs 10%,  $p=0.08$ ), three (8% vs 15%,  $p=0.02$ ), and four years (9% vs 19%,  $p=0.01$ ). Of the additional surgeries performed, the majority were to address recurrent stenosis or spondylolisthesis (4% vs 9%). A smaller number were addressed as a new condition (1.2% vs 3.2%).

Change in outcome measures in surgically treated patients is displayed in Table 3. Averaged over four years, there was statistically significant less improvement in SS >12 Months Patients versus SS <12 Months Patients in SF36 BP ( $p<0.001$ ), SF36 PF ( $p<0.001$ ), and ODI ( $p<0.001$ ). Specifically at the four year endpoint, the surgically treated patients with duration of symptoms < 12 months (SS <12 Months Patients) demonstrate more improvement than SS <12 Months Patients vs SS >12 Months Patients in SF36 BP (30.8 vs 23.8,  $p=0.007$ ), SF36 PF (24.7 vs 16.9,  $p=0.002$ ), ODI (-22.3 vs -16.2,  $p=0.002$ ), and patient satisfaction (70.1% vs 55%,  $p=0.015$ ). (Table 3 and Figure 1).

Averaged over four years, there was more improvement in the nonsurgically treated SS <12 Months Patients patient versus SS >12 Months Patients in SF36 BP ( $p=0.004$ ), SF36 PF ( $p=0.02$ ), and ODI ( $p=0.022$ ) (Table 3, Figure 1). At four years, there was more improvement in SS <12 Months Patients versus SS >12 Months Patients in SF36 BP (15.3 vs 6.2,  $p=0.019$ ), ODI (-10.3 vs -4.6,  $p=0.049$ ), Low Back Pain Bothersomeness Index (-1 vs -0.5,  $p=0.047$ ).

Comparing the change in outcome of the surgically treated patients minus the change in outcome of the nonsurgically treated patients (Table 3, Figure 1), there were no statistically significant differences in treatment effect of surgery between SS <12 Months Patients and SS >12 Months Patients in primary outcome measures or secondary outcome measures averaged over four years or at individual time endpoints. Additional analysis was performed using a cutoff of 6 months duration of symptoms. There were no significant differences in outcomes between those patients with a duration of symptoms greater or less than 6 months (Table 4, Figure 2).

In the DS study, there were three hundred and ninety seven patients with duration of symptoms < 12 months (DS <12 Months Patients – DS Table 1). There were two hundred and four patients with duration of symptoms  $\geq$  12 months (DS >12 Months Patients). There were decreased incidence of unlisted medical comorbidities in DS <12 Months Patients vs DS >12 Months Patients (36% vs 45%,  $p=0.05$ ). There was worse baseline SF36 MCS (49.1 vs 52.1,  $p=0.003$ ), Low Back Pain Bothersomeness (4.2 vs 4.5,  $p=0.039$ ) in DS <12 Months Patients vs DS >12 Months Patients. There was an increased percentage of patients reporting symptoms worsening in DS >12 Months Patients vs DS <12 Months Patients (66% vs 57%,  $p=0.009$ ). There was an increased percentage of asymmetric depressed reflexes (22% vs 30%,  $p=0.035$ ) and central stenosis (89% vs 96%,  $p=0.005$ ) in DS >12 Months Patients.

Operative details of the DS patient group are described in DS Table 2. In contrast to the SS patient population, approximately 94% of the patients in both DS Groups underwent a spinal fusion operation and only 6% underwent isolated decompression. There were no statistically significant differences in the method of fusion (in situ vs. instrumented) between Groups 3 and 4. There were no differences in the number of levels decompressed, fusion levels, or complications. There was a trend toward a higher percentage of patients in DS <12 Months Patients having no complications (73% vs 63%,  $p=0.051$ ). In contrast to the SS patients, there were no statistically significant differences in the incidence of additional surgeries between treatment groups.

There were no statistically significant differences in primary outcome measures (Figure 1) between surgically treated patients in Groups 3 and 4. There were no statistically significant

differences in secondary outcome measures between surgically treated patients in Groups 3 and 4. There were no statistically significant differences in primary or secondary outcome measures in nonsurgically treated patients between Groups 3 and 4. There were no statistically significant differences in treatment effect in primary or secondary outcome measures between DS <12 Months Patients and DS >12 Months Patients. Furthermore, there were no statistically significant differences in all outcome measures between DS patients with > or < 6 months of symptoms (Figure 2)

## Discussion

The results of this study show that patients with spinal stenosis symptoms  $\geq 12$  months have less improvement in outcome, regardless of treatment. The duration of degenerative spondylolisthesis symptoms  $\geq 12$  months is associated with no difference in outcome of surgical or nonsurgical treatment. The treatment effect of surgery compared to nonoperative treatment is not related to the duration of symptoms.

The disparity between the SS and DS groups may result from improved outcomes observed in the DS patients with > 12 months of symptoms (DS >12 Months Patients) relative to the SS patients with >12 months of symptoms (SS >12 Months Patients). Thus the surgically treated patients with DOS < 12 months with SS and DS achieve similar improvement. However, the surgically treated patients with DS for >12 months achieve a better outcome than patients with SS. Differences between the SS and DS groups in the nonoperatively treated patients with longer symptom duration were significant in the SF36 BP domain. Consequently, the treatment effect of surgery is significantly greater in the DS patients in SF36 PCS, percent satisfaction with symptoms, and trending toward significance in ODI.

There may be pathophysiological reasons for the differential outcome of DS and SS patients with longer symptom duration. DS may result in more episodic symptoms than pure SS. It may be better tolerated for a longer symptom duration because of the dynamic nature of the instability. Additionally, there is a difference in the distribution of stenosis with the DS patients having a higher incidence of central stenosis (89% vs 96%, DS Table 1). Central stenosis may be less likely to result in severe irreversible changes. Another possible explanation for the difference between the groups may result from the different treatment types delivered to each group. The majority (96%) of the DS patients underwent fusion, while only a small percentage of the SS patients (average 10%) underwent fusion. It is possible that fusion may reduce late dynamic instability and secondary nerve pain. Alternatively, surgeons may have performed more aggressive decompression consisting of wider laminectomy or more facetectomy in patients who underwent fusion where there was no concern about iatrogenic instability. However, there was no statistically significant difference in the percentage of patients who underwent fusion in the >12 months or <12 months groups. We would expect to find a significant difference if fusion were a major confounder.

At baseline, the SS symptom duration groups were well balanced. There were no clinically significant differences in baseline outcome measures, physical findings, or type of surgical intervention between SS symptom duration groups. The decreased improvement in SS patient outcome is associated with a significantly higher number of revision surgeries in SS >12 Months Patients.

The association between DOS and patient outcome in SS patients may be explained in part by the pathophysiology of chronic nerve compression. Studies of peripheral nerves have demonstrated that an early consequence of chronic nerve compression is local demyelination and remyelination.<sup>3</sup> Chronic nerve compression has also been shown to cause neurons

within the dorsal root ganglion to adopt a regenerative phenotype, thereby undergoing a phenotypic change.<sup>2</sup> These changes may be partly responsible for the alterations in nerve function during the early period post-compression and may account for the decreased improvement and increased revision rate in SS patients with a DOS >12 months. Furthermore, the changes in nerve physiology may be exacerbated by chronic ischemia in the lateral recess. There is a watershed vascular supply between the medullary arterial system of the spinal cord and the radicular arterial system of the nerve roots.<sup>24</sup> The relative hypovascularity of the spinal nerve roots renders them particularly susceptible to local ischemia from extrinsic compression.<sup>24, 25</sup> We hypothesize that since degenerative spondylolisthesis results in a dynamic, not constant, compression there is less long term nerve ischemia and demyelination since the nerves may recover if the spondylolisthesis reduces with posture.

Other studies in the literature do not show a significant effect of preoperative DOS on outcome of treatment of SS or DS<sup>1,4,6,9,15,16,23</sup> or did not examine DOS as a possible predictor of outcome of treatment on SS or DS.<sup>5,8,12,14,20,21,22</sup> Yasar et al report the results of a prospective study of 125 patients with spinal stenosis with 2 year followup. The authors found no correlation between DOS and outcome of treatment, although the incidence of DS is not specified in the population.<sup>23</sup> Jönsson and colleagues report on a series of 105 patients approximately 33% DS and 66% SS who underwent decompressive laminectomy for spinal stenosis. The authors report a nonsignificant trend toward a worse outcome associated with DOS > 4 years.<sup>7</sup> Among patients with lateral spinal stenosis, the authors also demonstrated that a long preoperative duration of sciatica was associated with poor outcome.<sup>10</sup> Several meta analyses have failed to report an effect of DOS on outcome of treatment of spinal stenosis or degenerative spondylolisthesis.<sup>17</sup> Finally, Katz et al report no effect of longer DOS on outcome of treatment of SS or DS. The authors report on a series of 99 patients with approximately 25% incidence of DS. There was no effect of DOS on medium term or long term outcome.<sup>11</sup>

There are several limitations to this subgroup analysis. The original SPORT study was designed and powered to compare the outcome of surgically and nonsurgically treated patients. There may be confounding variables that are not equally distributed between treatment groups in this “as treated” analysis. For instance, there were significant differences in mental status score and perception of worsening at baseline in the DS patients. Although baseline differences were controlled for in the calculation of change in primary outcome measures according to symptom duration, there is the possibility that baseline differences that have not been identified are confounding factors. Another possible difference is in the effect of medical comorbidities on outcome of treatment. Certainly patients with significant medical comorbidities may be considered more appropriate for nonsurgical treatment to reduce the risks of surgery. However, in both patient groups there was no statistically significant difference in the “major” medical comorbidities between groups (SS Table 1 and DS Table 1). There were differences in unlisted comorbidities although further information is not available. It is possible that patients with particular comorbidities may have an improved outcome with shorter or longer duration of symptoms since their underlying medical comorbidities may preclude full participation in therapy and nonsurgical treatment. Furthermore, the SPORT study was not specifically powered to include analysis of specific patient subgroups and consequently there is a possibility of type II error. However, the SPORT represents the largest study to date on SS and DS patients and is most likely to be powered to answer such detailed questions.

In summary, patients with SS who have symptom duration > 12 months have a significantly less improvement in outcome regardless of treatment. Patients who have DS have no difference in outcome associated with DOS. Evidence reveals that surgical intervention is

associated with an improved outcome compared to nonsurgical treatment. Prolonged duration of symptoms does not affect the efficacy of surgical intervention.

A retrospective subgroup analysis of the the Spine Outcomes Research Trial to determine if the duration of symptoms affects outcomes following the treatment of spinal stenosis (SS) or degenerative spondylolisthesis (DS).

### Key Points

The study evaluated whether timing of treatment affected outcome in patients with spinal stenosis and degenerative spondylolisthesis.

Regardless of the timing of treatment, patients in the surgery group had improved outcomes at all time points relative to the nonoperative treatment group.

Patients with spinal stenosis with greater than twelve months of symptoms had less improvement relative to those with less than twelve months. Patients treated with degenerative spondylolisthesis did not have different outcomes according to duration of symptoms.

## Acknowledgments

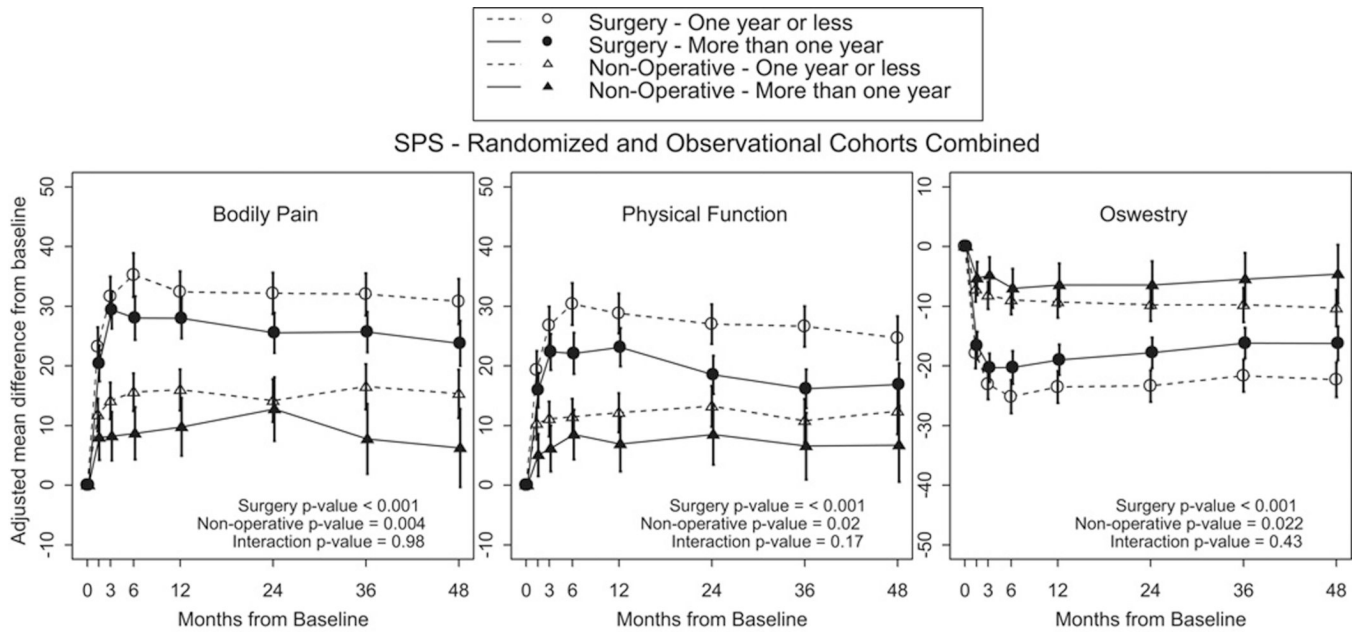
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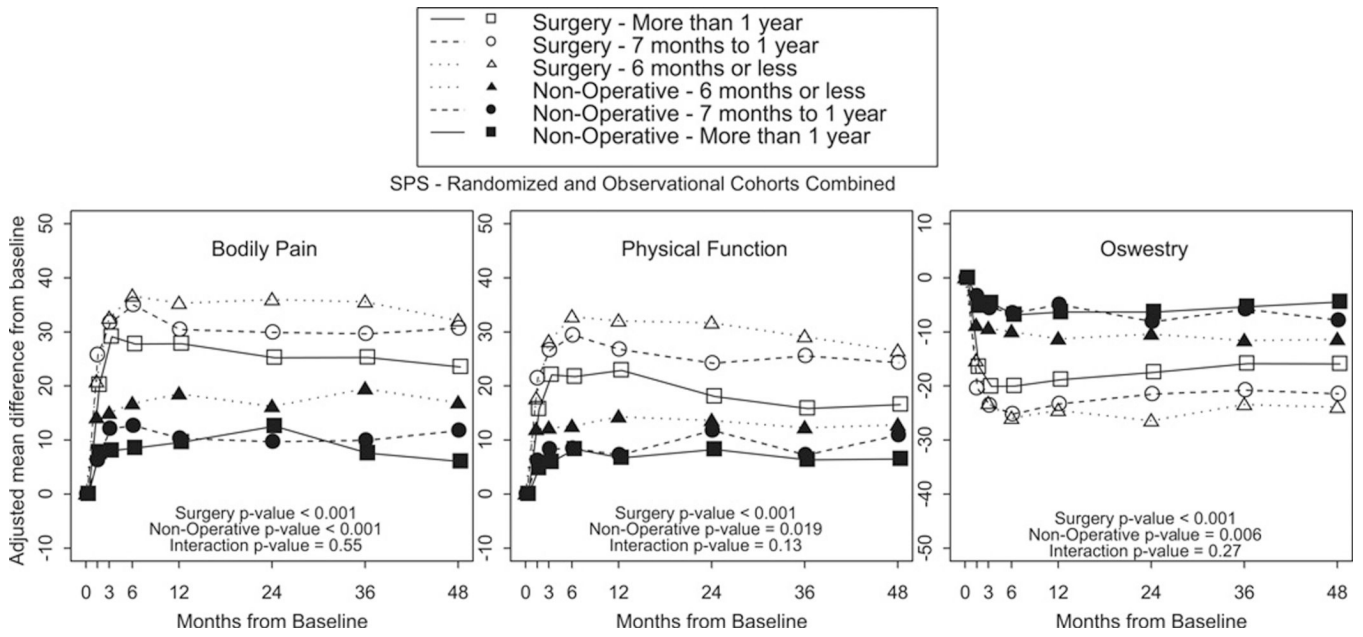




**Figure 1.** Primary outcomes over time for Spinal Stenosis Duration of Symptoms one year or less and More than 1 year.

- Surgery p-value compares duration of symptoms one year or less to more than 1 year among Surgery.
- Non-operative p-value compares duration of symptoms one year or less to more than 1 year among Non-operative.
- Interaction p-value compares treatment effect (surgery vs. non-operative) between duration of symptoms one year or less and more than 1 year.

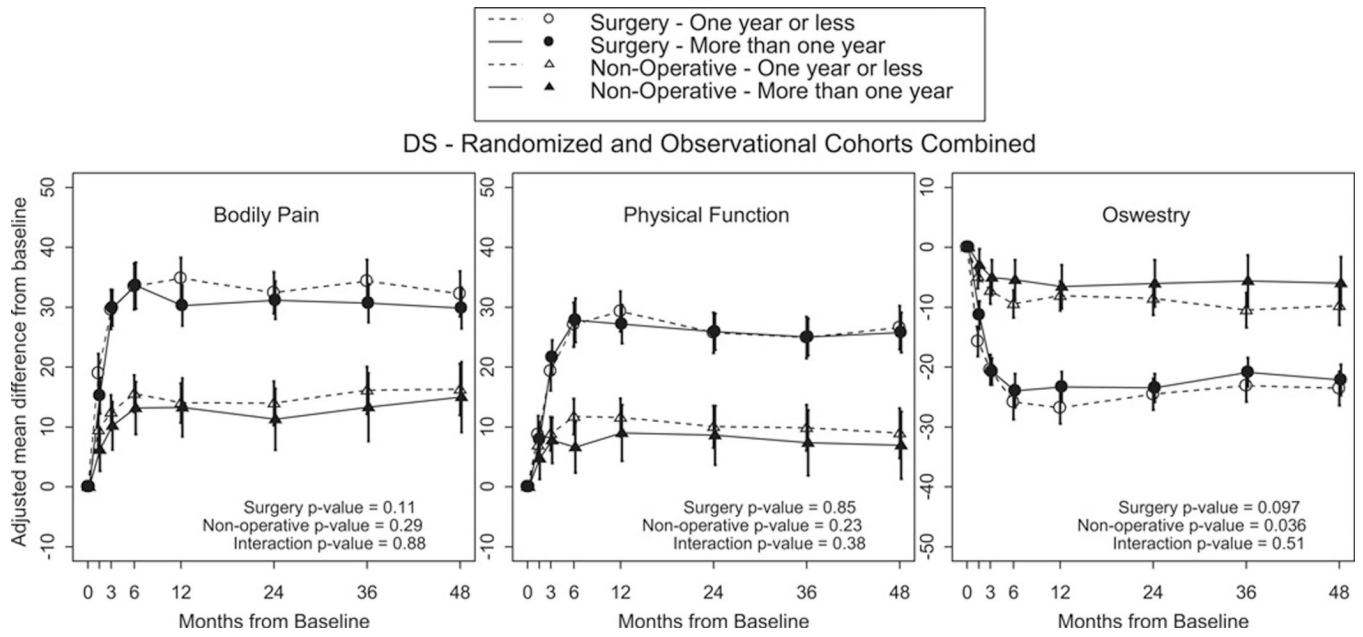
\* P-values are time weighted average 4 years (Area Under Curve p-values).



**Figure 2.** Primary outcomes over time for Spinal Stenosis Duration of Symptoms 6 months or less, 7 to 12 months and more than 1 year.

- Surgery p-value compares duration of symptoms 6 months or less, 7 to 12 months and more than 1 year among Surgery.
- Non-operative p-value compares duration of symptoms 6 months or less, 7 to 12 months and more than 1 year among Non-operative.
- Interaction p-value compares treatment effect (surgery vs. non-operative) among duration of symptoms 6 months or less, 7 to 12 months and more than 1 year.

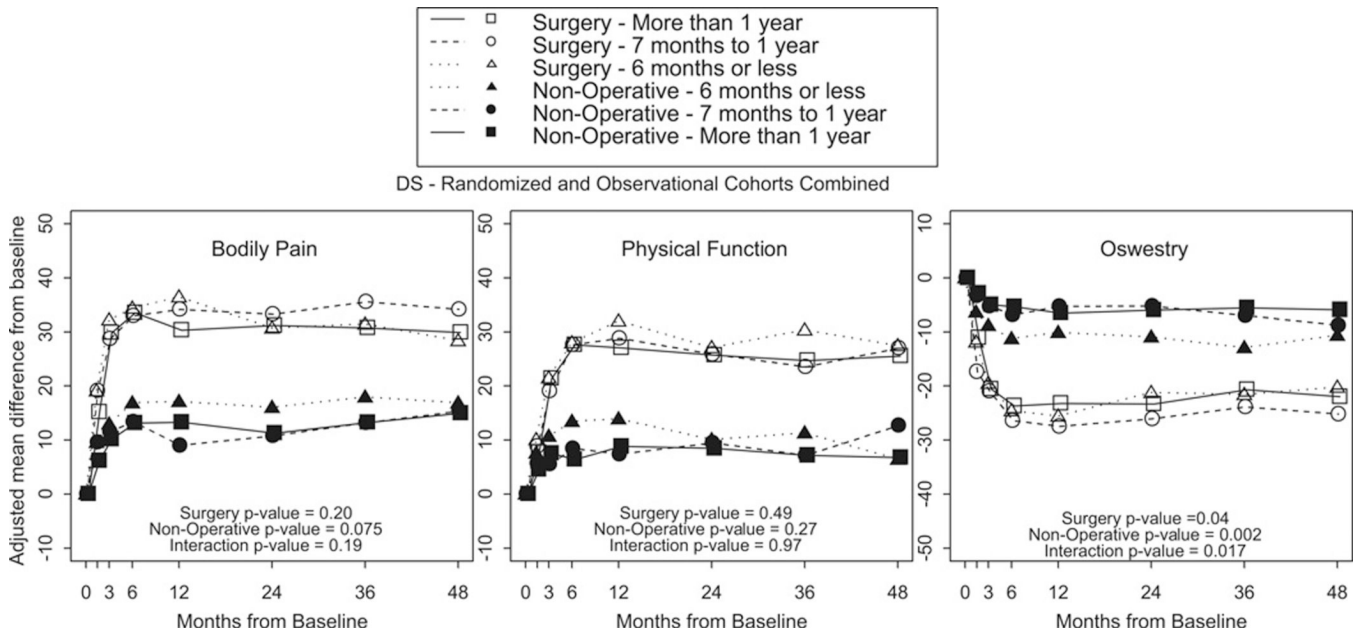
\* P-values are time weighted average 4 years (Area Under Curve p-values).



**Figure 3.** Primary outcomes over time for Degenerative Spondylolisthesis Duration of Symptoms one year or less and More than 1 year.

- Surgery p-value compares duration of symptoms one year or less to more than 1 year among Surgery.
- Non-operative p-value compares duration of symptoms one year or less to more than 1 year among Non-operative.
- Interaction p-value compares treatment effect (surgery vs. non-operative) between duration of symptoms one year or less and more than 1 year.

\* P-values are time weighted average 4 years (Area Under Curve p-values).



**Figure 4.** Primary outcomes over time for Degenerative Spondylolisthesis Duration of Symptoms 6 months or less, 7 to 12 months and more than 1 year.

- Surgery p-value compares duration of symptoms 6 months or less, 7 to 12 months and more than 1 year among Surgery.
- Non-operative p-value compares duration of symptoms 6 months or less, 7 to 12 months and more than 1 year among Non-operative.
- Interaction p-value compares treatment effect (surgery vs. non-operative) among duration of symptoms 6 months or less, 7 to 12 months and more than 1 year.

\* P-values are time weighted average 4 years (Area Under Curve p-values).

**Table 1**  
Baseline Characteristics, Comorbidities and Health Status Measures for Patients with Lumbar Spinal Stenosis (SpS)

Characteristics	One year or less (n=405)	More than one year (n=229)	p-value	6 months or less (n=266)	7 to 12 months (n=139)	More than one year (n=229)	p-value
Mean Age (SD)	64.6 (11.5)	64.7 (12)	0.90	64.7 (11.6)	64.2 (11.2)	64.7 (12)	0.90
Female - no.(%)	164 (40%)	85 (37%)	0.45	110 (41%)	54 (39%)	85 (37%)	0.63
Ethnicity: Not Hispanic	387 (96%)	218 (95%)	0.99	252 (95%)	135 (97%)	218 (95%)	0.54
Race - White <sup>†</sup>	346 (85%)	187 (82%)	0.26	227 (85%)	119 (86%)	187 (82%)	0.46
Education - At least some college	264 (65%)	137 (60%)	0.21	173 (65%)	91 (65%)	137 (60%)	0.40
Marital Status - Married	284 (70%)	162 (71%)	0.94	183 (69%)	101 (73%)	162 (71%)	0.71
Work Status	0.12						
Full or part time	143 (35%)	73 (32%)		87 (33%)	56 (40%)	73 (32%)	
Disabled	31 (8%)	29 (13%)		21 (8%)	10 (7%)	29 (13%)	
Retired	187 (46%)	109 (48%)		132 (50%)	55 (40%)	109 (48%)	
Other	44 (11%)	18 (8%)		26 (10%)	18 (13%)	18 (8%)	
Compensation - Any <sup>‡</sup>	28 (7%)	20 (9%)	0.50	17 (6%)	11 (8%)	20 (9%)	0.61
Mean Body Mass Index (BMI), (SD) <sup>§</sup>	29.4 (5.7)	29.7 (5.6)	0.51	29.4 (5.8)	29.4 (5.5)	29.7 (5.6)	0.80
Smoker	35 (9%)	27 (12%)	0.25	24 (9%)	11 (8%)	27 (12%)	0.41
Comorbidities - no.(%)							
Hypertension	172 (42%)	116 (51%)	0.057	112 (42%)	60 (43%)	116 (51%)	0.14
Diabetes	57 (14%)	39 (17%)	0.38	42 (16%)	15 (11%)	39 (17%)	0.25
Osteoporosis	38 (9%)	22 (10%)	0.96	27 (10%)	11 (8%)	22 (10%)	0.76
Heart Problem	103 (25%)	62 (27%)	0.72	70 (26%)	33 (24%)	62 (27%)	0.77
Stomach Problem	83 (20%)	56 (24%)	0.29	54 (20%)	29 (21%)	56 (24%)	0.51
Bowel or Intestinal Problem	49 (12%)	37 (16%)	0.19	35 (13%)	14 (10%)	37 (16%)	0.25
Depression	43 (11%)	27 (12%)	0.75	35 (13%)	8 (6%)	27 (12%)	0.071
Joint Problem	210 (52%)	136 (59%)	0.081	139 (52%)	71 (51%)	136 (59%)	0.18
Other <sup>¶</sup>	125 (31%)	95 (41%)	0.009	83 (31%)	42 (30%)	95 (41%)	0.026
SF-36 scores, mean (SD) <sup>††</sup>							

Characteristics SpS	One year or less (n=405)	More than one year (n=229)	p-value	6 months or less (n=266)	7 to 12 months (n=139)	More than one year (n=229)	p-value
Bodily Pain (BP)	33.4 (19.9)	33.6 (19.5)	0.87	33.1 (20.5)	33.8 (18.7)	33.6 (19.5)	0.94
Physical Functioning (PF)	35.3 (23.3)	34 (23.2)	0.53	35.8 (24.1)	34.2 (21.7)	34 (23.2)	0.65
Mental Component Summary (MCS)	49 (12)	49.9 (11.8)	0.40	48.8 (12.4)	49.4 (11.1)	49.9 (11.8)	0.63
Oswestry (ODI) (SD) <sup>†‡</sup>	42 (18)	43 (19.3)	0.53	42.4 (18.9)	41.4 (16.3)	43 (19.3)	0.72
Stenosis Frequency Index (0-24) (SD) <sup>§§</sup>	13.8 (5.9)	14 (5.7)	0.74	13.8 (6.1)	13.8 (5.4)	14 (5.7)	0.95
Stenosis Bothersome Index (0-24) (SD) <sup>§§</sup>	14.3 (5.7)	14.4 (5.8)	0.84	14.3 (5.9)	14.2 (5.5)	14.4 (5.8)	0.96
Low Back Pain Bothersomeness (0-6) (SD) <sup>¶¶</sup>	4 (1.8)	4.1 (1.8)	0.46	4.1 (1.8)	4 (1.9)	4.1 (1.8)	0.70
Leg Pain Bothersomeness (0-6) (SD) <sup>¶¶</sup>	4.4 (1.6)	4.2 (1.8)	0.32	4.4 (1.5)	4.3 (1.8)	4.2 (1.8)	0.55
Satisfaction with symptoms - very dissatisfied	281 (69%)	152 (66%)	0.49	180 (68%)	101 (73%)	152 (66%)	0.44
Patient self-assessed health trend - no.(%)			0.003				<0.001
Getting better	40 (10%)	6 (3%)		32 (12%)	8 (6%)	6 (3%)	
Staying about the same	129 (32%)	74 (32%)		93 (35%)	36 (26%)	74 (32%)	
Getting worse	232 (57%)	146 (64%)		138 (52%)	94 (68%)	146 (64%)	
Treatment preference at baseline - no.(%)			0.038				0.086
Preference for non-surg	161 (40%)	68 (30%)		111 (42%)	50 (36%)	68 (30%)	
Not sure	73 (18%)	48 (21%)		48 (18%)	25 (18%)	48 (21%)	
Preference for surgery	170 (42%)	113 (49%)		106 (40%)	64 (46%)	113 (49%)	
Pseudoclaudication - Any	321 (79%)	187 (82%)	0.53	210 (79%)	111 (80%)	187 (82%)	0.75
SLR or Femoral Tension	96 (24%)	36 (16%)	0.023	64 (24%)	32 (23%)	36 (16%)	0.057
Pain radiation - any	326 (80%)	173 (76%)	0.17	215 (81%)	111 (80%)	173 (76%)	0.33
Any Neurological Deficit	227 (56%)	122 (53%)	0.55	151 (57%)	76 (55%)	122 (53%)	0.73
Reflexes - Asymmetric Depressed	110 (27%)	58 (25%)	0.68	69 (26%)	41 (29%)	58 (25%)	0.66
Sensory - Asymmetric Decrease	117 (29%)	65 (28%)	0.97	78 (29%)	39 (28%)	65 (28%)	0.96
Motor - Asymmetric Weakness	121 (30%)	56 (24%)	0.17	87 (33%)	34 (24%)	56 (24%)	0.073
Listhesis Level							
L3-L4	0 (0%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)	
L4-L5	0 (0%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)	

Characteristics SPS	One year or less (n=405)	More than one year (n=229)	p-value	6 months or less (n=266)	7 to 12 months (n=139)	More than one year (n=229)	p-value
Stenosis Levels							
L2-L3	116 (29%)	63 (28%)	0.83	76 (29%)	40 (29%)	63 (28%)	0.95
L3-L4	262 (65%)	158 (69%)	0.31	172 (65%)	90 (65%)	158 (69%)	0.55
L4-L5	364 (90%)	215 (94%)	0.11	242 (91%)	122 (88%)	215 (94%)	0.13
L5-S1	107 (26%)	66 (29%)	0.58	61 (23%)	46 (33%)	66 (29%)	0.075
Stenotic Levels (Mod/Severe)							
None	8 (2%)	7 (3%)	0.32	5 (2%)	3 (2%)	7 (3%)	0.63
One	155 (38%)	79 (34%)		106 (40%)	49 (35%)	79 (34%)	
Two	158 (39%)	83 (36%)		102 (38%)	56 (40%)	83 (36%)	
Three+	84 (21%)	60 (26%)		53 (20%)	31 (22%)	60 (26%)	
Stenosis Locations							
Central	347 (86%)	196 (86%)	0.93	235 (88%)	112 (81%)	196 (86%)	0.11
Lateral Recess	310 (77%)	193 (84%)	0.027	206 (77%)	104 (75%)	193 (84%)	0.057
Neuroforamen	128 (32%)	79 (34%)	0.51	77 (29%)	51 (37%)	79 (34%)	0.22
Stenosis Severity							
Mild	8 (2%)	7 (3%)	0.68	5 (2%)	3 (2%)	7 (3%)	0.49
Moderate	180 (44%)	102 (45%)		126 (47%)	54 (39%)	102 (45%)	
Severe	217 (54%)	120 (52%)		135 (51%)	82 (59%)	120 (52%)	
Instability	0 (0%)	0 (0%)		0 (0%)	0 (0%)	0 (0%)	
Received surgery*	255 (63%)	158 (69%)	0.15	168 (63%)	87 (63%)	158 (69%)	0.31

\* 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 indicates 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 0 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 Bothersomeness and the Leg Pain Bothersomeness Scale range from 0 to 6, with lower scores indicating less severe symptoms.

\* Patients received surgery were classified according to whether they received surgical treatment during the first 4 years of enrollment.



**Table 2**

Operative treatments, complications and events.

Sps	One year or less (n=252)	More than one year (n=159)	p-value	6 months or less (n=168)	7 to 12 months (n=84)	More than one year (n=159)	p-value
Specific procedures <sup>†</sup>			0.11				0.13
Decompression only	224 (90%)	131 (85%)		152 (92%)	72 (87%)	131 (85%)	
Non-instrumented fusion	9 (4%)	13 (8%)		6 (4%)	3 (4%)	13 (8%)	
Instrumented fusion	15 (6%)	10 (6%)		7 (4%)	8 (10%)	10 (6%)	
Multi-level fusion	9 (4%)	7 (4%)	0.87	6 (4%)	3 (4%)	7 (4%)	0.91
Decompression level							
L2-L3	86 (35%)	61 (39%)	0.44	60 (37%)	26 (31%)	61 (39%)	0.49
L3-L4	167 (68%)	115 (74%)	0.23	112 (68%)	55 (66%)	115 (74%)	0.41
L4-L5	222 (90%)	151 (97%)	0.02	147 (90%)	75 (90%)	151 (97%)	0.04
L5-S1	91 (37%)	62 (40%)	0.63	57 (35%)	34 (41%)	62 (40%)	0.54
Levels decompressed			0.31				0.64
None	5 (2%)	3 (2%)		4 (2%)	1 (1%)	3 (2%)	
1	64 (25%)	29 (18%)		41 (24%)	23 (27%)	29 (18%)	
2	79 (31%)	49 (31%)		54 (32%)	25 (30%)	49 (31%)	
3+	104 (41%)	78 (49%)		69 (41%)	35 (42%)	78 (49%)	
Operation time, minutes (SD)	129.8 (65.7)	127.2 (66.1)	0.70	124.3 (61.9)	140.5 (71.8)	127.2 (66.1)	0.17
Blood loss, cc (SD)	304.7 (342.7)	321.9 (487.7)	0.68	303.9 (342.6)	306.3 (345)	321.9 (487.7)	0.92
Blood Replacement							
Intraoperative replacement	27 (11%)	12 (8%)	0.40	18 (11%)	9 (11%)	12 (8%)	0.60
Post-operative transfusion	13 (5%)	7 (4%)	0.93	6 (4%)	7 (8%)	7 (4%)	0.25
Length of hospital stay, days (SD)	3.3 (2.6)	3.1 (2.1)	0.50	3.2 (2.5)	3.5 (2.8)	3.1 (2.1)	0.50
Intraoperative complications <sup>‡</sup>							
Dural tear/ spinal fluid leak	25 (10%)	13 (8%)	0.68	13 (8%)	12 (14%)	13 (8%)	0.21
Other	2 (1%)	1 (1%)	0.68	1 (1%)	1 (1%)	1 (1%)	0.86
None	224 (89%)	144 (91%)	0.65	153 (92%)	71 (85%)	144 (91%)	0.17

Sps	One year or less (n=252)	More than one year (n=159)	p-value	6 months or less (n=168)	7 to 12 months (n=84)	More than one year (n=159)	p-value
Postoperative complications/events <sup>¶</sup>							
Wound hematoma	3 (1%)	1 (1%)	0.97	2 (1%)	1 (1%)	1 (1%)	0.86
Wound infection	6 (2%)	3 (2%)	0.98	3 (2%)	3 (4%)	3 (2%)	0.64
Other	14 (6%)	10 (6%)	0.90	9 (5%)	5 (6%)	10 (6%)	0.93
None	217 (87%)	137 (88%)	0.88	147 (89%)	70 (83%)	137 (88%)	0.48
Post-operative mortality (death within 6 weeks of surgery)	0 (0%)	1 (0.6%)	0.82	0 (0%)	0 (0%)	1 (0.6%)	0.45
Post-operative mortality (death within 3 months of surgery)	0 (0%)	1 (0.6%)	0.82	0 (0%)	0 (0%)	1 (0.6%)	0.45
Additional surgeries (1-year rate) <sup>‡</sup>	11 (4%)	11 (7%)	0.26	7 (4%)	4 (5%)	11 (7%)	0.52
Additional surgeries (2-year rate) <sup>‡</sup>	15 (6%)	17 (10%)	0.08	10 (6%)	5 (6%)	17 (10%)	0.22
Additional surgeries (3-year rate) <sup>‡</sup>	21 (8%)	25 (15%)	0.02	14 (8%)	7 (8%)	25 (15%)	0.07
Additional surgeries (4-year rate) <sup>‡</sup>	24 (9%)	30 (19%)	0.01	17 (10%)	7 (8%)	30 (19%)	0.02
Recurrent stenosis / progressive listhesis	9 (4%)	15 (9%)		7 (4%)	2 (2%)	15 (9%)	
Pseudarthrosis / fusion exploration	0	0		0	0	0	
Complication or Other	8 (3.2%)	10 (6.3%)		5 (3.1%)	3 (3.5%)	10 (6.3%)	
New condition	3 (1.2%)	5 (3.2%)		2 (1.2%)	1	5 (3.2%)	

\* Surgical information was available for 168 patients with duration of symptoms 6 months or less, 84 patients with duration of symptoms 7 to 12 months and 159 patients with duration of symptoms one year or more.

<sup>‡</sup> Specific procedure data were available for 165 patients with duration of symptoms 6 months or less, 83 patients with duration of symptoms 7 to 12 months and 154 patients with duration of symptoms more than one year.

<sup>§</sup> No cases were reported of aspiration into the respiratory tract, vascular injury or operation at wrong level.

<sup>¶</sup> Complications or events occurring up to 8 weeks after surgery are listed. There were no reported cases of bone-graft complication, cerebrospinal fluid leak, nerve root injury, paralysis, cauda equina injury, pseudarthrosis, wound dehiscence.

<sup>//</sup> Rates of repeated surgery at 1, 2,3, and 4 years are Kaplan-Meier estimates. P values were calculated with the use of the log-rank test. Numbers and percentages are based on the first additional surgery if more than one additional surgery.



Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)
<b>SpS</b>												
Stenosis	-8.4 (0.5)	-3.7 (0.5)	-4.8 (-6.1, -3.4)	-8.8 (0.5)	-4.4 (0.5)	-4.3 (-5.7, -2.9)	-8.2 (0.5)	-4.6 (0.5)	-3.6 (-5.1, -2.1)	-7.9 (0.5)	-4.2 (0.6)	-3.7 (-5.2, -2.1)
Bothersomeness Index (0-24) (SE)	-8.2 (0.5)	-3 (0.7)	-5.1 (-6.6, -3.6)	-7.2 (0.5)	-2.6 (0.7)	-4.5 (-6.2, -2.9)	-7 (0.5)	-2.8 (0.8)	-4.2 (-6, -2.4)	-7.4 (0.5)	-2.5 (0.9)	-4.9 (-6.9, -2.9)
<i>pvalue</i>	0.69	0.41	0.70	0.013	0.04	0.84	0.072	0.057	0.59	0.45	0.092	0.33
One year or less	-2.2 (0.1)	-0.9 (0.1)	-1.3 (-1.7, -0.9)	-2.3 (0.1)	-1.1 (0.1)	-1.2 (-1.6, -0.8)	-2.1 (0.1)	-1.1 (0.2)	-1 (-1.4, -0.6)	-1.9 (0.2)	-1 (0.2)	-0.9 (-1.3, -0.5)
More than 1 year	-2 (0.1)	-0.7 (0.2)	-1.3 (-1.7, -0.9)	-1.9 (0.1)	-0.5 (0.2)	-1.3 (-1.8, -0.8)	-1.8 (0.1)	-0.3 (0.2)	-1.5 (-2, -1)	-1.7 (0.2)	-0.5 (0.3)	-1.2 (-1.8, -0.6)
<i>pvalue</i>	0.30	0.34	0.99	0.027	0.05	0.71	0.082	0.002	0.15	0.43	0.047	0.27
One year or less	-2.8 (0.2)	-1.3 (0.2)	-1.4 (-1.8, -1)	-2.8 (0.1)	-1.4 (0.2)	-1.4 (-1.8, -1)	-2.7 (0.2)	-1.8 (0.2)	-0.9 (-1.4, -0.4)	-2.5 (0.2)	-1.5 (0.2)	-1 (-1.5, -0.5)
More than one year	-2.6 (0.1)	-1.1 (0.2)	-1.5 (-2, -1)	-2.4 (0.1)	-0.8 (0.2)	-1.6 (-2.1, -1.1)	-2.4 (0.1)	-0.9 (0.3)	-1.5 (-2.1, -0.9)	-2.7 (0.2)	-1.1 (0.3)	-1.6 (-2.2, -1)
<i>pvalue</i>	0.34	0.40	0.98	0.072	0.027	0.53	0.30	0.005	0.081	0.27	0.32	0.14
One year or less	70.3	29.1	41.2 (30.9, 51.6)	72	30.7	41.3 (30.6, 51.9)	71.5	41.3	30.1 (18.4, 41.9)	70.1	34.5	35.7 (23.4, 48)
More than 1 year	66.8	24.9	41.9 (29.9, 54)	67.4	20.7	46.7(34.3, 59.1)	60.2	21.6	38.6(24.7, 52.5)	55	25.2	29.8 (13.5, 46.1)
<i>pvalue</i>	0.51	0.53	0.90	0.38	0.17	0.50	0.04	0.029	0.38	0.015	0.33	0.69
One year or less	70.8	25.7	45.2 (35.2, 55.1)	70.2	31	39.2 (28.6, 49.8)	64.8	33.3	31.5 (20.1, 43)	53.3	25.6	27.7 (15.7, 39.7)
More than 1 year	66.6	22.1	44.5 (32.9, 56)	58.4	18.6	39.8 (27.6, 52)	58.7	15.1	43.6 (31.2, 56)	54.3	12.7	41.5 (28.2, 54.9)
<i>pvalue</i>	0.43	0.57	0.99	0.031	0.093	0.73	0.27	0.04	0.16	0.89	0.17	0.18

\* Adjusted for age, gender, BMI, race, smoking status, compensation, joint, stomach, bowel, osteoporosis, number of moderate/severe stenotic levels, self-assessed health trend at baseline, treatment preference, baseline stenosis bothersomeness, other \*\* comorbidity, baseline score and center.

\*\* Other comorbidities include: stroke, cancer, fibromyalgia, cfs, PTSD, alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, anxiety

<sup>7</sup> 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.

Table 4

Subgroup results from adjusted\* as-treated outcome analysis by three groups duration of symptoms for the randomized and observational cohorts combined patients with lumbar spinal stenosis.

Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)
SpS	35.3 (2.6)	18.5 (2.1)	16.8 (10.1, 23.5)	35.9 (2.7)	16.2 (2.2)	19.8 (12.8, 26.7)	35.5 (2.7)	19.5 (2.4)	16.1 (8.9, 23.2)	32.1 (2.8)	16.8 (2.5)	15.2 (7.8, 22.6)
	30.4 (2.4)	10.3 (3)	20.1 (12.6, 27.7)	29.9 (2.3)	9.6 (3.1)	20.2 (12.7, 27.8)	29.6 (2.4)	9.9 (3.3)	19.7 (11.7, 27.7)	30.7 (2.6)	11.7 (3.6)	18.9 (10.3, 27.6)
	27.8 (1.7)	9.6 (2.5)	18.2 (12.6, 23.8)	25.2 (1.7)	12.6 (2.7)	12.6 (6.6, 18.7)	25.3 (1.7)	7.6 (3)	17.7 (11.2, 24.3)	23.5 (1.9)	6 (3.3)	17.5 (10.1, 24.8)
<i>p</i> value	0.057	0.008	0.80	0.002	0.20	0.18	0.005	0.003	0.80	0.011	0.031	0.80
SF-36 Bodily Function (PF) (0-100)(SE)	32 (2.6)	14.2 (2)	17.8 (11.3, 24.3)	31.6 (2.6)	13.6 (2.1)	18.1 (11.3, 24.8)	29.1 (2.6)	12.2 (2.3)	16.9 (10, 23.7)	26.5 (2.7)	12.8 (2.4)	13.7 (6.6, 20.8)
	26.7 (2.3)	7.2 (2.8)	19.5(12.3, 26.7)	24.2 (2.2)	11.7 (2.9)	12.4 (5.3, 19.6)	25.5 (2.3)	7.2 (3.1)	18.3 (10.7, 25.9)	24.3 (2.5)	10.9 (3.4)	13.4 (5.1, 21.6)
	22.9 (1.6)	6.7 (2.3)	16.2 (11, 21.4)	18.1 (1.6)	8.3 (2.6)	9.8 (4.2, 15.5)	15.8 (1.7)	6.3 (2.8)	9.5 (3.3, 15.6)	16.5 (1.8)	6.5 (3.1)	10 (3.2, 16.9)
<i>p</i> value	0.01	0.022	0.76	<0.001	0.27	0.17	<0.001	0.19	0.13	0.002	0.27	0.72
Mental Component Summary (MCS)(0-100)(SE)	5.4 (1.1)	2.9 (0.9)	2.5 (-0.3, 5.3)	4.3 (1.1)	1.7 (0.9)	2.6 (-0.3, 5.5)	3.6 (1.1)	2.3 (1)	1.3 (-1.7, 4.2)	2.8 (1.1)	1.6 (1.1)	1.2 (-1.9, 4.3)
	4.3 (1)	2.8 (1.2)	1.5 (-1.7, 4.6)	4 (0.9)	0.8 (1.3)	3.2 (0, 6.3)	3.9 (1)	-0.8 (1.4)	4.6 (1.3, 8)	2.6 (1.1)	-0.9 (1.5)	3.5 (-0.2, 7.2)
	2.3 (0.7)	1.3 (1)	0.9 (-1.4, 3.3)	3 (0.7)	0.6 (1.1)	2.4 (-0.2, 4.9)	1.6 (0.7)	-0.3 (1.3)	1.9 (-0.9, 4.7)	2.1 (0.8)	-1.7 (1.4)	3.8 (0.7, 6.9)
<i>p</i> value	0.032	0.44	0.69	0.49	0.70	0.93	0.099	0.12	0.29	0.85	0.13	0.45
Oswestry Disability Index (ODI) (0-100)(SE)	-24.5 (2)	-11.3 (1.6)	-13.2 (-18.3, -8.1)	-26.5 (2.1)	-10.4 (1.7)	-16 (-21.4, -10.7)	-23.4 (2.1)	-11.6 (1.8)	-11.8 (-17.3, -6.4)	-24 (2.2)	-11.4 (1.9)	-12.6 (-18.3, -6.9)
	-23.3 (1.8)	-5 (2.3)	-18.4 (-24.1, -12.6)	-21.5 (1.7)	-8.2 (2.3)	-13.4 (-19, -7.7)	-20.8 (1.8)	-5.9 (2.5)	-15 (-21, -8.9)	-21.5 (2)	-7.9 (2.7)	-13.6 (-20.1, -7)



Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)	Surgical	Non-operative	Treatment Effect <sup>†</sup> (95% CI)
SpS	66.8	24.9	41.9 (29.9, 53.9)	67	20.7	46.3 (33.9, 58.8)	59.8	21.5	38.2 (24.3, 52.1)	54.5	25.2	29.3 (13.1, 45.6)
	<i>p</i> value	0.33	0.39	0.35	0.37	0.53	0.073	0.064	0.78	0.032	0.42	0.85
6 months or less	69.4	29.1	40.3 (26.6, 54)	72.3	30.1	42.1 (28.1, 56.1)	61.6	35.7	25.9 (10.1, 41.6)	50.1	26.8	23.3 (7.3, 39.2)
7 to 12 months	72.1	19.4	52.7 (38.7, 66.8)	68.6	32.9	35.6 (19.4, 51.9)	67.9	28.8	39.1 (22.3, 55.9)	56.7	23.6	33.2 (15.2, 51.2)
More than 1 year	66.7	22.2	44.5 (32.9, 56.1)	58.2	18.7	39.6 (27.4, 51.8)	58.8	15.1	43.7 (31.2, 56.1)	54.4	12.8	41.6 (28.2, 55)
	<i>p</i> value	0.70	0.46	0.075	0.22	0.80	0.41	0.092	0.19	0.75	0.37	0.31

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\* Adjusted for age, gender, BMI, race, smoking status, compensation, joint, stomach, bowel, osteoporosis, number of moderate/severe stenotic levels, self-assessed health trend at baseline, treatment preference, baseline stenosis bothersomeness, other \*

\*\* Other comorbidities include: stroke, cancer, fibromyalgia, cfs, PTSD, alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, anxiety

<sup>†</sup> 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.



**Table 5**

Patient Baseline Characteristics, Comorbidities and Health Status Measures for Patients with Lumbar Degenerative Spondylolisthesis (DS)

Characteristics	One year or less (n=397)	More than one year (n=204)	p-value	6 months or less (n=240)	7 to 12 months (n=157)	More than one year (n=204)	p-value
Mean Age (SD)	66.1 (10.4)	65.9 (10.2)	0.79	67.1 (10.2)	64.6 (10.4)	65.9 (10.2)	0.062
Female - no.(%)	281 (71%)	131 (64%)	0.12	161 (67%)	120 (76%)	131 (64%)	0.038
Ethnicity: Not Hispanic	390 (98%)	197 (97%)	0.32	238 (99%)	152 (97%)	197 (97%)	0.14
Race - White <sup>†</sup>	329 (83%)	177 (87%)	0.26	202 (84%)	127 (81%)	177 (87%)	0.32
Education - At least some college	266 (67%)	134 (66%)	0.82	155 (65%)	111 (71%)	134 (66%)	0.43
Marital Status - Married	259 (65%)	137 (67%)	0.70	155 (65%)	104 (66%)	137 (67%)	0.85
Work Status	0.70						
Full or part time	142 (36%)	76 (37%)		86 (36%)	56 (36%)	76 (37%)	
Disabled	34 (9%)	17 (8%)		15 (6%)	19 (12%)	17 (8%)	
Retired	167 (42%)	90 (44%)		113 (47%)	54 (34%)	90 (44%)	
Other	54 (14%)	21 (10%)		26 (11%)	28 (18%)	21 (10%)	
Compensation - Any <sup>‡</sup>	27 (7%)	14 (7%)	0.89	17 (7%)	10 (6%)	14 (7%)	0.96
Mean Body Mass Index (BMI), (SD) <sup>§</sup>	29.1 (5.9)	29.3 (6.8)	0.60	28.9 (5.7)	29.3 (6.1)	29.3 (6.8)	0.67
Smoker	37 (9%)	14 (7%)	0.38	25 (10%)	12 (8%)	14 (7%)	0.37
Comorbidities - no.(%)							
Hypertension	179 (45%)	96 (47%)	0.71	114 (48%)	65 (41%)	96 (47%)	0.44
Diabetes	60 (15%)	20 (10%)	0.091	33 (14%)	27 (17%)	20 (10%)	0.12
Osteoporosis	46 (12%)	23 (11%)	0.98	25 (10%)	21 (13%)	23 (11%)	0.66
Heart Problem	76 (19%)	46 (23%)	0.38	50 (21%)	26 (17%)	46 (23%)	0.36
Stomach Problem	78 (20%)	55 (27%)	0.052	42 (18%)	36 (23%)	55 (27%)	0.055
Bowel or Intestinal Problem	26 (7%)	17 (8%)	0.52	12 (5%)	14 (9%)	17 (8%)	0.24
Depression	68 (17%)	30 (15%)	0.52	28 (12%)	40 (25%)	30 (15%)	<0.001
Joint Problem	241 (61%)	103 (50%)	0.021	149 (62%)	92 (59%)	103 (50%)	0.045
Other <sup>¶</sup>	143 (36%)	91 (45%)	0.05	75 (31%)	68 (43%)	91 (45%)	0.007
SF-36 scores, mean (SD) <sup>††</sup>							

Characteristics DS	One year or less (n=397)	More than one year (n=204)	p-value	6 months or less (n=240)	7 to 12 months (n=157)	More than one year (n=204)	p-value
Bodily Pain (BP)	33 (20)	33.8 (17.4)	0.65	32.7 (20.4)	33.5 (19.6)	33.8 (17.4)	0.83
Physical Functioning (PF)	33.9 (22.7)	35.2 (21.8)	0.48	33.2 (21.8)	34.8 (24)	35.2 (21.8)	0.61
Mental Component Summary (MCS)	49.1 (11.6)	52.1 (11)	0.003	49.7 (11.8)	48.1 (11.4)	52.1 (11)	0.004
Oswestry (ODI) (SD) <sup>‡‡</sup>	41.3 (18.3)	42 (17)	0.65	41.1 (17.7)	41.7 (19.2)	42 (17)	0.85
Stenosis Frequency Index (0–24) (SD) <sup>§§</sup>	13.7 (5.6)	14.4 (5.5)	0.19	14.1 (5.6)	13.2 (5.6)	14.4 (5.5)	0.14
Stenosis Bothersome Index (0–24) (SD) <sup>§§</sup>	14.5 (5.8)	15 (5.3)	0.26	14.9 (5.8)	13.8 (5.7)	15 (5.3)	0.087
Low Back Pain Bothersomeness (0–6) (SD) <sup>¶¶</sup>	4.2 (1.9)	4.5 (1.7)	0.039	4.2 (1.8)	4 (1.9)	4.5 (1.7)	0.072
Leg Pain Bothersomeness (0–6) (SD) <sup>¶¶</sup>	4.5 (1.7)	4.7 (1.6)	0.17	4.5 (1.7)	4.4 (1.7)	4.7 (1.6)	0.30
Satisfaction with symptoms - very dissatisfied	276 (70%)	140 (69%)	0.90	163 (68%)	113 (72%)	140 (69%)	0.68
Patient self-assessed health trend - no.(%)			0.009				0.008
Getting better	33 (8%)	5 (2%)		23 (10%)	10 (6%)	5 (2%)	
Staying about the same	131 (33%)	63 (31%)		85 (35%)	46 (29%)	63 (31%)	
Getting worse	226 (57%)	135 (66%)		127 (53%)	99 (63%)	135 (66%)	
Treatment preference at baseline - no.(%)			0.072				0.048
Preference for non-surg	167 (42%)	68 (33%)		109 (45%)	58 (37%)	68 (33%)	
Not sure	90 (23%)	47 (23%)		47 (20%)	43 (27%)	47 (23%)	
Preference for surgery	139 (35%)	89 (44%)		83 (35%)	56 (36%)	89 (44%)	
Pseudoclaudication - Any	331 (83%)	180 (88%)	0.14	199 (83%)	132 (84%)	180 (88%)	0.27
SLR or Femoral Tension	58 (15%)	27 (13%)	0.74	32 (13%)	26 (17%)	27 (13%)	0.60
Pain radiation - any	313 (79%)	155 (76%)	0.49	193 (80%)	120 (76%)	155 (76%)	0.47
Any Neurological Deficit	220 (55%)	107 (52%)	0.55	138 (57%)	82 (52%)	107 (52%)	0.46
Reflexes - Asymmetric Depressed	88 (22%)	62 (30%)	0.035	51 (21%)	37 (24%)	62 (30%)	0.077
Sensory - Asymmetric Decrease	115 (29%)	54 (26%)	0.58	73 (30%)	42 (27%)	54 (26%)	0.59
Motor - Asymmetric Weakness	97 (24%)	49 (24%)	0.99	62 (26%)	35 (22%)	49 (24%)	0.72
Listhesis Level			0.13				0.13
L3–L4	32 (8%)	25 (12%)		16 (7%)	16 (10%)	25 (12%)	
L4–L5	365 (92%)	179 (88%)		224 (93%)	141 (90%)	179 (88%)	

Characteristics DS	One year or less (n=397)	More than one year (n=204)	p-value	6 months or less (n=240)	7 to 12 months (n=157)	More than one year (n=204)	p-value
Stenosis Levels							
L2-L3	32 (8%)	21 (10%)	0.45	18 (8%)	14 (9%)	21 (10%)	0.58
L3-L4	152 (38%)	84 (41%)	0.55	88 (37%)	64 (41%)	84 (41%)	0.57
L4-L5	385 (97%)	195 (96%)	0.52	234 (98%)	151 (96%)	195 (96%)	0.53
L5-S1	40 (10%)	17 (8%)	0.59	27 (11%)	13 (8%)	17 (8%)	0.48
Stenotic Levels (Mod/Severe)							
None	18 (5%)	5 (2%)	0.31	11 (5%)	7 (4%)	5 (2%)	0.66
One	239 (60%)	131 (64%)		146 (61%)	93 (59%)	131 (64%)	
Two	119 (30%)	53 (26%)		72 (30%)	47 (30%)	53 (26%)	
Three+	21 (5%)	15 (7%)		11 (5%)	10 (6%)	15 (7%)	
Stenosis Locations							
Central	353 (89%)	196 (96%)	0.005	212 (88%)	141 (90%)	196 (96%)	0.011
Lateral Recess	355 (89%)	191 (94%)	0.12	215 (90%)	140 (89%)	191 (94%)	0.24
Neuroforamen	159 (40%)	84 (41%)	0.86	101 (42%)	58 (37%)	84 (41%)	0.57
Stenosis Severity							
Mild	18 (5%)	5 (2%)	0.20	11 (5%)	7 (4%)	5 (2%)	0.21
Moderate	148 (37%)	67 (33%)		82 (34%)	66 (42%)	67 (33%)	
Severe	231 (58%)	132 (65%)		147 (61%)	84 (54%)	132 (65%)	
Instability	35 (9%)	12 (6%)	0.27	14 (6%)	21 (13%)	12 (6%)	0.011
Received surgery*	254 (64%)	137 (67%)	0.49	151 (63%)	103 (66%)	137 (67%)	0.64

\* 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 indicates 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 0 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 Bothersomeness and the Leg Pain Bothersomeness Scale range from 0 to 6, with lower scores indicating less severe symptoms.

\* Patients received surgery were classified according to whether they received surgical treatment during the first 4 years of enrollment

**Table 6**

Operative treatments, complications and events.

DS	One year or less (n=251)	More than one year (n=138)	p-value	6 months or less (n=149)	7 to 12 months (n=102)	More than one year (n=138)	p-value
Specific procedures <sup>†</sup>			0.48				0.45
Decompression only	17 (7%)	7 (5%)		9 (6%)	8 (8%)	7 (5%)	
Non-instrumented fusion	48 (20%)	33 (24%)		25 (17%)	23 (23%)	33 (24%)	
Instrumented fusion	181 (74%)	96 (71%)		114 (77%)	67 (68%)	96 (71%)	
Multi-level fusion	49 (20%)	42 (30%)	0.021	34 (23%)	15 (15%)	42 (30%)	0.017
Decompression level							
L2-L3	25 (10%)	20 (15%)	0.23	14 (10%)	11 (11%)	20 (15%)	0.37
L3-L4	122 (50%)	67 (50%)	0.97	72 (49%)	50 (50%)	67 (50%)	0.99
L4-L5	240 (97%)	134 (98%)	0.79	144 (97%)	96 (96%)	134 (98%)	0.70
L5-S1	68 (28%)	45 (33%)	0.28	42 (29%)	26 (26%)	45 (33%)	0.45
Levels decompressed			0.52				0.52
None	3 (1%)	1 (1%)		1 (1%)	2 (2%)	1 (1%)	
1	105 (42%)	54 (39%)		59 (40%)	46 (45%)	54 (39%)	
2	92 (37%)	46 (33%)		60 (40%)	32 (31%)	46 (33%)	
3+	51 (20%)	37 (27%)		29 (19%)	22 (22%)	37 (27%)	
Operation time, minutes (SD)	201.7 (81.5)	215.2 (86.8)	0.13	199.2 (78.2)	205.4 (86.6)	215.2 (86.8)	0.27
Blood loss, cc (SD)	550.2 (432.3)	638.8 (525.8)	0.075	516.9 (383.9)	599.4 (493.2)	638.8 (525.8)	0.081
Blood Replacement							
Intraoperative replacement	76 (31%)	56 (41%)	0.063	42 (28%)	34 (34%)	56 (41%)	0.094
Post-operative transfusion	45 (18%)	36 (26%)	0.096	25 (17%)	20 (20%)	36 (26%)	0.16
Length of hospital stay, days (SD)	4.8 (3.6)	7.2 (31.3)	0.25	4.9 (3.7)	4.7 (3.5)	7.2 (31.3)	0.51
Intraoperative complications <sup>‡</sup>							
Dural tear/ spinal fluid leak	22 (9%)	19 (14%)	0.17	12 (8%)	10 (10%)	19 (14%)	0.28
Vascular injury	0 (0%)	1 (1%)	0.76	0 (0%)	0 (0%)	1 (1%)	0.40
Other	6 (2%)	3 (2%)	0.83	3 (2%)	3 (3%)	3 (2%)	0.88

DS	One year or less (n=251)	More than one year (n=138)	p-value	6 months or less (n=149)	7 to 12 months (n=102)	More than one year (n=138)	p-value
None	223 (89%)	117 (85%)	0.32	134 (90%)	89 (87%)	117 (85%)	0.42
Postoperative complications/events <sup>¶</sup>							
Nerve root injury	1 (0%)	0 (0%)	0.77	1 (1%)	0 (0%)	0 (0%)	0.45
Wound dehiscence	0 (0%)	1 (1%)	0.77	0 (0%)	0 (0%)	1 (1%)	0.41
Wound hematoma	0 (0%)	1 (1%)	0.77	0 (0%)	0 (0%)	1 (1%)	0.41
Wound infection	4 (2%)	7 (5%)	0.10	1 (1%)	3 (3%)	7 (5%)	0.083
Other	22 (9%)	15 (11%)	0.66	16 (11%)	6 (6%)	15 (11%)	0.39
None	180 (73%)	87 (63%)	0.051	110 (74%)	70 (71%)	87 (63%)	0.10
Post-operative mortality (death within 6 weeks of surgery)	1 (0.4%)	0 (0%)	0.76	0 (0%)	1 (1%)	0 (0%)	0.25
Post-operative mortality (death within 3 months of surgery)	2 (0.8%)	0 (0%)	0.76	1 (0.7%)	1 (1%)	0 (0%)	0.55
Additional surgeries (1-year rate) <sup>††</sup>	17 (7%)	8 (6%)	0.73	11 (7%)	6 (6%)	8 (6%)	0.83
Additional surgeries (2-year rate) <sup>††</sup>	29 (11%)	19 (14%)	0.51	19 (13%)	10 (10%)	19 (14%)	0.616
Additional surgeries (3-year rate) <sup>††</sup>	33 (13%)	21 (15%)	0.55	21 (14%)	12 (12%)	21 (15%)	0.716
Additional surgeries (4-year rate) <sup>††</sup>	35 (14%)	23 (17%)	0.46	21 (14%)	14 (14%)	23 (17%)	0.754
Recurrent stenosis / progressive listhesis	11 (5%)	8 (6%)		6 (4%)	5 (5%)	8 (6%)	
Pseudarthrosis / fusion exploration	2 (0.8%)	2 (1.5%)		0	2 (2.1%)	2 (1.5%)	
Complication or Other	16 (6.5%)	9 (6.6%)		10 (6.8%)	6 (6.1%)	9 (6.6%)	
New condition	5 (2.1%)	4 (2.9%)		4 (2.7%)	1	4 (2.9%)	

\*Surgical information was available for 149 patients with duration of symptoms 6 months or less, 102 patients with duration of symptoms 7 to 12 months and 138 patients with duration of symptoms one year or more.

<sup>†</sup>Specific procedure data were available for 148 patients with duration of symptoms 6 months or less, 98 patients with duration of symptoms 7 to 12 months and 136 patients with duration of symptoms more than one year.

<sup>§</sup>No cases were reported of aspiration into the respiratory tract or operation at wrong level.

<sup>¶</sup>Complications or events occurring up to 8 weeks after surgery are listed. There were no reported cases of bone-graft complication, cerebrospinal fluid leak, paralysis, cauda equina injury or pseudarthrosis.

<sup>//</sup>Rates of repeated surgery at 1, 2,3, and 4 years are Kaplan-Meier estimates. P values were calculated with the use of the log-rank test. Numbers and percentages are based on the first additional surgery if more than one additional surgery.

**Table 7**

Subgroup results from adjusted\* as-treated outcome analysis by two groups duration of symptoms (One year or less vs. More than one year) for the randomized and observational cohorts combined patients with lumbar degenerative spondylolisthesis.

Outcome	1-Year		2-Year		3-Year		4-Year	
	Surgical	Non-operative	Surgical	Non-operative	Surgical	Non-operative	Surgical	Non-operative
<b>DS</b>								
<i>Primary Outcomes</i>								
One year or less	34.8 (1.8)	14 (1.7)	32.4 (1.8)	14 (1.9)	34.3 (1.8)	16.1 (2)	32.2 (1.9)	16.2 (2.2)
More than 1 year	30.3 (1.7)	13.3 (2.5)	31.2 (1.6)	11.3 (2.6)	30.7 (1.6)	13.3 (2.9)	29.9 (1.8)	15 (3)
<i>pvalue</i>	0.065	0.81	0.59	0.40	0.12	0.42	0.35	0.73
One year or less	29.3 (1.7)	11.6 (1.6)	25.7 (1.7)	10 (1.8)	24.9 (1.8)	9.9 (1.9)	26.6 (1.9)	8.9 (2.1)
More than 1 year	27.2 (1.7)	9 (2.4)	25.9 (1.6)	8.6 (2.5)	25 (1.6)	7.3 (2.8)	25.8 (1.7)	6.9 (2.9)
<i>pvalue</i>	0.37	0.36	0.93	0.64	0.66	0.45	0.74	0.57
<b>SF-36 Physical Function (PF) (0-100) (SE)</b>								
One year or less	3.4 (0.7)	1.7 (0.7)	2.8 (0.7)	1.3 (0.8)	2.1 (0.8)	0.3 (0.8)	2.5 (0.8)	1 (1)
More than 1 year	2.5 (0.7)	1 (1)	2.4 (0.7)	0 (1.1)	2.9 (0.7)	-0.2 (1.2)	2.1 (0.8)	-1.6 (1.3)
<i>pvalue</i>	0.36	0.61	0.73	0.35	0.57	0.73	0.76	0.12
<b>Mental Component Summary (MCS) (0-100) (SE)</b>								
One year or less	-26.8 (1.3)	-8.1 (1.3)	-24.5 (1.3)	-8.6 (1.4)	-23.1 (1.4)	-10.5 (1.5)	-23.6 (1.4)	-9.8 (1.6)
More than 1 year	-23.3 (1.3)	-6.6 (1.9)	-23.5 (1.2)	-6 (2)	-20.9 (1.2)	-5.6 (2.2)	-22.1 (1.3)	-6 (2.2)
<i>pvalue</i>	0.055	0.48	0.54	0.29	0.60	0.063	0.44	0.16
<b> Oswestry Disability Index (ODI) (0-100) (SE)</b>								
One year or less	18.2	18.2	18.4	18.4	18.4	18.4	18.2	18.2
More than 1 year	17.4	17.4	19.9	19.9	19.9	19.9	17.4	17.4
<i>pvalue</i>	0.51	0.51	0.66	0.66	0.66	0.45	0.44	0.26
<b> Oswestry Disability Index (ODI) (0-100) (SE)</b>								
One year or less	-13.8	-13.8	-16	-16	-16	-16	-12.6	-13.8
More than 1 year	-16.2	-16.2	-17.5	-17.5	-17.5	-17.5	-15.3	-16.2
<i>pvalue</i>	0.46	0.46	0.60	0.60	0.60	0.063	0.39	0.46
<i>Secondary Outcomes</i>								

Spine (Phila Pa 1976). Author manuscript; available in PMC December 1.

Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect† (95% CI)	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 year or less	-3.9 (0.5)	-5.6 (-7, -4.2)	-9 (0.5)	-4.2 (0.5)	-4.8 (-6.2, -3.3)	-9.4 (0.5)	-4.6 (0.6)	-4.9 (-6.4, -3.3)	-9.1 (0.5)	-4.2 (0.6)	-4.8 (-6.5, -3.2)
	More than 1 year	-9.5 (0.5)	-5.5 (-7, -4)	-9.1 (0.4)	-3.3 (0.7)	-5.8 (-7.4, -4.2)	-8.8 (0.5)	-3.7 (0.8)	-5.1 (-6.8, -3.3)	-9.1 (0.5)	-2.7 (0.8)	-6.4 (-8.2, -4.6)
Low Back Pain Bothersomeness (0-6) (SE)	<i>pvalue</i>	0.98	0.91	0.89	0.30	0.36	0.35	0.40	0.87	0.90	0.15	0.20
	One year or less	-2.3 (0.1)	-1.1 (0.1)	-2.1 (0.1)	-1.4 (0.1)	-0.8 (-1.2, -0.4)	-2.2 (0.1)	-1.5 (0.2)	-0.7 (-1.1, -0.3)	-2.1 (0.2)	-1.2 (0.2)	-0.9 (-1.4, -0.4)
More than 1 year	-2.4 (0.1)	-1.1 (0.2)	-2.1 (0.1)	-0.9 (0.2)	-1.3 (-1.8, -0.8)	-2 (0.1)	-1.1 (0.2)	-0.9 (-1.4, -0.4)	-2 (0.1)	-1 (0.2)	-1.1 (-1.6, -0.6)	
<i>pvalue</i>	0.80	0.93	0.93	0.032	0.11	0.28	0.16	0.64	0.66	0.39	0.67	
Leg pain (0-6) (SE)	One year or less	-3 (0.2)	-1.5 (0.1)	-2.8 (0.2)	-1.6 (0.2)	-1.3 (-1.8, -0.8)	-3 (0.2)	-1.7 (0.2)	-1.3 (-1.8, -0.8)	-3.1 (0.2)	-1.7 (0.2)	-1.4 (-1.9, -0.9)
	More than 1 year	-3.1 (0.1)	-1.4 (0.2)	-3 (0.1)	-1.2 (0.2)	-1.8 (-2.3, -1.3)	-2.9 (0.1)	-1.5 (0.2)	-1.4 (-2, -0.8)	-3 (0.2)	-1.2 (0.3)	-1.8 (-2.4, -1.2)
<i>pvalue</i>	0.86	0.77	0.72	0.48	0.074	0.61	0.55	0.83	0.63	0.15	0.34	
Very/somewhat satisfied with symptoms (%)	One year or less	76.4	31.8	44.6 (34.6, 54.7)	73.3	35.9	37.5 (26.3, 48.6)	69.5	39.5	30 (17.7, 42.3)	29.7	36.9 (24.2, 49.6)
	More than 1 year	69.3	16.5	52.8 (42, 63.7)	65.7	24.5	41.2 (28.7, 53.7)	63	28.5	34.5 (20.4, 48.6)	28.4	32 (16.6, 47.3)
<i>pvalue</i>	0.19	0.024	0.29	0.15	0.69	0.25	0.21	0.67	0.31	0.89	0.70	
Self-rated progress major improvement (%)	One year or less	78.2	28.2	50 (40.2, 59.8)	72	26.8	45.2 (34.4, 56)	73.9	28.4	45.5 (34.1, 56.8)	27.9	40.5 (27.8, 53.1)
	More than 1 year	72.6	19.8	52.8 (41.4, 64.2)	73.8	17.8	56.1 (44.8, 67.3)	67.5	18.5	49.1 (36.5, 61.7)	9.1	54.7 (43.4, 66)
<i>pvalue</i>	0.29	0.23	0.73	0.72	0.20	0.20	0.25	0.64	0.45	0.052	0.12	

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\* Adjusted for age, gender, BMI, race, smoking status, compensation, joint, stomach, bowel, osteoporosis, number of moderate/severe stenotic levels, self-assessed health trend at baseline, treatment preference, baseline stenosis bothersomeness, other \*\* comorbidity, baseline score and center.

\*\*\* Other comorbidities include: stroke, cancer, fibromyalgia, cfs, PTSD, alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, anxiety



<sup>7</sup> 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.

**Table 8**

Subgroup results from adjusted\* as-treated outcome analysis by three groups duration of symptoms for the randomized and observational cohorts combined patients with lumbar degenerative spondylolisthesis.

Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)
<i>Primary Outcomes</i>												
6 months or less	36.5 (3.3)	17.1 (2.1)	19.4 (11.6, 27.2)	30.7 (3.3)	16 (2.4)	14.7 (6.6, 22.8)	31.4 (3.6)	18 (2.6)	13.5 (4.8, 22.1)	28.4 (3.6)	16.8 (2.8)	11.6 (2.6, 20.5)
7 to 12 months	34.1 (2.1)	9 (2.7)	25.2 (18.5, 31.8)	33.2 (2.1)	10.7 (2.9)	22.5 (15.5, 29.5)	35.5 (2.1)	13.2 (3.2)	22.4 (14.9, 29.9)	34.1 (2.3)	15.3 (3.5)	18.8 (10.6, 27)
More than 1 year	30.3 (1.7)	13.3 (2.5)	17 (11.4, 22.7)	31.2 (1.6)	11.2 (2.6)	19.9 (14.1, 25.7)	30.7 (1.6)	13.2 (2.9)	17.4 (11.1, 23.8)	29.9 (1.8)	14.9 (3)	15 (8.3, 21.6)
<i>pvalue</i>	0.16	0.052	0.18	0.66	0.26	0.34	0.16	0.36	0.29	0.22	0.88	0.49
6 months or less	32 (3.3)	13.9 (2)	18.1 (10.5, 25.7)	27.1 (3.3)	10.1 (2.3)	17 (9.1, 24.9)	30.4 (3.4)	11.3 (2.5)	19 (10.7, 27.4)	27.4 (3.5)	6.4 (2.7)	21 (12.3, 29.6)
7 to 12 months	28.8 (2)	7.3 (2.6)	21.5 (15.1, 27.8)	25.8 (2)	9.4 (2.8)	16.4 (9.7, 23.1)	23.5 (2)	7.1 (3.1)	16.4 (9.2, 23.6)	27 (2.2)	12.7 (3.4)	14.3 (6.4, 22.2)
More than 1 year	27 (1.7)	8.8 (2.4)	18.2 (12.8, 23.6)	25.7 (1.6)	8.4 (2.5)	17.2 (11.7, 22.8)	24.7 (1.6)	7.2 (2.8)	17.6 (11.5, 23.6)	25.5 (1.7)	6.8 (2.9)	18.8 (12.5, 25.1)
<i>pvalue</i>	0.38	0.083	0.70	0.93	0.89	0.98	0.22	0.42	0.89	0.81	0.29	0.50
6 months or less	3.6 (1.3)	2.3 (0.9)	1.3 (-1.9, 4.5)	3.5 (1.4)	1.4 (1)	2.1 (-1.2, 5.5)	2.1 (1.5)	1.8 (1.1)	0.3 (-3.3, 3.9)	2.4 (1.5)	2.3 (1.2)	0.1 (-3.7, 3.8)
7 to 12 months	3.5 (0.9)	0.6 (1.1)	2.8 (0.1, 5.6)	2.5 (0.9)	1.1 (1.2)	1.5 (-1.5, 4.4)	2.1 (0.9)	-2 (1.4)	4.2 (1, 7.4)	2.6 (1)	-1.2 (1.5)	3.8 (0.3, 7.3)
More than 1 year	2.5 (0.7)	1 (1)	1.5 (-0.9, 3.9)	2.4 (0.7)	0 (1.1)	2.4 (-0.1, 4.8)	2.9 (0.7)	-0.2 (1.2)	3.1 (0.4, 5.7)	2.1 (0.8)	-1.6 (1.3)	3.7 (0.7, 6.6)
<i>pvalue</i>	0.61	0.43	0.69	0.75	0.65	0.90	0.74	0.074	0.25	0.91	0.054	0.25
6 months or less	-25.6 (2.6)	-10.1 (1.6)	-15.5 (-21.4, -9.5)	-21.2 (2.6)	-10.9 (1.8)	-10.3 (-16.4, -4.1)	-21.6 (2.7)	-12.9 (1.9)	-8.7 (-15.2, -2.2)	-20.2 (2.7)	-10.7 (2)	-9.6 (-16.3, -2.9)
7 to 12 months	-27.5 (1.6)	-5.3 (2)	-22.2 (-27.1, -17.3)	-26.1 (1.5)	-5.2 (2.2)	-20.8 (-26.1, -15.6)	-23.9 (1.6)	-7 (2.4)	-16.9 (-22.5, -11.4)	-25.2 (1.7)	-8.8 (2.6)	-16.4 (-22.5, -10.3)

Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)
DS												
More than 1 year	-23.2 (1.3)	-6.5 (1.9)	-16.7 (-20.9, -12.6)	-23.4 (1.2)	-6 (2)	-17.4 (-21.7, -13.1)	-20.7 (1.2)	-5.5 (2.2)	-15.2 (-19.9, -10.5)	-22 (1.3)	-5.9 (2.2)	-16.1 (-21, -11.2)
<i>p</i> value	0.11	0.11	0.14	0.17	0.063	0.031	0.24	0.022	0.14	0.17	0.29	0.23
<i>Secondary Outcomes</i>												
6 months or less	-10.3 (0.9)	-4.1 (0.6)	-6.2 (-8.4, -4)	-9 (0.9)	-4.5 (0.7)	-4.5 (-6.8, -2.3)	-9.3 (1)	-5.3 (0.7)	-4 (-6.4, -1.6)	-9.1 (1)	-4.4 (0.8)	-4.7 (-7.2, -2.2)
7 to 12 months	-9.1 (0.6)	-3.4 (0.7)	-5.7 (-7.6, -3.8)	-9 (0.6)	-3.8 (0.8)	-5.2 (-7.2, -3.2)	-9.5 (0.6)	-3.4 (0.9)	-6.1 (-8.2, -4)	-9 (0.6)	-3.9 (1)	-5.2 (-7.5, -2.9)
More than 1 year	-9.5 (0.5)	-4 (0.7)	-5.5 (-7, -4)	-9.1 (0.4)	-3.3 (0.7)	-5.8 (-7.4, -4.2)	-8.8 (0.5)	-3.7 (0.8)	-5.1 (-6.8, -3.4)	-9.2 (0.5)	-2.7 (0.8)	-6.4 (-8.3, -4.6)
<i>p</i> value	0.52	0.71	0.88	0.99	0.49	0.65	0.66	0.18	0.42	0.99	0.32	0.49
6 months or less	-2.4 (0.2)	-1.1 (0.2)	-1.3 (-1.9, -0.7)	-2.2 (0.3)	-1.5 (0.2)	-0.6 (-1.2, 0)	-2 (0.3)	-1.6 (0.2)	-0.5 (-1.2, 0.2)	-2.1 (0.3)	-1.2 (0.2)	-0.9 (-1.6, -0.2)
7 to 12 months	-2.3 (0.2)	-1.1 (0.2)	-1.2 (-1.7, -0.7)	-2.1 (0.2)	-1.1 (0.2)	-1 (-1.6, -0.4)	-2.2 (0.2)	-1.3 (0.3)	-0.9 (-1.5, -0.3)	-2.2 (0.2)	-1.3 (0.3)	-0.9 (-1.6, -0.2)
More than 1 year	-2.4 (0.1)	-1.1 (0.2)	-1.3 (-1.7, -0.9)	-2.1 (0.1)	-0.9 (0.2)	-1.3 (-1.8, -0.8)	-2 (0.1)	-1.1 (0.2)	-0.9 (-1.4, -0.4)	-2.1 (0.1)	-1 (0.2)	-1.1 (-1.6, -0.6)
<i>p</i> value	0.86	0.99	0.91	1	0.043	0.25	0.48	0.25	0.53	0.86	0.68	0.87
6 months or less	-3.2 (0.3)	-1.8 (0.2)	-1.4 (-2.1, -0.7)	-2.8 (0.3)	-1.9 (0.2)	-0.9 (-1.6, -0.2)	-3 (0.3)	-2 (0.2)	-1 (-1.7, -0.3)	-3.3 (0.3)	-1.8 (0.2)	-1.5 (-2.3, -0.7)
7 to 12 months	-3 (0.2)	-1 (0.2)	-1.9 (-2.5, -1.3)	-2.9 (0.2)	-1.1 (0.3)	-1.8 (-2.4, -1.2)	-3 (0.2)	-1.2 (0.3)	-1.8 (-2.5, -1.1)	-3 (0.2)	-1.5 (0.3)	-1.5 (-2.2, -0.8)
More than 1 year	-3.1 (0.1)	-1.4 (0.2)	-1.6 (-2.1, -1.1)	-3 (0.1)	-1.1 (0.2)	-1.8 (-2.3, -1.3)	-2.9 (0.1)	-1.5 (0.2)	-1.4 (-2, -0.8)	-3 (0.2)	-1.2 (0.3)	-1.8 (-2.4, -1.2)
<i>p</i> value	0.74	0.096	0.55	0.74	0.018	0.056	0.86	0.099	0.26	0.46	0.23	0.79
6 months or less	81.2	35	46.3 (31.3, 61.2)	76	41.8	34.3 (17.1, 51.4)	78.7	45.2	33.5 (15.5, 51.5)	69.3	27.3	42 (23.1, 60.9)
7 to 12 months	74.6	26.4	48.2 (34.7, 61.8)	72.5	27	45.4 (30.9, 60)	66.2	30.6	35.6 (19.2, 52)	65.8	32.6	33.2 (14.9, 51.5)

Outcome	1-Year			2-Year			3-Year			4-Year		
	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)	Surgical	Non-operative	Treatment Effect† (95% CI)
DS												
More than 1 year	69.4	16.5	52.9 (42.1, 63.7)	65.7	24.5	41.2 (28.7, 53.7)	62.9	28.4	34.5 (20.4, 48.6)	60.4	28.4	32 (16.7, 47.3)
<i>p</i> value	0.31	0.038	0.78	0.31	0.083	0.72	0.18	0.12	1	0.53	0.88	0.75
6 months or less	72.4	32	40.4 (23.6, 57.2)	73.2	28.9	44.3 (27.1, 61.4)	70.9	37.7	33.2 (13.9, 52.4)	60.1	30.6	29.6 (8.9, 50.2)
7 to 12 months	80.5	22.7	57.8 (45.2, 70.3)	71.7	23.5	48.3 (34, 62.5)	75.2	15.9	59.3 (46.1, 72.5)	71.8	23.6	48.2 (31.6, 64.8)
Self-rated major improvement (%)	72.4	19.6	52.8 (41.5, 64.1)	73.5	17.6	55.9 (44.7, 67.1)	67.3	18.2	49.1 (36.6, 61.7)	63.6	8.9	54.7 (43.4, 65.9)
<i>p</i> value	0.32	0.22	0.25	0.95	0.36	0.50	0.41	0.029	0.10	0.32	0.12	0.12

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\* Adjusted for age, gender, BMI, race, smoking status, compensation, joint, stomach, bowel, osteoporosis, number of moderate/severe stenotic levels, self-assessed health trend at baseline, treatment preference, baseline stenosis bothersomeness, other \*

\*\* Other comorbidities include: stroke, cancer, fibromyalgia, cfs, PTSD, alcohol, drug dependency, lung, liver, kidney, blood vessel, nervous system, migraine, anxiety

† 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 patient's 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.