Does obesity affect outcomes of treatment for lumbar stenosis and degenerative spondylolisthesis? Analysis of the Spine Patient Outcomes Research Trial (SPORT)

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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 obesity affects treatment outcomes for lumbar stenosis (SpS) and degenerative spondylolisthesis (DS).

Summary of Background Data—Obesity is thought to be associated with increased complications and potentially less favorable outcomes following the treatment of degenerative conditions of the lumbar spine. This, however, remains a matter of debate in the existing literature.

Methods—An as-treated analysis was performed on patients enrolled in the Spine Patient Outcomes Research Trial (SPORT) for the treatment of SpS or DS. A comparison was made between patients with a body mass index (BMI) <30 ("non-obese", n=373 SpS, 376 DS) and those with a BMI ≥ 30 ("obese", n=261 SpS, 225 DS). Baseline patient characteristics, intraoperative data, and complications were documented. Primary and secondary outcomes were measured at baseline and regular follow-up time intervals up to 4 years. The difference in improvement over baseline between surgical and nonsurgical treatment (i.e. treatment effect) was determined at each follow-up interval for the obese and nonobese groups.

Results—At 4-years follow-up, operative and nonoperative treatment provided improvement in all primary outcome measures over baseline in patients with BMI of < 30 and ≥ 30. For SpS patients, there were no differences in the surgical complication or reoperation rates between groups. DS patients with BMI ≥ 30 had a higher postoperative infection rate (5% vs. 1%, p=0.05) and twice the reoperation rate at 4-years follow-up (20% vs. 11%, p=0.01) than those with BMI < 30. At 4-years, surgical treatment of SpS and DS was equally effective in both BMI groups in terms of the primary outcome measures, with the exception that obese DS patients had less improvement from baseline in the SF36 physical function score compared to nonobese patients (22.6 vs. 27.9, p=0.022). With nonoperative treatment, SpS patients with BMI ≥ 30 did worse in regards to all three primary outcome measures, and DS patients with BMI ≥ 30 had similar SF-36

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bodily pain scores but less improvement over baseline in the SF-36 physical function and ODI scores. Treatment effects for SpS and DS were significant within each BMI group for all primary outcome measures, in favor of surgery. Obese patients had a significantly greater treatment effect compared to nonobese patients with SpS (ODI, p=0.037) and DS (SF36 PF, p=0.004), largely due to the relatively poor outcome of nonoperative treatment in obese patients.

Conclusion—Obesity does not affect the clinical outcome of operative treatment for SpS. There are higher rates of infection and reoperation and less improvement from baseline in the SF-36 physical function score in obese patients following surgery for DS. Nonoperative treatment may not be as effective in obese patients with SpS or DS.

Keywords

surgery; lumbar; spinal stenosis; degenerative spondylolisthesis; outcomes; body mass index (BMI)

Introduction

The obesity epidemic in the United States has come to the forefront of medical debate over the last decade. Based on 2005-2006 epidemiological data, 32.7 percent of U.S. adults 20 years and older are overweight, 34.3 percent are obese and 5.9 percent are extremely obese [1]. Body mass index (BMI), expressed as a weight to height ratio (kg/m^2), is used to characterize an individual's body fat. A BMI greater than 30 defines obesity. Obesity has been shown to be a significant risk factor for and contributor to increased morbidity and mortality, cardiovascular disease, diabetes, osteoarthritis, sleep apnea, and depression, and reduced quality of life [2,3]. Additionally, obesity has been shown to be an independent predictor of back pain and its severity [5], and may also play a role in the chronicity and recurrence of low back pain [4]. More specifically, obesity has been associated with lumbar disc degeneration leading to low back pain, sciatica, and lumbar spinal stenosis [6].

The mechanism by which obesity causes lumbar disc degeneration is not well understood, but is likely the result of a combination of factors. Both static compressive loading and increased pressures with particular postures may result in damage to the integrity of the disc, followed by mechanical compression or chemical damage to the nerve roots [7]. In addition, the acute response of the spine to loading may represent a risk factor for low back pain in the obese. A greater period of recovery is necessary for obese individuals to re-establish intervertebral disc height after such a load [8]. Recent studies indicate a genetic component in disc degeneration in the obese. A collagen IX polymorphism (Trp3 allele) seems to act synergistically with persistent obesity in the development posterior disc bulge, decreased disc height, and dark nucleus pulposis [9]. The systemic effects of a common inflammatory mechanism have also been implicated in the development of disc degeneration [10].

Several studies have shown a clear link between obesity and increased complication rates after spine surgery [11]. Complications include wound infection, cerebrospinal fluid leak, deep vein thrombosis, cardiac events, pneumonia, prolonged intubation, pseudoarthrosis, urological issues, and position-related palsies. Obesity was found to be an independent risk factor for surgical site infection, both superficial and deep [34]. Obese spine patients also have increased transfusion requirements and utilize more resources [12]. The increased complication rate may be related to more difficult exposure, dissection, retraction and longer operating times [22].

There remains much controversy as to whether obesity influences the outcome of surgical treatment of spinal disease [23]. Most recent studies conclude that obese patients can achieve similar benefits to non-obese patients provided the indications for surgical

intervention are based on sound clinical judgment [24,25,26,27]. There is equivocal evidence on the influence of obesity on the outcome of treatment of patients with lumbar spinal stenosis and degenerative spondylolisthesis. The purpose of this study is to use the SPORT database to determine whether or not obesity affects the clinical outcome of the treatment of stenosis and degenerative spondylolisthesis. We hypothesize that obesity will be associated with a worse outcome after treatment of lumbar spinal stenosis and degenerative spondylolisthesis.

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. [13] [14] [15]

Patient Population

All patients had neurogenic claudication or radicular leg pain with associated neurological signs, spinal stenosis 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 degenerative spondylolisthesis 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

Stenosis and degenerative spondylolisthesis 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 can 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 and physical function domains of the SF-36 [16] and the American Academy of Orthopaedic Surgeons MODEMS (Musculoskeletal Outcomes Data Evaluation and Management System) version of the Oswestry Disability Index. [17] Secondary measures included patient self-reported

improvement, work status, and satisfaction with current symptoms and with care, and the mental component score of the SF-36. [18] Symptom severity was measured by the low back pain bothersomeness scale (Ranges from 0 to 6, with lower scores indicating less severe symptoms), the sciatica bothersomeness index (SBI, Range from 0 to 24, with lower scores indicating less severe symptoms), and leg pain bothersomeness index. [19] [20] [21] 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.

Statistical Analysis

Baseline characteristics between nonobese (BMI 30) and obese groups (BMI>30) were compared using a chi-square test for categorical variables and t-tests for continuous variables. Primary analyses compared surgical and non-operative treatments using changes from baseline at each follow-up, with a mixed effects longitudinal regression model including a random individual effect to account for correlation between repeated measurements within individuals. Because of the crossover, analyses were based on treatments actually received in the combined randomized and observational cohorts. In these as-treated analyses, the treatment indicator was a time-varying covariate, allowing for variable times of surgery. Times are measured from the beginning of treatment, i.e. the time of surgery for the surgical group and the time of enrollment for the non-operative group. Therefore, all changes from baseline prior to surgery were included in the estimates of the non-operative treatment effect. After surgery, changes were assigned to the surgical group with follow-up measured from the date of surgery. Repeated measures of outcomes were used as the dependent variables, and treatment received was included as a time-varying covariate. To adjust for potential confounding, baseline variables associated with missing data or treatment received were included as adjusting covariates in longitudinal regression models. In addition, age, gender, race, smoking status, compensation, comorbidities, diagnosis, center, treatment preference, self-assessed health trend, and baseline outcome scores (for SF36 and ODI) were included in longitudinal regression models. Secondary and binary outcomes were analyzed using generalized estimating equations (GEE) that assumed a compound symmetry working correlation structure. The outcomes were stratified by obesity and outcomes between these sub-groups at each time-point were compared using a multiple degrees of freedom Wald test. Across the four- year follow-up, overall comparisons of area-under-curve between these sub-groups were made by using a Wald test. Computations were done using SAS procedures PROC MIXED for continuous data and PROC GENMOD for binary and non-normal secondary outcomes (SAS version 9.1 Windows XP Pro, Cary, NC). Statistical significance was defined as p < 0.05 based on a two-sided hypothesis test with no adjustments made for multiple comparisons.

Results

Spinal Stenosis

There were 373 patients in the spinal stenosis group with a BMI < 30 and 261with a BMI 30. Differences between the groups at baseline are noted in Table 1. Significant demographic differences were noted between the groups in mean age, education, income under 50,000, work status, and compensation claim. The mean BMI in the nonobese and obese groups for the stenosis cohort was 25.9 ± 2.9 and 34.6 ± 4.5, respectively (p<0.001). Comorbidities differed significantly between the groups at baseline (Table 1). The obese patient group was noted to contain a higher percentage of hypertension, diabetes, depression, heart problems, stomach problems, bowel problems, and other problems. The obese patients were noted to have worse baseline self reported scores on the SF36 physical functioning,

vitality, and physical component summary domains. At baseline, a larger percentage of the obese patients had an asymmetric sensory decrease (Table 1).

Operative details of the spinal stenosis patients are presented in Table 2. Obese patients were more likely to have the L2-3 level included in the decompression compared to the nonobese patients (43% versus 32%, p=0.029). There were no significant differences in operation time, blood loss, and length of hospital stay between the groups. There were no significant differences between the groups in the incidence of nerve root injury, wound hematoma, wound infection, perioperative mortality, recurrence, or need for additional surgeries.

The change in primary outcome measures of the surgically treated spinal stenosis patients can be seen in Supplemental Digital Content Appendix Table A. At 4-years follow-up, there were no statistically significant differences between surgically treated obese and nonobese patients in all three of the primary outcome measures. Furthermore, at 4-years follow-up, there were no statistically significant differences noted between the two groups in the secondary outcome measures (Supplemental Digital Content Appendix Table C)).

Of the nonoperatively treated spinal stenosis patients, the obese patients had significantly less improvement from baseline in the ODI (-3.7 versus -12.7, p<0.001), SF36 bodily pain (8.2 versus 16.6, p=0.017), and SF36 physical function scores (5.4 versus 15.1, p=0.004) at 4-years follow-up (Supplemental Digital Content Appendix Table B). There were no significant differences between obese and nonobese patients in the SF36 mental component scores. Obese patients had significantly less improvement over baseline than the nonobese patients in low back pain bothersomeness (-0.3 versus -1.1, p=0.014) and a significantly worse self rated assessment of progress (13% versus 30.2%, p=0.017) at 4-years follow-up (Supplemental Digital Content Appendix Table D).

The treatment effect of surgery is the change in outcome of the surgically treated patients minus the change in outcome of the nonsurgically treated patients, i.e. the differential benefit in improvement of surgically treated patients and the nonsurgically treated patients. There was a statistically significant difference in treatment effect of surgery between obese and nonobese patients in the Oswestry Disability Index at four years (Table 3), with a greater treatment effect observed in the obese patients. This suggests that surgery has a significantly greater benefit over nonsurgical treatment in obese patients, largely due to the relatively poor outcome observed with nonsurgical treatment in obese patients (Figure 1). However, the treatment effects were not significantly different for the other primary and secondary outcome measures between obese and nonobese patients (Table 3 and Table 4).

Degenerative Spondylolisthesis

In the DS study, there were 376 patients with a BMI of <30 ("nonobese") and 225 patients with a BMI of 30 ("obese"). Differences between the groups at baseline are noted in Table 1. Significant baseline differences between the DS patient subgroups were present in the mean age, gender, race, education, income, marital status, and work status. The mean BMI in the nonobese and obese groups for the degenerative spondylolisthesis cohort was 25.5 ± 2.9 and 35.3 ± 5.4, respectively (p<0.001). The obese patients group had a higher incidence of medical comorbidities, including hypertension, diabetes, depression, stomach problem, and other comorbidities. Baseline SF36 scores, ODI scores, back pain bothersomeness index, and self-perceived health trend were significantly worse in the obese patient group. There was a significant difference in the number of stenotic levels. There was a higher incidence of central stenosis. There was a lower incidence of severe stenosis in the obese group compared to the nonobese patient group.

Operative details of the DS patient group are described in Table 2. A higher proportion of obese patients underwent instrumented fusion and a lower percentage underwent decompression alone. Operative time was significantly higher in the obese patient group (mean 220.2 minutes versus 197.2 minutes, p=0.008). The incidence of intraoperative complications was significantly lower in the obese patient group; in particular the incidence of dural tear, which occurred in 5% of the obese patients and 14 % of the nonobese patients (p=0.007). There was a trend towards an increased rate of wound infection in the obese patients compared to the nonobese patients (5% versus 1%, p=0.051). There was a significantly higher rate of additional surgeries at 4-year follow-up (20% versus 11%, p=0.013) in the obese patient group compared to the nonobese patient group.

The change in primary outcome measures in the surgically treated DS patients demonstrated that obese patients had significantly less improvement from baseline compared to the nonobese patients in regards to the SF36 physical function scores (22.1 versus 27.9, 4-yr follow-up, p=0.022) (Supplemental Digital Content Appendix Table A). The other primary outcome measures did not display significant differences between the obese and nonobese patients (Supplemental Digital Content Appendix Table A). There were no significant differences in the secondary outcome measures between the obese and nonobese patients who were treated surgically for DS, with the exception of a significantly less improvement over baseline in obese patients compared to nonobese patients (-6.8 vs. -8.1, p value=0.04) in the stenosis bothersomeness index at the 3-year follow-up time point (Supplemental Digital Content Appendix Table C).

Obese nonsurgically treated DS patients demonstrated significantly worse in SF36 physical function and ODI scores compared to nonobese patients (Supplemental Digital Content Appendix Table B). At 4-years follow-up, obese patients treated nonoperatively had SF-36 physical function scores that worsened from baseline by a mean of mean 3.5. This is in comparison to a mean improvement of 13.9 points in the SF36 physical function score over baseline in nonoperatively treated nonobese patients at same follow-up time period (p<0.001). Obese nonsurgically treated patients also had significantly less improvement from baseline in the stenosis bothersomeness index compared to nonobese patients at 4-years follow-up (-8.2 versus -9.7, p=0.039) (Supplemental Digital Content Appendix Table D).

The treatment effect for the SF36 Physical Function score was significantly higher for the obese group at 4-years follow-up (25.6 versus 14.0, p=0.004, Table 3). This suggests that surgery has a significantly greater benefit over nonsurgical treatment of degenerative spondylolisthesis in obese patients, largely due to the relatively poor outcome observed with nonsurgical treatment in obese patients (Figure 2). There was no significant difference in the treatment effects for other primary outcome measures or secondary outcome measures between obese and nonobese patients (Table 3 and Table 4).

Discussion

In the original SPORT publications dealing with spinal stenosis and degenerative spondylolisthesis, an as-treated analysis combining the randomized and observational cohorts demonstrated that the clinically relevant advantages of surgery that had been previously reported through two years were maintained at four years [28]. This finding is also supported by findings of the Maine Lumbar Spine Study, in which 8- to 10-year follow-up favored those patients initially receiving surgical treatment [29]. Amundsen, Weber et al., in another long-term follow-up study comparing surgical and conservative treatment of lumbar spinal stenosis, found favorable outcomes in those treated surgically [30]. Despite

similar findings favoring surgery in these long-term prospective studies, they did not take into account the effects of obesity on outcomes.

The results of the current study support the hypothesis that obesity is associated with worse outcome after nonoperative treatment of both lumbar spinal stenosis and degenerative spondylolisthesis. However, obesity does not seem to be associated with worse outcome after surgical treatment of these conditions, with the exception of an increased reoperation rate and a lower SF-36 Physical Function score in the obese patients with degenerative spondylolisthesis. There were no differences noted at 4-years follow-up between obese and nonobese patients treated surgically for lumbar stenosis.

There was noted, in the current, study to be significant differences in treatment effect between obese and nonobese patients. This was true for the ODI treatment effect in the SpS cohort and the SF-36 Physical function treatment effect in the DS cohort, with obese patients demonstrating a significantly greater treatment effect than the nonobese patients. This significant difference in treatment effect in both instances is largely the result not of overwhelming improvement in surgical outcomes in obese patients, but rather an overwhelming lack of improvement or even a worsening of outcomes following nonoperative treatment in the obese patients. The lack of efficacy of nonoperative treatment in obese patients is an important finding, and explanation of which is not readily apparent. There is a relative lack of evidence regarding the affect of obesity on nonoperative interventions for lumbar degenerative conditions. It is possible that current nonoperative interventions are not as effective in obese patient and that alternative nonoperative treatments should be developed and further investigated for this patient population. It also suggests that currently, surgery may be a better option than the available nonsurgical options in obese patients.

Previous studies have found no influence of obesity on clinical outcome. In a prospective study of mixed lumbar diagnoses, Andreshak et al. found no significant differences between obese and control patients relative to blood loss, operative time, length of hospital stay, rate of complications, and functional outcome [25]. Gepstein et al. similarly showed similar reduction in pain, improvement of daily activities and overall satisfaction in obese and non-obese elderly patients undergoing lumbar spine surgery [31]. Djurasovic et al., in a retrospective analysis of obese and non-obese patients undergoing lumbar fusion, found no significant difference in back pain, leg pain, SF-36, or ODI scores at two-year follow up [26]. In a prospective review of patients undergoing anterior lumbar disc procedures, Peng et al. showed no significant difference in complication rates in obese patients, but did find longer duration of anterior exposure, duration of entire surgery, and longer incision. Obesity did not affect blood loss, analgesic use, length of time to ambulation, or length of hospitalization [32]. In obese and non-obese patients undergoing minimally invasive lumbar fusion, Rosen et al showed no significant difference with most self-reported outcome measures, operative time, length of hospital stay, or complications [33]. In regard to patients being treated surgically for spinal stenosis, our report supports the finding that obese patients have similar complication rates, reoperation rates, and clinical outcomes compared to nonobese patients. Obese patients with degenerative spondylolisthesis, on the other hand, were found to have an increased wound infection rate and twice the reoperation rate at 4-years follow-up. With the exception of having a lower SF-36 Physical function score, however, obese patients with DS who were treated surgically did similar to the nonobese patients at 4-years follow-up. Interestingly, obese patients with DS treated surgically had a lower intraoperative complication rate than nonobese patients, including a significantly lower dural tear rate.

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 are confounding variables that are not equally distributed between treatment groups in this "as treated" analysis. For instance, there are significant differences in the demographic characteristics, outcome scores, and preference for surgery between obese and nonobese patients in both groups. Additionally, the SPORT was not specifically powered to include analysis of specific patient subgroups. However, the SPORT represents the largest study to date on SpS and DS patients and is the most likely to be powered to address questions posed in subgroup analysis.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Key Points

- Regardless of body mass index, patients treated surgically had improved outcomes at all time points relative to those treated nonoperatively

- Obese patients undergoing surgery for degenerative spondylolisthesis have an increased wound infection rate and have two times the reoperation rate than nonobese patients at 4-years follow-up.

- Body mass index does not have an effect on clinical outcome following the surgery treatment of lumbar stenosis.

- Obese patients treated nonoperatively had worse clinical outcomes than nonobese patients treated nonoperatively for both the lumbar stenosis and degenerative spondylolisthesis cohorts.
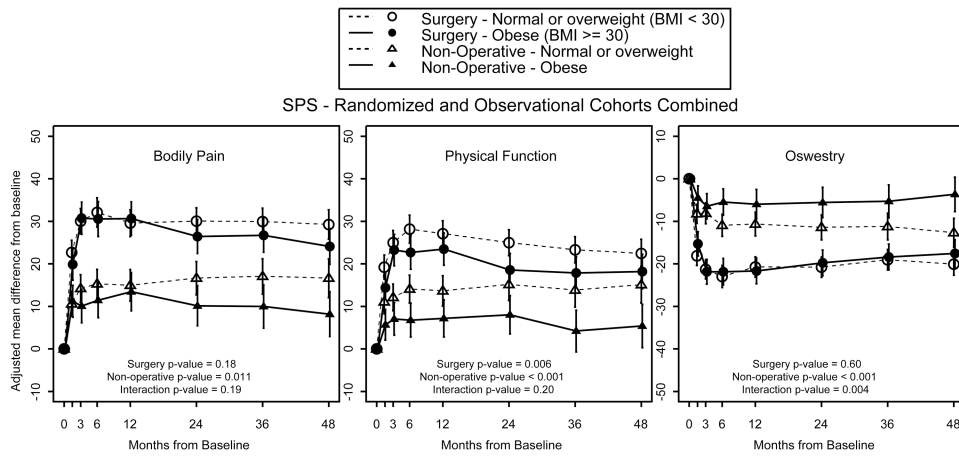
Figure 1.
Comparison of primary outcome measures for patients with stenosis treated surgically versus nonoperatively at baseline and at follow-up time periods out to 4-years.
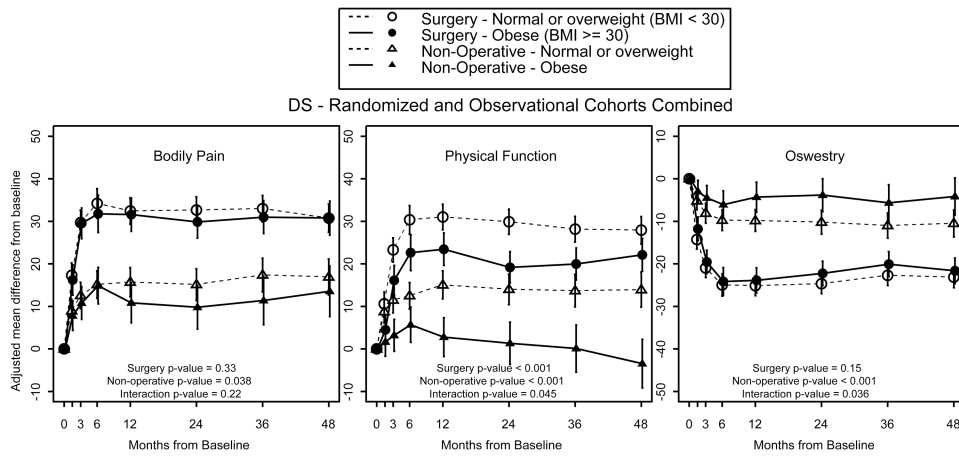
Figure 2.
Comparison of primary outcome measures for patients with degenerative spondylolisthesis treated surgically versus nonoperatively at baseline and at follow-up time periods out to 4-years.

Table 1

Patient Baseline Demographic Characteristics, Comorbid Conditions, Clinical Findings, and Health Status Measures.

Characteristics	Spinal Stenosis			Degenerative Spondylolisthesis		
	Normal or overweight (BMI<30)	Obese (BMI ≥30)	p-value	Normal or overweight (BMI<30)	Obese (BMI ≥30)	p-value
	(n=373)	(n=261)		(n=376)	(n=225)	
Mean Age (SD)	66.2 (12.2)	62.3 (10.5)	<0.001	67.4 (10.5)	63.7 (9.5)	<0.001
Female - no.(%)	139 (37%)	110 (42%)	0.25	241 (64%)	171 (76%)	0.003
Ethnicity: Not Hispanic†	356 (95%)	249 (95%)	0.87	366 (97%)	221 (98%)	0.68
Race - White†	319 (86%)	214 (82%)	0.28	326 (87%)	180 (80%)	0.039
Education - At least some college	249 (67%)	152 (58%)	0.035	263 (70%)	137 (61%)	0.029
Income - Under $50,000	58 (16%)	64 (25%)	0.007	67 (18%)	70 (31%)	<0.001
Marital Status - Married	261 (70%)	185 (71%)	0.87	260 (69%)	136 (60%)	0.037
Work Status			<0.001			0.043
Full or part time	109 (29%)	89 (34%)		115 (31%)	77 (34%)	
Disabled	24 (6%)	36 (14%)		25 (7%)	26 (12%)	
Other	240 (64%)	136 (52%)		236 (63%)	122 (54%)	
Compensation - no. (%)‡	14 (4%)	34 (13%)	<0.001	23 (6%)	18 (8%)	0.47
Mean Body Mass Index (BMI), (SD)§	25.9 (2.9)	34.6 (4.5)	<0.001	25.5 (2.9)	35.3 (5.4)	<0.001
Smoker	41 (11%)	21 (8%)	0.27	35 (9%)	16 (7%)	0.43
Comorbidities - no.(%)						
Hypertension	151 (40%)	137 (52%)	0.004	144 (38%)	131 (58%)	<0.001
Diabetes	32 (9%)	64 (25%)	<0.001	30 (8%)	50 (22%)	<0.001
Depression	29 (8%)	41 (16%)	0.003	50 (13%)	48 (21%)	0.014
Heart Problem	110 (29%)	55 (21%)	0.022	71 (19%)	51 (23%)	0.31
Lung Problem	28 (8%)	20 (8%)	0.94	25 (7%)	20 (9%)	0.40
Stomach Problem	76 (20%)	63 (24%)	0.30	66 (18%)	67 (30%)	<0.001
Bowel or Intestinal Problem	39 (10%)	47 (18%)	0.009	26 (7%)	17 (8%)	0.90
Liver Problem	6 (2%)	4 (2%)	0.80	3 (1%)	5 (2%)	0.27
Kidney Problem	16 (4%)	13 (5%)	0.83	13 (3%)	14 (6%)	0.17

Characteristics	Spinal Stenosis			Degenerative Spondylolisthesis		
	Normal or overweight (BMI<30) (n=373)	Obese (BMI ≥30) (n=261)	p-value	Normal or overweight (BMI<30) (n=376)	Obese (BMI ≥30) (n=225)	p-value
Blood Vessel Problem	19 (5%)	19 (7%)	0.33	26 (7%)	12 (5%)	0.55
Nervous System Problem	5 (1%)	8 (3%)	0.22	13 (3%)	9 (4%)	0.91
Joint Problem	197 (53%)	149 (57%)	0.33	207 (55%)	137 (61%)	0.19
Other¶	289 (77%)	209 (80%)	0.49	278 (74%)	198 (88%)	<0.001
SF-36 scores, mean(SD) ††						
Bodily Pain (BP)	34.5 (20.2)	32 (18.9)	0.12	34.6 (19)	31.2 (19.3)	0.033
Physical Functioning (PF)	36.7 (23.9)	32.1 (22.2)	0.013	38.2 (22.9)	27.9 (20)	<0.001
Vitality (VT)	45.3 (22.1)	38.5 (20.6)	<0.001	46.8 (21.6)	37.8 (22.2)	<0.001
Physical Component Summary (PCS)	30.4 (8.8)	28.7 (8.3)	0.018	30.7 (8.3)	27.6 (8.2)	<0.001
Mental Component Summary (MCS)	49.8 (12.2)	48.6 (11.4)	0.20	50.6 (11.2)	49.2 (12)	0.13
Oswestry Disability Index (ODI)(SD)‡‡	41.3 (19.2)	44 (17.4)	0.067	39.7 (17.8)	44.7 (17.6)	0.001
Sciatica Frequency Index (0-24)(SD)§§	13.9 (5.6)	13.8 (6)	0.84	13.9 (5.6)	14 (5.5)	0.77
Sciatica Bothersome Index (0-24)(SD)§§	14.4 (5.4)	14.3 (6.2)	0.83	14.5 (5.7)	15.1 (5.4)	0.22
Back Pain Bothersomeness (0-6)(SD)¶¶	4 (1.8)	4.2 (1.9)	0.31	4.1 (1.9)	4.5 (1.6)	0.005
Satisfaction with symptoms - very dissatisfied	259 (69%)	174 (67%)	0.52	253 (67%)	163 (72%)	0.22
Patient self-assessed health trend - no.(%)			0.79			0.044
Getting better	26 (7%)	20 (8%)		29 (8%)	9 (4%)	
Staying about the same	123 (33%)	80 (31%)		128 (34%)	66 (29%)	
Getting worse	219 (59%)	159 (61%)		212 (56%)	149 (66%)	
Treatment preference at baseline - no.(%)			0.66			0.10
Preference for non-surg	140 (38%)	89 (34%)		158 (42%)	77 (34%)	
Not sure	70 (19%)	51 (20%)		77 (20%)	60 (27%)	
Preference for surgery	162 (43%)	121 (46%)		141 (38%)	87 (39%)	
Pseudoclaudication - Any	303 (81%)	205 (79%)	0.46	319 (85%)	192 (85%)	0.96
SLR or Femoral Tension	71 (19%)	61 (23%)	0.22	60 (16%)	25 (11%)	0.13
Pain radiation - any	299 (80%)	200 (77%)	0.33	293 (78%)	175 (78%)	0.95

Characteristics	Spinal Stenosis			Degenerative Spondylolisthesis		
	Normal or overweight (BMI<30) (n=373)	Obese (BMI ≥ 30) (n=261)	p-value	Normal or overweight (BMI<30) (n=376)	Obese (BMI ≥ 30) (n=225)	p-value
Any Neurological Deficit	204 (55%)	145 (56%)	0.89	203 (54%)	124 (55%)	0.86
Reflexes - Asymmetric Depressed	101 (27%)	67 (26%)	0.76	90 (24%)	60 (27%)	0.51
Sensory - Asymmetric Decrease	95 (25%)	87 (33%)	0.039	105 (28%)	64 (28%)	0.97
Motor - Asymmetric Weakness	113 (30%)	64 (25%)	0.13	91 (24%)	55 (24%)	0.98
Listhesis Level						0.27
L3-L4	0 (0%)	0 (0%)		40 (11%)	17 (8%)	
L4-L5	0 (0%)	0 (0%)		336 (89%)	208 (92%)	
Stenosis Levels						
L2-L3	101 (27%)	78 (30%)	0.49	31 (8%)	22 (10%)	0.62
L3-L4	250 (67%)	170 (65%)	0.68	144 (38%)	92 (41%)	0.59
L4-L5	340 (91%)	239 (92%)	0.97	363 (97%)	217 (96%)	0.87
L5-S1	101 (27%)	72 (28%)	0.96	40 (11%)	17 (8%)	0.27
Number of Moderate/Severe Stenotic Levels			0.36			0.006
None	8 (2%)	7 (3%)		8 (2%)	15 (7%)	
One	141 (38%)	93 (36%)		238 (63%)	132 (59%)	
Two	148 (40%)	93 (36%)		102 (27%)	70 (31%)	
Three+	76 (20%)	68 (26%)		28 (7%)	8 (4%)	
Stenosis Locations						
Central	316 (85%)	227 (87%)	0.50	351 (93%)	198 (88%)	0.035
Lateral Recess	293 (79%)	210 (80%)	0.63	348 (93%)	198 (88%)	0.084
Neuroforamen	120 (32%)	87 (33%)	0.83	149 (40%)	94 (42%)	0.66
Stenosis Severity			0.62			0.009
Mild	8 (2%)	7 (3%)		8 (2%)	15 (7%)	
Moderate	161 (43%)	121 (46%)		130 (35%)	85 (38%)	
Severe	204 (55%)	133 (51%)		238 (63%)	125 (56%)	
Instability	0 (0%)	0 (0%)		28 (7%)	19 (8%)	0.78
Received surgery *	250 (67%)	163 (62%)	0.27	235 (62%)	156 (69%)	0.11

† 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 Sciatica Bothersomeness index range from 0 to 24, with lower scores indicating less severe symptoms.

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

* 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.

Characteristics	Spinal Stenosis			Degenerative Spondylolisthesis		
	Normal or overweight (BMI<30) (n=249)	Obese (BMI≥30) (n=162)	p-value	Normal or overweight (BMI<30) (n=233)	Obese (BMI≥30) (n=156)	p-value
Specific procedures†			0.73			0.044
Decompression only	215 (87%)	141 (90%)		20 (9%)	4 (3%)	
Non-instrumented fusion	15 (6%)	7 (4%)		45 (20%)	36 (23%)	
Instrumented fusion	16 (7%)	9 (6%)		163 (71%)	114 (74%)	
Multi-level fusion	10 (4%)	6 (4%)	0.92	51 (22%)	40 (26%)	0.46
Decompression level						
L2-L3	78 (32%)	69 (43%)	0.026	26 (11%)	19 (13%)	0.82
L3-L4	173 (71%)	109 (69%)	0.70	119 (52%)	70 (46%)	0.33
L4-L5	225 (92%)	148 (93%)	0.90	225 (97%)	149 (97%)	0.94
L5-S1	96 (39%)	57 (36%)	0.55	71 (31%)	42 (27%)	0.53
Levels decompressed			0.69			0.37
None	5 (2%)	3 (2%)	-	1 (0%)	3 (2%)	
1	54 (22%)	39 (24%)	-	91 (39%)	68 (44%)	
2	83 (33%)	45 (28%)	-	85 (36%)	53 (34%)	
3+	107 (43%)	75 (46%)	-	56 (24%)	32 (21%)	
Operation time, minutes (SD)	126.2 (66.5)	132.8 (64.7)	0.33	197.2 (78.5)	220.2 (88.9)	0.008
Blood loss, cc (SD)	286.3 (327.4)	350.1 (499.1)	0.12	545.4 (474.6)	636.2 (457)	0.062
Blood Replacement						
Intraoperative replacement	25 (10%)	14 (9%)	0.75	70 (30%)	62 (40%)	0.063
Post-operative transfusion	14 (6%)	6 (4%)	0.52	52 (23%)	29 (19%)	0.48
Length of hospital stay, days (SD)	3.3 (2.3)	3.1 (2.6)	0.54	6 (24.3)	5.1 (3.6)	0.66
Intraoperative complications§						
Dural tear/spinal fluid leak	23 (9%)	15 (9%)	0.88	33 (14%)	8 (5%)	0.007
Vascular injury	0 (0%)	0 (0%)	0 (0%)	1 (0%)	0 (0%)	0.84

Characteristics	Spinal Stenosis			Degenerative Spondylolisthesis		
	Normal or overweight (BMI<30)	Obese (BMI≥30)	p-value	Normal or overweight (BMI<30)	Obese (BMI≥30)	p-value
	(n=249)	(n=162)		(n=233)	(n=156)	
Other	3 (1%)	0 (0%)	0.41	7 (3%)	2 (1%)	0.45
None	221 (89%)	147 (91%)	0.80	194 (83%)	146 (94%)	0.004
Postoperative complications/events ¶						
Nerve root injury	0 (0%)	0 (0%)	(0%)	1 (0%)	0 (0%)	0.84
Wound dehiscence	0 (0%)	0 (0%)	(0%)	0 (0%)	1 (1%)	0.84
Wound hematoma	3 (1%)	1 (1%)	0.94	0 (0%)	1 (1%)	0.84
Wound infection	6 (2%)	3 (2%)	0.97	3 (1%)	8 (5%)	0.051
Other	17 (7%)	7 (4%)	0.40	20 (9%)	17 (11%)	0.53
None	209 (85%)	145 (91%)	0.13	165 (71%)	102 (67%)	0.38
Post-operative mortality (death within 6 weeks of surgery)	1 (0.4%)	0 (0%)	0.82	1 (0.4%)	0 (0%)	0.83
Post-operative mortality (death within 3 months of surgery)	1 (0.4%)	0 (0%)	0.82	1 (0.4%)	1 (0.6%)	0.67
Additional surgeries (1-year rate) ∥	15 (6%)	7 (4%)	0.486	10 (4%)	15 (10%)	0.029
Additional surgeries (2-year rate) ∥	20 (8%)	12 (7%)	0.845	23 (10%)	25 (16%)	0.054
Additional surgeries (3-year rate) ∥	30 (12%)	16 (10%)	0.535	24 (10%)	30 (19%)	0.01
Additional surgeries (4-year rate) ∥	35 (14%)	19 (12%)	0.541	27 (11%)	32 (20%)	0.013
Recurrent stenosis/progressive listhesis	14 (6%)	10 (6%)		14 (6%)	6 (4%)	
Pseudarthrosis/fusion exploration	0	0		0	4 (2.6%)	
Complication or Other	11 (4.5%)	7 (4.3%)		9 (3.9%)	16 (10.5%)	
New condition	4 (1.6%)	4 (2.4%)		4 (1.7%)	5 (3.3%)	

*
Surgical information was available for 82 normal, 167 overweight, and 162 obese patients.

†
Specific procedure data was available for 81 normal, 165 overweight, and 157 obese patients.

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

¶
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, caudaequina injury or pseudarthrosis.

∥
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 3

Treatment Effect of Surgery By Primary Outcome Measures of Spinal Stenosis and Degenerative Spondylolisthesis Patients According to Body Mass Index*

Outcome	Obesity (2 groups)	1 Year Treatment Effect (95% CI)	2 Years Treatment Effect (95% CI)	3 Years Treatment Effect (95% CI)	4 Years Treatment Effect (95% CI)
SPS (RCT & OBS)					
SF-36 Bodily Pain (BP) (0-100) (SE)[††]	Normal or overweight (BMI < 30)	14.6 (10.1,19.1)	13.4 (8.7,18.1)	12.9 (7.9,17.8)	12.6 (7.2,18.1)
	Obese (BMI ≥ 30)	17.2 (11.6,22.8)	16.3 (10.5,22.1)	16.7 (10.6,22.9)	15.9 (9.4,22.4)
	pvalue	0.47	0.44	0.32	0.44
SF-36 Physical Function(PF) (0-100) (SE)[††]	Normal or overweight	13.5 (9.3,17.6)	9.8 (5.5,14.2)	9.5 (4.9,14.1)	7.4 (2.3,12.4)
	Obese	16.3 (11,21.6)	10.6 (5.1,16)	13.6 (7.8,19.4)	12.8 (6.7,18.9)
	pvalue	0.40	0.84	0.26	0.17
Oswestry Disability Index (ODI) (0-100) (SE)[‡‡]	Normal or overweight	-10.1 (-13.4,-6.8)	-9.3 (-12.8,-5.9)	-7.8 (-11.5,-4.1)	-7.4 (-11.4,-3.3)
	Obese	-15.7 (-19.9,-11.5)	-14.2 (-18.5,-9.9)	-13.1 (-17.7,-8.5)	-13.9 (-18.8,-9)
	pvalue	0.036	0.076	0.07	0.037
DS (RCT & OBS)					
SF-36 Bodily Pain (BP) (0-100) (SE)[††]	Normal or overweight (BMI < 30)	16.7 (12.4,21)	17.6 (13,22.1)	15.6 (10.8,20.4)	13.8 (8.7,19)
	Obese (BMI ≥ 30)	20.7 (15,26.4)	20 (14,26.1)	19.6 (13,26.1)	17.2 (10.4,24)
	pvalue	0.26	0.51	0.32	0.43
SF-36 Physical Function(PF) (0-100) (SE)[††]	Normal or overweight	16 (11.9,20.1)	15.9 (11.6,20.2)	14.4 (9.9,19)	14 (9,18.9)
	Obese	20.7 (15.3,26.1)	17.9 (12.2,23.6)	19.9 (13.6,26.1)	25.6 (19.1,32.1)
	pvalue	0.17	0.58	0.16	0.004
Oswestry Disability Index (ODI) (0-100) (SE)[‡‡]	Normal or overweight	-15.4 (-18.5,-12.2)	-14.5 (-17.8,-11.1)	-11.7 (-15.3,-8.2)	-12.6 (-16.4,-8.8)
	Obese	-19.6 (-23.8,-15.4)	-18.4 (-22.8,-14)	-14.4 (-19.2,-9.6)	-17.5 (-22.5,-12.5)

Outcome	Obesity (2 groups)	1 Year	2 Years	3 Years	4 Years
	pvalue	0.11	0.15	0.37	0.12

*
Adjusted for age, gender, 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.

†
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.

††
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.

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

Table 4

Treatment Effect of Surgery By Secondary Outcome Measures of Spinal Stenosis and Degenerative Spondylolisthesis Patients According to Body Mass Index[*]

Outcome	Obesity (2 groups)	1 Year Treatment Effect (95% CI)	2 Years Treatment Effect (95% CI)	3 Years Treatment Effect (95% CI)	4 Years Treatment Effect (95% CI)
SPS (RCT & OBS)					
Stenosis Bothersomeness Index (0–24) (SE)[§§]	Normal or overweight (BMI < 30)	-4.4 (-5.6,-3.2)	-3 (-4.3,-1.8)	-3.5 (-4.9,-2.2)	-3.5 (-5,-2)
	Obese (BMI ≥ 30)	-5.3 (-6.8,-3.7)	-5.3 (-6.9,-3.7)	-3.3 (-5,-1.6)	-4 (-5.8,-2.2)
	pvalue	0.36	0.021	0.83	0.67
Low Back Pain Bothersomeness (0–6) (SE)[¶¶]	Normal or overweight	-1.3 (-1.7,-0.9)	-1.3 (-1.7,-0.9)	-1.3 (-1.7,-0.9)	-1 (-1.5,-0.5)
	Obese	-1.8 (-2.3,-1.3)	-1.6 (-2.1,-1.1)	-1.3 (-1.9,-0.7)	-1.4 (-2,-0.8)
	pvalue	0.15	0.33	0.98	0.26
Very/somewhat satisfied with symptoms (%)	Normal or overweight	34.5 (24.3,44.8)	36.7 (26.1,47.4)	29.8 (18.2,41.5)	33.6 (21,46.1)
	Obese	50.7 (39.5,61.9)	51 (39.3,62.7)	33 (19,47)	31.2 (16.4,46)
	pvalue	0.044	0.08	0.73	0.85
Self-rated progress: major improvement (%)	Normal or overweight	37.9 (28,47.7)	29.3 (18.6,40)	28.6 (17.2,39.9)	26.7 (14.3,39)
	Obese	53.3 (42.5,64)	49 (37.5,60.5)	42 (29.7,54.4)	36.2 (23.9,48.5)
	pvalue	0.042	0.02	0.11	0.15
Mental Component Summary (MCS)(0–100) (SE)[††]	Normal or overweight	1.5 (-0.4,3.4)	1.4 (-0.6,3.3)	0.9 (-1.2,3)	1.9 (-0.5,4.2)
	Obese	0.6 (-1.8,2.9)	3.9 (1.5,6.4)	3.4 (0.8,6)	3.1 (0.3,5.9)
	pvalue	0.53	0.099	0.13	0.49
DS (RCT & OBS)					
Stenosis Bothersomeness Index (0–24) (SE)[§§]	Normal or overweight (BMI < 30)	-5.2 (-6.4,-4)	-5.1 (-6.3,-3.8)	-4.7 (-6,-3.3)	-5.1 (-6.5,-3.6)
	Obese (BMI ≥ 30)	-6.6 (-8.1,-5)	-5.6 (-7.2,-3.9)	-5.5 (-7.3,-3.6)	-6.6 (-8.5,-4.8)

Outcome	Obesity (2 groups)	1 Year	2 Years	3 Years	4 Years
	pvalue	0.16	0.63	0.48	0.18
Low Back Pain Bothersomeness (0-6) (SE) [¶¶]	Normal or overweight	-1.2 (-1.6,-0.8)	-0.8 (-1.2,-0.4)	-0.7 (-1.1,-0.3)	-0.9 (-1.4,-0.4)
	Obese	-1.5 (-2,-1)	-1.2 (-1.7,-0.7)	-0.8 (-1.4,-0.2)	-1.3 (-1.9,-0.7)
	pvalue	0.35	0.28	0.69	0.31
	Normal or overweight	42.7 (33.3,52.2)	39.4 (29.3,49.5)	26.5 (15.1,37.9)	30.3 (18.3,42.4)
	Obese	50.8 (39.5,62.1)	31.5 (17.3,45.7)	36.1 (21.2,50.9)	43 (28.5,57.5)
Very/somewhat satisfied with symptoms (%)	pvalue	0.26	0.38	0.34	0.24
	Normal or overweight	44.4 (35,53.8)	47.9 (38.3,57.6)	48.4 (38.3,58.4)	43.7 (32.6,54.7)
Self-rated progress: major improvement (%)	Obese	59.4 (48.4,70.3)	52.4 (40.2,64.6)	40.3 (25.6,54.9)	49.7 (35.6,63.8)
	pvalue	0.071	0.58	0.46	0.56
	Normal or overweight	0.3 (-1.5,2.2)	1.2 (-0.7,3.2)	1.8 (-0.2,3.9)	2.7 (0.5,5)
	Obese	3.5 (1.1,5.9)	2.5 (0,5.1)	3.7 (0.9,6.5)	1.6 (-1.4,4.6)
Mental Component Summary (MCS)(0-100) (SE) [††]	pvalue	0.038	0.41	0.29	0.56

[*] Adjusted for age, gender, 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 ** comorbiditiy, baseline score and center.

[†] 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.

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

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

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

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