The Effect of Extreme Obesity on Outcomes of Treatment for Lumbar Spinal Conditions: Subgroup Analysis of the Spine Patient Outcomes Research Trial (SPORT)

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Abstract

Study Design/Setting—SPORT subgroup analysis

Objective—To evaluate the effect of extreme obesity on management of lumbar spinal stenosis (SpS), degenerative spondylolisthesis (DS), and intervertebral disc herniation (IDH)

Summary of Background Data—Prior SPORT analyses compared nonobese and obese. This study compares nonobese to class I obesity and class II/III extreme obesity.

Methods—For SpS, 250/634 nonobese, 104/167 obese, and 59/94 extremely obese patients underwent surgery. For DS, 233/376 nonobese, 90/129 obese, and 66/96 extremely obese patients had surgery. For IDH, 542/854 nonobese, 151/207 obese, 94/129 extremely obese patients had surgery. Outcomes included SF-36, Oswestry Disability Index, Stenosis/Sciatica Bothersomeness Index, Low Back Pain Bothersomeness Index, operative events, complications, and reoperations.

Results—Extremely obese patients had increased comorbidities. Baseline SF-36 physical function scores were lower for obese; lowest for extremely obese. For SpS, surgical treatment effect and operative events among groups were not significantly different.

For DS, 4-year SF-36 physical function scores had greatest treatment effect in extremely obese. This observation was found in most primary outcome measures, and is attributable to the significantly poorer nonoperative outcomes. Operative times and wound infection rates were greatest for the extremely obese. Additional surgery at 3 and 4 years was higher in both obese cohorts.

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Conflicts of Interest:
None were declared.

For IDH, extremely obese experienced less improvement post-op than obese and nonobese; however, nonoperative treatment for extremely obese patients was worse, resulting in treatment effect still greater in almost all measures. Operative time was greatest for extremely obese. Blood loss and length of stay was greater for both obese cohorts compared to non-obese.

Conclusions—Extremely obese with DS experienced longer operative times and increased infection. Operative time was greatest for extremely obese with IDH. DS and IDH saw greater surgical treatment effect for extremely obese due to poor outcomes of nonsurgical management.

Keywords

Spine Patient Outcomes Research Trial (SPORT); Extreme obesity in spine surgery; lumbar spinal stenosis; Degenerative spondylolisthesis; Intervertebral disc herniation; Nonsurgical management of spine injuries; SF36 physical function score

Introduction

Several modern healthcare initiatives focus on the obesity epidemic due to associated comorbidities, including hypertension, heart disease, diabetes and osteoarthritis.[1,2] Obesity is associated with an increased prevalence of low back pain as well as seeking care for it.[3] Being overweight increases the risk of lumbar disc degeneration, particularly at a young age.[4]

Obesity has been associated with inferior results of surgery for lumbar spinal stenosis[5] as well as increased complication rates,[6] particularly with regards to surgical site infections.[7] Nonetheless, the literature is conflicted regarding the effect of obesity on outcomes of lumbar surgery. With appropriate indications, obese patients may benefit from surgical treatment.[8,9] The Spine Patient Outcomes Research Trial (SPORT) represents one of the largest studies of operative and non-operative care of patients with lumbar spinal stenosis (SpS), degenerative spondylolisthesis (DS), and intervertebral disc herniation (IDH).

A previous subgroup analysis of SPORT comparing surgical and nonsurgical outcomes for nonobese patients (BMI<30) and obese patients (BMI 30) demonstrated significant treatment effects of surgery for all groups. Obesity did not affect outcome of surgery for SpS. For DS, it was associated with higher rates of infection, twice the reoperation rate, and less improvement in SF36 physical function scores.[10] For IDH, obese patients experienced less benefit from both operative and nonoperative treatment, particularly with SF36 physical function scores and Oswestry Disability Index (ODI). Both groups benefited from surgery over nonsurgical management.[11]

Obesity represents a heterogeneous classification. The severely obese have more comorbidities and higher health care demands than the moderately obese. From 1986–2000, while the prevalence of obesity (BMI 30) doubled from 1 in 10 to 1 in 5, the prevalence of BMI 40 quadrupled from 1 in 200 to 1 in 50, and that of BMI 50 quintupled from 1 in 2000 to 1 in 400.[12] Extreme obesity is fast growing and represents the greatest disability and cost.

The severely obese face further risks of comorbidities and lifestyle limitations. The purpose of this study was to use SPORT to assess the impact of extreme obesity (BMI 35) on

outcomes of surgical and nonsurgical management of lumbar pathology. We hypothesized that this group would experience poorer outcomes of treatment for SpS, DS, and IDH.

Materials and Methods

Study Design

SPORT involves prospective enrollment of patients with lumbar pathology at 13 multidisciplinary spine centers across 11 states. The details of the design are thoroughly explained.[13]

Patients

Institutional Review Board approval was obtained at each center; enrollees were greater than 18 years old. Patients were enrolled between March 2000 and February 2005. For SpS, all had neurogenic claudication or radicular symptoms for greater than one week. Stenosis was demonstrated on axial imaging, and the patient was confirmed a surgical candidate by the physician. Spondylolyses or isthmic spondylolistheses were excluded. Many underwent pre-enrollment conservative management including non-steroidal anti-inflammatories (NSAIDs), opiods, physical therapy, chiropractic care, and epidural injections. For DS, patients had upright lateral radiographs demonstrating listhesis. The IDH group had radicular symptoms for greater than 6 weeks with a neurological deficit and/or positive nerve root tension sign. Axial imaging demonstrated a disk herniation at the appropriate level and laterality. Patients with cauda equina syndrome, progressive neurology, disc herniation superior to L2, prior lumbar surgery, scoliosis >15°, or any contraindication to surgical intervention were excluded.

Interventions

For each pathology, random computer-generated treatment assignments of operative versus nonoperative were made in the cohort. Patients in the observational cohort arm chose their treatment after physician consultation. Nonoperative groups had education, physical therapy with a home exercise program, and NSAIDs, if possible. For SpS and DS, surgery consisted of decompressive laminectomy with or without single level fusion (iliac crest bone autograft, +/− pedicle screw instrumentation). For IDH, surgery entailed discectomy. Extensive crossover occurred in the randomized cohort: patients assigned to nonoperative treatment went on to receive surgery and vice versa. Therefore, an as-treated analysis was undertaken with both groups combined. Similar baseline characteristics and outcomes between the two groups made this possible.

Measures

Patients completed questionnaires at baseline, 6 weeks, 3 months, 1 year, 2 years, 3 years, and 4 years after surgery or enrollment. Primary outcome measures were the components of the Short Form-36 (SF-36)[14] and the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS) version of the ODI[15]. The SF-36 is scored from 1 to 100 points; higher scores indicate less severe symptoms. The ODI is scored from 0–100 points; higher scores indicate more severe symptoms. Secondary outcomes were patient satisfaction, self-reported improvement, and work status.[16]

Symptom severity was measured via the Sciatica Bothersome Index and the Low Back Pain Bothersomeness Index.[17,18] The former is scored from 0 to 24 and the latter, 0 to 6; higher scores indicate more severe symptoms. The Stenosis Bothersomeness Index was also used for the SpS and DS patients. This is scored from 0 to 24 with higher scores indicating more severe symptoms.

Statistical Analysis

Patients were divided into three groups based on the BMI at enrollment: non-obese (BMI $<30 \text{kg/m}^2$), obese (30kg/m^2 BMI $< 35 \text{kg/m}^2$), and extremely obese (BMI 35kg/m^2). Baseline characteristics were compared with ANOVA tests for the continuous variables and chi-square tests for categorical values. Primary analysis involved a comparison of operative and nonoperative outcomes by change from baseline at each follow-up interval. This was analyzed with a mixed effects longitudinal regression model, including a random individual effect to account for correlation between repeated measurements for a particular patient. In the as-treated analysis, necessitated by the crossover, treatment was a time-varying covariate. In the operative group, time was measured from surgery, and in the nonoperative group, time was measured from enrollment. In crossover to surgery, preoperative data was retained from the time of enrollment for inclusion into nonoperative treatment effect analysis. Adjusting covariates were used in the longitudinal regression models to adjust for potential confounding (marital status, smoking status, compensation, herniation location, working status, depression, other comorbidities, self-rated health trend, duration of the most recent episode, or treatment preference). Race, center, age, sex, and baseline outcome measure scores were included in the longitudinal regression models. Secondary and binary outcome analysis involved the use of generalized estimating equations assuming a compound symmetry working correlation structure. The outcomes stratified by the obesity subgroups at each time point were compared with a multiple-degrees-of-freedom Wald test. Over four years of follow-up, overall comparisons of area-under-curve between subgroups were made with a Wald test. Computations were done with SAS procedures PROC MIXED for continuous data and PROC GENMOD for binary and non-normal secondary outcomes (SAS version 9.1, Windows XP Pro; SAS Institutes, Cary, North Carolina). Significance was $p<0.05$ based on a two-sided hypothesis test. No adjustment for multiple comparisons was made because the current study was not looking for a single result, but instead for a longitudinal assessment over time of different dimensions of outcome, including symptoms, function, and disability.[10]

Results

Lumbar Spinal Stenosis (SpS)

The spinal stenosis arm included 373 patients with BMI<30, 167 with 30 BMI<35, and 94 with BMI 35. Baseline differences are noted in Appendix A. Mean age was significantly different among the groups with the nonobese being oldest and the extremely obese being youngest. Other significant differences included disabled work status, rates of hypertension, diabetes, depression, heart problems, and bowel or intestinal problems. Baseline outcome scores were not significantly different except for SF-36 vitality scores where the obese

cohort reported lower mean scores, and the extremely obese reported lowest. Extremely obese had the highest rate of asymmetric sensory decrease.

Table 1 demonstrates operative details, complications and events. There were no significant differences between groups. Although mean operative time was highest in extremely obese, the difference was not significant. Appendix B notes change scores and treatment effects in primary and secondary outcomes. No significant difference was observed in treatment effect among the groups for any of the outcomes.

Degenerative Spondylolisthesis (DS)

In the DS arm, 376 patients had BMI <30, 129 had 30 BMI 35, and 96 had BMI 35. Appendix C notes significant baseline differences in demographics, comorbidities, and health status. Again, mean age was significantly different with the extremely obese youngest. This group also had a higher percentage of female patients. Notable socioeconomic differences existed. Extremely obese had the highest percentage with income<$50,000 and the lowest rates of marriage. Rates of hypertension, diabetes, depression, stomach problems, kidney problems, and other comorbidities were highest.

The extremely obese had the lowest SF-36 scores in all categories indicating more severe symptoms. Except for the Mental Component Summary, the symptom severity was directly correlated with level of obesity. ODI scores were also highest for the most obese, indicating more severe symptoms. This group had the highest percentage of patients reporting worsening symptoms. Preference for surgery was highest in the extremely obese. In contrast, the rate of severe stenosis as indicated by imaging was higher in nonobese (63%) versus obese (55%) and extremely obese (56%).

Table 2 describes operative treatments, complications, and events. Mean operative times were longest in the extremely obese. Interestingly, intraoperative complication rate was highest in the nonobese. The obese experienced more wound issues. Only one wound dehiscence occurred; this was in an obese patient. The only wound hematoma was in an extremely obese patient. The rate of wound infection was directly correlated with BMI with the highest occurrence in the extremely obese group (8%) versus the obese (3%) and the nonobese (1%). Rate of additional surgeries within one year was highest in the extremely obese; however, at 3 and 4 years it was highest in the moderately obese. Reoperation rate was nearly double for both obese groups compared to nonobese throughout the study.

Table 3 shows change scores and treatment effects. In year 1, the SF-36 mental component summary score had a greater treatment effect for the extremely obese (6.5) versus the obese (1.2) and the nonobese (0.4); p=0.015. The 4-year SF-36 physical function score had greater treatment effect in the extremely obese (26) versus obese (25.4) and nonobese (13.9), p=0.016. Though the differences may not have come to significance, greater surgical treatment effect is noted for extremely obese in nearly all of the primary outcome measures. This is likely attributable to the significantly poorer outcomes with nonoperative treatment for the extremely obese.

Intervertebral Disc Herniation (IDH)

In the IDH arm, 854 patients had BMI<30, 207 had 30 BMI<35, and 129 had BMI 35. Baseline demographics, comorbidities and health status are reported in Appendix D. No significant difference in age was noted among the groups; however the extremely obese had a higher percentage of females. Socioeconomic differences were apparent. The extremely obese had the highest percentage with income less than $50,000 and the lowest percentage with some college. Again, extremely obese suffered highest rates of hypertension, diabetes, stomach problems, and other comorbidities.

The extremely obese had the lowest SF-36 scores indicating worse bodily pain, physical functioning, vitality, and physical component summary. This group reported the highest percentage of patients reporting getting worse (51%) versus the nonobese (38%) and the obese (40%). The obese and extremely obese had higher preference for surgery (56% and 54%, respectively) in comparison to the nonobese (48%). Interestingly, however, the nonobese group had the highest scores for the ODI, indicating greater disability.

Table 4 describes operative treatments, complications, and events among the three groups in this arm of the study. Mean operative time was directly related to BMI: 90.5min for the extremely obese versus the obese (84min) and the nonobese (72.3min). Blood loss was higher for the obese (84.8cc) and extremely obese (80.7cc) than the nonobese (56.1cc). Significantly longer lengths of stay were observed for the obese (1.2 d) and extremely obese (1.1 d) versus the nonobese (0.89 d). The only nerve root injury occurred in an extremely obese patient. No differences existed in the rate of wound complications following discectomy.

Table 5 shows change scores and treatment effects. SF-36 physical function change with surgery was lower for the obese and extremely obese than for the nonobese at each year. However, the difference in change scores among the cohorts was of greater magnitude for nonsurgical management. Although all showed improvement, nonobese had the highest positive change while obese had less, and extremely obese had the least. Therefore surgical treatment effect was greatest for extremely obese, followed by nonobese, and finally obese. This trend came to significance particularly in years 2 and 3 for the SF-36 physical function variable.

Change in ODI for nonoperative treatment was indirectly related to BMI; extremely obese had least improvement in each year. Although this trend persisted, it came to significance in years 1 and 3. Because this difference was not as drastic for surgical management, treatment effect for surgery was greatest for extremely obese each year. This was significant only in year 1. Although similar trends existed for other outcomes, differences were not consistently significant.

Discussion

Obesity is accepted to be a major risk factor for a number of health problems.[1,2] Extreme obesity (BMI 35), however, is a unique subcategory with a singular set of health concerns. We hypothesized extreme obesity would be associated with poorer outcomes of treatment

for lumbar pathology. Previous subgroup analysis of SPORT has suggested that obese and nonobese patients had similar outcomes from surgery for SpS. Obesity was associated with increased rates of infection and reoperation, as well as less improved SF36 physical scores in surgical management for DS.[10] Obese also had less improvement in SF36 physical function scores and ODI from both operative and nonoperative treatment for IDH.[11]

This study reanalyzes the SPORT database to assess the impact of extreme obesity (BMI 35) on outcomes. A significant percentage of patients in each arm of the study were in this category – 14.8% SpS patients, 16% DS patients, and 10.8% IDH patients. Extreme obesity has had an increased prevalence in recent years.[1] Extremely obese had the highest rates of hypertension, diabetes, and depression. Socioeconomic factors are known to play a role in lumbar surgical outcomes.[19] For DS and IDH, extremely obese had the highest percentage of income < $50,000, and for IDH, they had the lowest education. It is possible, that these factors may have played some role in differences in surgical treatment effect in these two arms.

For DS and IDH, operative time was significantly longest for the extremely obese. For DS, wound infection and reoperation within 1 year was highest for the extremely obese. It must be noted that the majority of surgeries for SpS and all surgeries for IDH involved only decompression. Conversely, nearly ¾ of the surgeries for DS involved instrumented fusion. Average operative times were longer than in the other arms of the study. Possibly, instrumentation and longer operative times may play a role in the increased adverse events for extremely obese in the DS arm.

For SpS, extremely obese reported worse baseline physical scores for the SF36. Nonetheless, there was no significant difference in treatment effect from surgery between the 3 groups for the primary or secondary patient-reported outcomes at any time point. This finding is in agreement with studies that suggest no negative impact of obesity on the outcomes of spinal surgery.[8,9] Other studies, however, suggest a higher dissatisfaction and poorer outcomes after surgery for lumbar spinal stenosis.[8]

For DS and IDH, differences were noted in change scores and surgical treatment effect for several primary and secondary outcome measures at different time intervals. Although all cohorts improved with either treatment over time, nonobese had better change scores with nonoperative treatment. In some cases, nonoperative change score was actually negative for the extremely obese. Consequently, surgical treatment effect was greater for obese and greatest for extremely obese. Greater preoperative preference for surgery in the both obese cohorts may have played a role; however, the differences in preference were not significant.

The reanalysis of the SPORT suggests that the extremely obese (BMI 35) may have played a significant role in the differences originally observed between obese (BMI 30) and nonobese (BMI<30) patients.[10] The SPORT study was not designed for subgroup analysis, and this study highlights this limitation by further separating the obese subcategory. Nonetheless, SPORT is the largest study to date analyzing outcomes of patients treated for SpS, DS, and IDH, making it more likely powered for subgroup analysis.

Acknowledgments

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Appendix A

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

Characteristics SPS	(BMI<30) (n=373)	(30 BMI<35) (n=167)	(BMI 35) (n=94)	p-value
Mean Age (SD)	66.2 (12.2)	62.8 (11)	61.4 (9.4)	<0.001
Female - no. (%)	139 (37%)	61 (37%)	49 (52%)	0.022
Ethnicity: Not Hispanic	356 (95%)	159 (95%)	90 (96%)	0.98
Race - White	319 (86%)	136 (81%)	78 (83%)	0.46
Education - At least some college	249 (67%)	95 (57%)	57 (61%)	0.076
Income - Under $50,000	58 (16%)	46 (28%)	18 (19%)	0.005
Marital Status - Married	261 (70%)	114 (68%)	71 (76%)	0.45
Work Status - no. (%)				<0.001
Full or part time	109 (29%)	54 (32%)	35 (37%)	
Disabled	24 (6%)	18 (11%)	18 (19%)	
Other	240 (64%)	95 (57%)	41 (44%)	
Compensation - no. (%)[‡]	14 (4%)	19 (11%)	15 (16%)	<0.001
Mean Body Mass Index (BMI), (SD)[§]	25.9 (2.9)	32 (1.4)	39.4 (4.1)	<0.001
Smoker - no. (%)	41 (11%)	15 (9%)	6 (6%)	0.37
Comorbidities - no.(%)				
Hypertension	151 (40%)	76 (46%)	61 (65%)	<0.001
Diabetes	32 (9%)	30 (18%)	34 (36%)	<0.001
Depression	29 (8%)	26 (16%)	15 (16%)	0.007
Heart Problem	110 (29%)	33 (20%)	22 (23%)	0.048
Lung Problem	28 (8%)	13 (8%)	7 (7%)	0.99
Stomach Problem	76 (20%)	39 (23%)	24 (26%)	0.49
Bowel or Intestinal Problem	39 (10%)	35 (21%)	12 (13%)	0.004
Liver Problem	6 (2%)	2 (1%)	2 (2%)	0.84
Kidney Problem	16 (4%)	8 (5%)	5 (5%)	0.90
Blood Vessel Problem	19 (5%)	12 (7%)	7 (7%)	0.52
Nervous System Problem	5 (1%)	5 (3%)	3 (3%)	0.32
Joint Problem	197 (53%)	88 (53%)	61 (65%)	0.093
Other[¶]	289 (77%)	128 (77%)	81 (86%)	0.15
SF-36 scores, mean (SD)[††]				
Bodily Pain (BP)	34.5 (20.2)	33.5 (19.2)	29.4 (18.1)	0.079
Physical Functioning (PF)	36.7 (23.9)	34.3 (22.6)	28.2 (21)	0.006
Vitality (VT)	45.3 (22.1)	40 (21.3)	35.8 (19.2)	<0.001
Physical Component Summary (PCS)	30.4 (8.8)	29.4 (8.3)	27.5 (8.2)	0.012

Characteristics SPS	(BMI<30) (n=373)	(30 BMI<35) (n=167)	(BMI 35) (n=94)	p-value
Mental Component Summary (MCS)	49.8 (12.2)	49 (11.5)	48 (11.3)	0.37
Oswestry Disability Index (ODI) (SD)[‡‡]	41.3 (19.2)	42.8 (18.3)	46.1 (15.6)	0.073
Stenosis Frequency Index (0–24) (SD)[§§]	13.9 (5.6)	13.5 (5.8)	14.4 (6.5)	0.43
Stenosis Bothersome Index (0–24) (SD)[§§]	14.4 (5.4)	14 (6)	14.8 (6.4)	0.60
Back Pain Bothersomeness (0–6) (SD)[¶¶]	4 (1.8)	4.2 (1.8)	4.1 (2)	0.55
Satisfaction with symptoms - very dissatisfied	259 (69%)	111 (66%)	63 (67%)	0.76
Patient self-assessed health trend - no. (%)				0.84
Getting better	26 (7%)	14 (8%)	6 (6%)	
Staying about the same	123 (33%)	54 (32%)	26 (28%)	
Getting worse	219 (59%)	99 (59%)	60 (64%)	
Treatment preference at baseline - no. (%)				0.87
Preference for non-surg	140 (38%)	59 (35%)	30 (32%)	
Not sure	70 (19%)	33 (20%)	18 (19%)	
Preference for surgery	162 (43%)	75 (45%)	46 (49%)	
Pseudoclaudication - Any	303 (81%)	133 (80%)	72 (77%)	0.59
SLR or Femoral Tension	71 (19%)	38 (23%)	23 (24%)	0.39
Pain radiation - any	299 (80%)	123 (74%)	77 (82%)	0.17
Any Neurological Deficit - no. (%)	204 (55%)	89 (53%)	56 (60%)	0.60
Reflexes - Asymmetric Depressed	101 (27%)	39 (23%)	28 (30%)	0.49
Sensory - Asymmetric Decrease	95 (25%)	46 (28%)	41 (44%)	0.002
Motor - Asymmetric Weakness	113 (30%)	43 (26%)	21 (22%)	0.24
Stenosis Levels - no. (%)				
L2–L3	101 (27%)	49 (29%)	29 (31%)	0.72
L3–L4	250 (67%)	108 (65%)	62 (66%)	0.87
L4–L5	340 (91%)	151 (90%)	88 (94%)	0.67
L5-S1	101 (27%)	45 (27%)	27 (29%)	0.94
Number of Moderate/Severe Stenotic Levels				0.19
None	8 (2%)	6 (4%)	1 (1%)	
One	141 (38%)	65 (39%)	28 (30%)	
Two	148 (40%)	52 (31%)	41 (44%)	
Three+	76 (20%)	44 (26%)	24 (26%)	
Stenosis Locations - no. (%)				
Central	316 (85%)	139 (83%)	88 (94%)	0.052
Lateral Recess	293 (79%)	136 (81%)	74 (79%)	0.74
Neuroforamen	120 (32%)	54 (32%)	33 (35%)	0.86
Stenosis Severity - no. (%)				0.12
Mild	8 (2%)	6 (4%)	1 (1%)	
Moderate	161 (43%)	85 (51%)	36 (38%)	
Severe	204 (55%)	76 (46%)	57 (61%)	

Characteristics SPS	(BMI<30) (n=373)	(30 BMI<35) (n=167)	(BMI 35) (n=94)	p-value
Received surgery - no. (%)[*]	250 (67%)	104 (62%)	59 (63%)	0.49

[†] 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,

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

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

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

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

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

Appendix B

SPS – Change Scores and Treatment Effects for Primary and Secondary Outcomes in the Randomized and Observational SPS Cohorts Combined, According to BMI and Treatment Received*

SPS Outcome	BMI	1-Year Surgical	1-Year Non-operative	1-Year Treatment Effect[†] (95% CI)	2-Year Surgical	2-Year Non-operative	2-Year Treatment Effect[†] (95% CI)	3-Year Surgical	3-Year Non-operative	3-Year Treatment Effect[†] (95% CI)	4-Year Surgical	4-Year Non-operative	4-Year Treatment Effect[†] (95% CI)
SF-36 Bodily Pain (BP) (0–100) (SE)[††]	BMI <30	29.6 (1.6)	15 (1.9)	14.6 (10.1, 19.1)	30 (1.6)	16.6 (2)	13.4 (8.7, 18.1)	29.9 (1.6)	17 (2.1)	12.9 (8, 17.8)	29.2 (1.8)	16.6 (2.3)	12.6 (7.1, 18)
	BMI 30<35	31 (2.4)	13.9 (2.9)	17.1 (10.1, 24.2)	28.1 (2.5)	10 (3.1)	18.1 (10.6, 25.5)	26.6 (2.5)	11.2 (3.2)	15.4 (7.7, 23.1)	25.8 (2.7)	7.4 (3.4)	18.4 (10.3, 26.6)
	BMI ≥35	30.1 (3.5)	12.6 (3.8)	17.5 (8.3, 26.8)	23.6 (3.3)	10.2 (3.9)	13.4 (4.2, 22.6)	26.9 (3.3)	7.4 (4.4)	19.5 (9.4, 29.6)	21 (3.5)	9.4 (4.4)	11.6 (1.1, 22.1)
	pvalue	0.88	0.84	0.76	0.19	0.11	0.55	0.45	0.081	0.49	0.085	0.054	0.44
SF-36 Physical Function (PF) (0–100) (SE)[††]	BMI <30	27.1 (1.5)	13.6 (1.8)	13.5 (9.3, 17.7)	24.9 (1.5)	15.1 (1.9)	9.8 (5.4, 14.2)	23.3 (1.6)	13.8 (2)	9.5 (4.9, 14.1)	22.5 (1.7)	15.1 (2.2)	7.4 (2.3, 12.5)
	BMI 30<35	24.2 (2.4)	5.1 (2.8)	19.1 (12.5, 25.7)	20.6 (2.4)	7.2 (2.9)	13.4 (6.5, 20.4)	17.8 (2.5)	4.4 (3.1)	13.4 (6.1, 20.6)	18.4 (2.6)	3.2 (3.2)	15.2 (7.6, 22.9)
	BMI ≥35	22.2 (3.3)	10.7 (3.6)	11.5 (2.8, 20.2)	15 (3.2)	9.2 (3.7)	5.9 (−2.7, 14.5)	18 (3.2)	3.7 (4.2)	14.3 (4.8, 23.8)	17.9 (3.4)	9.2 (4.3)	8.7 (−1.3, 18.6)
	pvalue	0.32	0.037	0.27	0.012	0.053	0.39	0.089	0.011	0.52	0.26	0.009	0.23
Mental Component Summary (MCS) (0–100) (SE)[††]	BMI <30	3.9 (0.7)	2.3 (0.8)	1.5 (−0.4, 3.4)	3.1 (0.7)	1.7 (0.8)	1.4 (−0.6, 3.4)	2.3 (0.7)	1.5 (0.9)	0.9 (−1.2, 3)	2.9 (0.7)	1 (1)	1.9 (−0.4, 4.3)
	BMI 30<35	3.4 (1)	2.5 (1.2)	0.9 (−2, 3.8)	4.6 (1)	−0.9 (1.3)	5.6 (2.5, 8.7)	3.7 (1)	−1.2 (1.3)	4.9 (1.6, 8.1)	1.7 (1.1)	−1.5 (1.4)	3.2 (−0.3, 6.6)
	BMI ≥35	2.9 (1.4)	2.8 (1.5)	0.2 (−3.7, 4.1)	4.2 (1.3)	2.8 (1.6)	1.4 (−2.5, 5.3)	2.4 (1.4)	1.5 (1.8)	0.9 (−3.4, 5.2)	3.1 (1.5)	−0.2 (1.9)	3.2 (−1.3, 7.7)
	pvalue	0.80	0.97	0.81	0.38	0.13	0.064	0.53	0.22	0.10	0.62	0.36	0.77
Oswestry Disability Index (ODI) (0–100) (SE)[‡‡]	BMI <30	−20.8 (1.2)	−10.6 (1.4)	−10.1 (−13.4, −6.8)	−20.8 (1.2)	−11.4 (1.5)	−9.3 (−12.8, −5.8)	−19.1 (1.2)	−11.2 (1.6)	−7.8 (−11.5, −4.2)	−20.1 (1.3)	−12.7 (1.7)	−7.4 (−11.4, −3.3)
	BMI 30<35	−21.3 (1.9)	−5.1 (2.2)	−16.2 (−21.5, −11)	−20.6 (1.9)	−5.6 (2.3)	−15 (−20.5, −9.5)	−17.6 (1.9)	−5.4 (2.4)	−12.3 (−18.1, −6.5)	−17.6 (2)	−2.3 (2.6)	−15.3 (−21.4, −9.2)
	BMI ≥35	−22.4 (2.6)	−7.7 (2.9)	−14.7 (−21.6, −7.8)	−18.2 (2.5)	−5.7 (2.9)	−12.5 (−19.2, −5.7)	−19.5 (2.5)	−5.4 (3.3)	−14.1 (−21.5, −6.6)	−17.3 (2.7)	−6.4 (3.4)	−10.9 (−18.9, −3)
	pvalue	0.84	0.096	0.11	0.63	0.048	0.20	0.78	0.069	0.20	0.46	0.003	0.091
Stenosis Bothersomeness Index (0–24) (SE)[§§]	BMI <30	−8.2 (0.4)	−3.9 (0.5)	−4.4 (−5.6, −3.2)	−8.4 (0.4)	−5.4 (0.5)	−3 (−4.3, −1.7)	−8.2 (0.4)	−4.6 (0.6)	−3.5 (−4.9, −2.2)	−8.1 (0.5)	−4.6 (0.6)	−3.5 (−5, −2)
	BMI 30<35	−8.4 (0.7)	−3.1 (0.8)	−5.3 (−7.3, −3.4)	−7.4 (0.7)	−2.2 (0.8)	−5.2 (−7.2, −3.1)	−6.8 (0.7)	−3.2 (0.9)	−3.6 (−5.7, −1.5)	−7 (0.7)	−3.2 (0.9)	−3.8 (−6.1, −1.6)
	BMI ≥35	−8.3 (0.9)	−3.1 (1)	−5.1 (−7.6, −2.6)	−6.9 (0.9)	−1.4 (1)	−5.5 (−7.9, −3)	−6.7 (0.9)	−4 (1.2)	−2.7 (−5.3, 0)	−6.4 (0.9)	−2.2 (1.2)	−4.2 (−7, −1.4)
	pvalue	0.97	0.63	0.66	0.21	<0.001	0.072	0.11	0.37	0.82	0.18	0.15	0.90
Low Back Pain Bothersomeness (0–6) (SE)[∥∥]	BMI <30	−2 (0.1)	−0.9 (0.1)	−1 (−1.4, −0.6)	−2.1 (0.1)	−1.1 (0.2)	−1.1 (−1.5, −0.7)	−2.1 (0.1)	−1 (0.2)	−1.1 (−1.5, −0.7)	−2 (0.1)	−1.2 (0.2)	−0.7 (−1.2, −0.2)
	BMI 30<35	−2.3 (0.2)	−1 (0.2)	−1.3 (−1.9, −0.7)	−2.1 (0.2)	−0.7 (0.2)	−1.4 (−2, −0.8)	−1.7 (0.2)	−1 (0.3)	−0.7 (−1.3, −0.1)	−1.5 (0.2)	−0.5 (0.3)	−1 (−1.7, −0.3)
	BMI ≥35	−2.1 (0.3)	−0.2 (0.3)	−1.9 (−2.6, −1.2)	−1.8 (0.2)	−0.5 (0.3)	−1.3 (−2, −0.6)	−1.8 (0.3)	−0.4 (0.3)	−1.4 (−2.2, −0.6)	−1.6 (0.3)	−0.4 (0.3)	−1.3 (−2.1, −0.5)

SPS

Outcome	BMI	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)
	pvalue	0.29	0.011	0.076	0.51	0.18	0.64	0.14	0.26	0.40	0.11	0.012	0.52
Very/somewhat satisfied with symptoms (%)	BMI <30	66.2	31.8	34.4 (24.1, 44.6)	66.7	30.1	36.5 (25.9, 47.2)	66.4	36.9	29.6 (17.9, 41.3)	66.5	33.1	33.4 (20.8, 46)
	30 ≤ BMI < 35	70.5	26.7	43.8 (29, 58.7)	75.4	23.6	51.8 (37, 66.5)	69.3	39.6	29.7 (11.8, 47.6)	59.1	30.5	28.6 (10, 47.2)
	BMI ≥ 35	75.7	14	61.7 (45.6, 77.9)	73.1	23.3	49.8 (31.4, 68.2)	59.7	21.8	37.8 (17, 58.7)	61.9	26.3	35.7 (12.8, 58.6)
	pvalue	0.44	0.13	0.057	0.31	0.60	0.21	0.54	0.36	0.79	0.58	0.84	0.90
Self-rated progress: major improvement (%)	BMI <30	66.5	28.8	37.7 (27.8, 47.6)	61	32	29 (18.3, 39.8)	61.9	33.4	28.5 (17.1, 39.9)	56.8	30.3	26.5 (14.1, 38.9)
	30 ≤ BMI < 35	74.1	20.4	53.7 (40.2, 67.2)	73.1	20.6	52.5 (38.3, 66.7)	60.9	20.3	40.6 (25.1, 56.1)	49.6	13.1	36.6 (21.3, 51.8)
	BMI ≥ 35	67	16	50.9 (33.2, 68.7)	62.2	20	42.2 (23.7, 60.7)	63.1	19.9	43.2 (23.4, 63)	47.4	12.9	34.5 (14.7, 54.3)
	pvalue	0.46	0.20	0.14	0.17	0.20	0.054	0.97	0.18	0.30	0.48	0.056	0.35

*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.

§§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

**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.

Appendix C

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

Characteristics DS	(BMI<30) (n=376)	(30 BMI<35) (n=129)	(BMI 35) (n=96)	p-value
Mean Age (SD)	67.4 (10.5)	65.9 (9)	60.8 (9.4)	<0.001
Female - no.(%)	241 (64%)	93 (72%)	78 (81%)	0.003
Ethnicity: Not Hispanic[†]	366 (97%)	127 (98%)	94 (98%)	0.76
Race - White[†]	326 (87%)	104 (81%)	76 (79%)	0.089
Education - At least some college	263 (70%)	81 (63%)	56 (58%)	0.058
Income - Under $50,000	67 (18%)	37 (29%)	33 (34%)	<0.001
Marital Status - Married	260 (69%)	83 (64%)	53 (55%)	0.034
Work Status				0.098
Full or part time	115 (31%)	42 (33%)	35 (36%)	
Disabled	25 (7%)	13 (10%)	13 (14%)	
Other	236 (63%)	74 (57%)	48 (50%)	
Compensation - no. (%)[‡]	23 (6%)	8 (6%)	10 (10%)	0.31
Mean Body Mass Index (BMI), (SD)[§]	25.5 (2.9)	32.1 (1.4)	39.5 (5.7)	<0.001
Smoker	35 (9%)	8 (6%)	8 (8%)	0.55
Comorbidities - no.(%)				
Hypertension	144 (38%)	71 (55%)	60 (62%)	<0.001
Diabetes	30 (8%)	23 (18%)	27 (28%)	<0.001
Depression	50 (13%)	18 (14%)	30 (31%)	<0.001
Heart Problem	71 (19%)	30 (23%)	21 (22%)	0.52
Lung Problem	25 (7%)	8 (6%)	12 (12%)	0.12
Stomach Problem	66 (18%)	39 (30%)	28 (29%)	0.002
Bowel or Intestinal Problem	26 (7%)	10 (8%)	7 (7%)	0.95
Liver Problem	3 (1%)	1 (1%)	4 (4%)	0.03
Kidney Problem	13 (3%)	5 (4%)	9 (9%)	0.041
Blood Vessel Problem	26 (7%)	7 (5%)	5 (5%)	0.74
Nervous System Problem	13 (3%)	4 (3%)	5 (5%)	0.67
Joint Problem	207 (55%)	74 (57%)	63 (66%)	0.17
Other[¶]	278 (74%)	111 (86%)	87 (91%)	<0.001
SF-36 scores, mean(SD)[††]				
Bodily Pain (BP)	34.6 (19)	33.6 (19.8)	27.8 (18.1)	0.008
Physical Functioning (PF)	38.2 (22.9)	31.1 (19.8)	23.6 (19.5)	<0.001
Vitality (VT)	46.8 (21.6)	41.9 (22.1)	32.3 (21.1)	<0.001
Physical Component Summary (PCS)	30.7 (8.3)	28.9 (7.8)	25.9 (8.3)	<0.001
Mental Component Summary (MCS)	50.6 (11.2)	50.7 (11.6)	47.1 (12.1)	0.021
Oswestry Disability Index (ODI)(SD)[‡‡]	39.7 (17.8)	42.5 (16.7)	47.6 (18.4)	<0.001

Characteristics DS	(BMI<30) (n=376)	(30 BMI<35) (n=129)	(BMI 35) (n=96)	p-value
Sciatica Frequency Index (0–24)(SD)§§	13.9 (5.6)	13.7 (5.3)	14.6 (5.8)	0.46
Sciatica Bothersome Index (0–24)(SD)§§	14.5 (5.7)	14.9 (5.2)	15.3 (5.7)	0.41
Back Pain Bothersomeness (0–6)(SD)¶¶	4.1 (1.9)	4.6 (1.7)	4.5 (1.6)	0.017
Satisfaction with symptoms - very dissatisfied	253 (67%)	94 (73%)	69 (72%)	0.41
Patient self-assessed health trend - no.(%)				0.005
Getting better	29 (8%)	2 (2%)	7 (7%)	
Staying about the same	128 (34%)	47 (36%)	19 (20%)	
Getting worse	212 (56%)	79 (61%)	70 (73%)	
Treatment preference at baseline - no.(%)				0.011
Preference for non-surg	158 (42%)	42 (33%)	35 (36%)	
Not sure	77 (20%)	43 (33%)	17 (18%)	
Preference for surgery	141 (38%)	43 (33%)	44 (46%)	
Pseudoclaudication - Any	319 (85%)	107 (83%)	85 (89%)	0.50
SLR or Femoral Tension	60 (16%)	13 (10%)	12 (12%)	0.22
Pain radiation - any	293 (78%)	98 (76%)	77 (80%)	0.75
Any Neurological Deficit	203 (54%)	67 (52%)	57 (59%)	0.52
Reflexes - Asymmetric Depressed	90 (24%)	35 (27%)	25 (26%)	0.74
Sensory - Asymmetric Decrease	105 (28%)	33 (26%)	31 (32%)	0.54
Motor - Asymmetric Weakness	91 (24%)	34 (26%)	21 (22%)	0.74
Listhesis Level				0.15
L3–L4	40 (11%)	13 (10%)	4 (4%)	
L4–L5	336 (89%)	116 (90%)	92 (96%)	
Stenosis Levels				
L2–L3	31 (8%)	14 (11%)	8 (8%)	0.66
L3–L4	144 (38%)	60 (47%)	32 (33%)	0.11
L4–L5	363 (97%)	123 (95%)	94 (98%)	0.58
L5-S1	40 (11%)	11 (9%)	6 (6%)	0.39
Number of Moderate/Severe Stenotic Levels				0.014
None	8 (2%)	7 (5%)	8 (8%)	
One	238 (63%)	74 (57%)	58 (60%)	
Two	102 (27%)	45 (35%)	25 (26%)	
Three+	28 (7%)	3 (2%)	5 (5%)	
Stenosis Locations				
Central	351 (93%)	114 (88%)	84 (88%)	0.076
Lateral Recess	348 (93%)	117 (91%)	81 (84%)	0.046
Neuroforamen	149 (40%)	49 (38%)	45 (47%)	0.35
Stenosis Severity				0.028
Mild	8 (2%)	7 (5%)	8 (8%)	
Moderate	130 (35%)	51 (40%)	34 (35%)	

Characteristics DS	(BMI<30) (n=376)	(30 BMI<35) (n=129)	(BMI 35) (n=96)	p-value
Severe	238 (63%)	71 (55%)	54 (56%)	
Instability	28 (7%)	11 (9%)	8 (8%)	0.91
Received surgery*	235 (62%)	90 (70%)	66 (69%)	0.23

[†] 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,

[††] 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.

Appendix D

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

Characteristics IDH	(BMI<30) (n=854)	(30 BMI<35) (n=207)	(BMI 35) (n=129)	p-value
Mean Age (SD)	42 (11.7)	40.7 (10)	41.3 (11.4)	0.29
Female - no. (%)	346 (41%)	76 (37%)	85 (66%)	<0.001
Ethnicity: Not Hispanic	815 (95%)	198 (96%)	123 (95%)	0.99
Race - White	750 (88%)	179 (86%)	103 (80%)	0.045
Education - At least some college	653 (76%)	152 (73%)	78 (60%)	<0.001
Income - Under $50,000	346 (41%)	110 (53%)	79 (61%)	<0.001
Marital Status - Married	599 (70%)	153 (74%)	82 (64%)	0.13
Work Status - no. (%)				0.28
Full or part time	522 (61%)	128 (62%)	71 (55%)	
Disabled	104 (12%)	30 (14%)	24 (19%)	
Other	228 (27%)	49 (24%)	34 (26%)	
Compensation - no. (%)[‡]	136 (16%)	44 (21%)	28 (22%)	0.079
Mean Body Mass Index (BMI), (SD)[§]	25.2 (2.8)	32.2 (1.4)	39.5 (4)	<0.001
Smoker - no. (%)	213 (25%)	43 (21%)	26 (20%)	0.27
Comorbidities - no. (%)				
Hypertension	89 (10%)	39 (19%)	34 (26%)	<0.001
Diabetes	22 (3%)	12 (6%)	14 (11%)	<0.001
Depression	90 (11%)	25 (12%)	26 (20%)	0.007

Characteristics IDH	(BMI<30) (n=854)	(30 BMI<35) (n=207)	(BMI 35) (n=129)	p-value
Heart Problem	45 (5%)	9 (4%)	7 (5%)	0.85
Lung Problem	25 (3%)	12 (6%)	6 (5%)	0.11
Stomach Problem	82 (10%)	39 (19%)	21 (16%)	<0.001
Bowel or Intestinal Problem	45 (5%)	21 (10%)	14 (11%)	0.006
Liver Problem	8 (1%)	3 (1%)	2 (2%)	0.71
Kidney Problem	24 (3%)	2 (1%)	2 (2%)	0.24
Blood Vessel Problem	9 (1%)	2 (1%)	5 (4%)	0.03
Nervous System Problem	11 (1%)	3 (1%)	4 (3%)	0.29
Joint Problem	147 (17%)	45 (22%)	29 (22%)	0.16
Other[¶]	346 (41%)	99 (48%)	80 (62%)	<0.001
SF-36 scores, mean (SD)[††]				
Bodily Pain (BP)	27.9 (20.2)	26.5 (20.2)	22.8 (18.6)	0.021
Physical Functioning (PF)	39.7 (25.8)	35 (24.2)	28.5 (23.1)	<0.001
Vitality (VT)	40.1 (20.1)	35.7 (19.9)	32.1 (19.3)	<0.001
Physical Component Summary (PCS)	31.3 (8.5)	29.2 (8)	27.4 (8)	<0.001
Mental Component Summary (MCS)	45.4 (11.6)	45 (11.6)	43.6 (11.3)	0.27
Oswestry Disability Index (ODI) (SD)[‡‡]	48.4 (21.3)	51.4 (20.7)	54 (21.1)	0.007
Sciatica Frequency Index (0–24) (SD)[§§]	15.7 (5.4)	16 (5.5)	16.8 (5.1)	0.096
Sciatica Bothersome Index (0–24) (SD)[§§]	15.4 (5.3)	15.9 (5.3)	16.3 (5.3)	0.13
Back Pain Bothersomeness (0–6) (SD)[¶¶]	3.8 (1.9)	4 (1.8)	4.2 (1.8)	0.068
Satisfaction with symptoms - very dissatisfied	685 (80%)	168 (81%)	101 (78%)	0.81
Patient self-assessed health trend - no. (%)				0.01
Getting better	135 (16%)	22 (11%)	21 (16%)	
Staying about the same	389 (46%)	102 (49%)	42 (33%)	
Getting worse	324 (38%)	82 (40%)	66 (51%)	
Treatment preference at baseline - no. (%)				0.015
Preference for non-surg	307 (36%)	50 (24%)	36 (28%)	
Not sure	133 (16%)	41 (20%)	23 (18%)	
Preference for surgery	413 (48%)	115 (56%)	70 (54%)	
Pain Radiation - no. (%)	831 (97%)	201 (97%)	128 (99%)	0.40
Straight Leg Raise Test - Ipsilateral	529 (62%)	128 (62%)	91 (71%)	0.16
Straight Leg Raise Test - Contralateral/Both	136 (16%)	39 (19%)	13 (10%)	0.099
Any Neurological Deficit - no. (%)	655 (77%)	150 (72%)	95 (74%)	0.38
Reflexes - Asymmetric Depressed	345 (40%)	80 (39%)	55 (43%)	0.77
Sensory - Asymmetric Decrease	436 (51%)	107 (52%)	60 (47%)	0.60
Motor - Asymmetric Weakness	368 (43%)	83 (40%)	48 (37%)	0.38
Herniation Level - no. (%)				0.22
L2–L3 / L3–L4	66 (8%)	10 (5%)	12 (9%)	
L4–L5	316 (37%)	92 (44%)	47 (36%)	

Characteristics IDH	(BMI<30) (n=854)	(30 BMI<35) (n=207)	(BMI 35) (n=129)	p-value
L5-S1	472 (55%)	105 (51%)	69 (53%)	
Herniation Type - no. (%)				0.95
Protruding	229 (27%)	60 (29%)	32 (25%)	
Extruded	564 (66%)	132 (64%)	87 (67%)	
Sequestered	61 (7%)	15 (7%)	9 (7%)	
Posterolateral herniation - no. (%)	672 (79%)	152 (73%)	93 (72%)	0.099
Received surgery - no. (%)*	542 (63%)	152 (73%)	94 (73%)	0.006

[†]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, diabetes, osteoporosis, cancer, fibromyalgia, CFS, PTSD, alcohol, drug dependence, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine,

[††]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 Bothersomness 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.

Key points

Extremely obese patients had greatest rates of comorbidity and the lowest SF36 physical function scores in each arm of the study – lumbar spinal stenosis, degenerative spondylolisthesis, and intervertebral disc herniation.

No significant differences in surgical treatment effect or operative events found among nonobese, obese, and extremely obese treated for lumbar spinal stenosis.

Increased operative times and infection rates were seen by the extremely obese who underwent surgery for spondylolisthesis.

The majority of surgery for spondylolisthesis involved instrumentation and longer operative times.

Surgical treatment effect was greatest for the extremely obese treated for spondylolisthesis and disc herniation, largely due to the much poorer outcomes of nonsurgical management.

Table 1

Lumbar Spinal Stenosis (SPS) Operative treatments, complications and events[*]

SPS	(BMI<30) (n=249)	(30 BMI<35) (n=103)	(BMI 35) (n=59)	p-value
Specific procedures - no. (%)[†]				0.72
Decompression only	215 (87%)	91 (92%)	50 (86%)	
Non-instrumented fusion	15 (6%)	4 (4%)	3 (5%)	
Instrumented fusion	16 (7%)	4 (4%)	5 (9%)	
Multi-level fusion -no. (%)	10 (4%)	5 (5%)	1 (2%)	0.60
Decompression level - no. (%)				
L2–L3	78 (32%)	46 (46%)	23 (40%)	0.05
L3–L4	173 (71%)	72 (71%)	37 (64%)	0.54
L4–L5	225 (92%)	94 (93%)	54 (93%)	0.95
L5-S1	96 (39%)	33 (33%)	24 (41%)	0.43
Levels decompressed - no. (%)				0.49
None	5 (2%)	2 (2%)	1 (2%)	
1	54 (22%)	27 (26%)	12 (20%)	
2	83 (33%)	23 (22%)	22 (37%)	
3+	107 (43%)	51 (50%)	24 (41%)	
Operation time, minutes (SD)	126.2 (66.5)	127.8 (63.4)	141.4 (66.7)	0.28
Blood loss, cc (SD)	286.3 (327.4)	354.4 (570.5)	342.6 (345.7)	0.30
Blood Replacement - no. (%)				
Intraoperative replacement	25 (10%)	6 (6%)	8 (14%)	0.24
Post-operative transfusion	14 (6%)	1 (1%)	5 (9%)	0.068
Length of hospital stay, days (SD)	3.3 (2.3)	2.8 (1.7)	3.6 (3.7)	0.14
Intraoperative complications - no. (%)[§]				
Dural tear/ spinal fluid leak	23 (9%)	10 (10%)	5 (8%)	0.97
Other	3 (1%)	0 (0%)	0 (0%)	0.37
None	221 (89%)	93 (90%)	54 (92%)	0.89
Postoperative complications/events - no. (%)[¶]				
Wound hematoma	3 (1%)	1 (1%)	0 (0%)	0.70
Wound infection	6 (2%)	1 (1%)	2 (3%)	0.55
Other	17 (7%)	2 (2%)	5 (9%)	0.13
None	209 (85%)	97 (95%)	48 (83%)	0.02
Post-operative mortality (death within 6 weeks of surgery) - no. (%)	1 (0.4%)	0 (0%)	0 (0%)	0.72
Post-operative mortality (death within 3 months of surgery) - no. (%)	1 (0.4%)	0 (0%)	0 (0%)	0.72
Additional surgeries (1-year rate) - no. (%)[‖]	15 (6%)	4 (4%)	3 (5%)	0.75
Additional surgeries (2-year rate) - no. (%)[‖]	20 (8%)	8 (8%)	4 (7%)	0.96
Additional surgeries (3-year rate) - no. (%)[‖]	30 (12%)	10 (10%)	6 (10%)	0.82

SPS	(BMI<30) (n=249)	(30 BMI<35) (n=103)	(BMI 35) (n=59)	p-value
Additional surgeries (4-year rate) - no. (%)[//]	35 (14%)	13 (13%)	6 (10%)	0.76
Recurrent stenosis / progressive listhesis	14 (6%)	7 (7%)	3 (5%)	
Pseudarthrosis / fusion exploration	0	0	0	
Complication or Other	11 (4.5%)	4 (3.9%)	3 (5%)	
New condition	4 (1.6%)	4 (3.9%)	0	

[*]Surgical information was available for 249 (BMI<30), 103 (30 BMI<35), and 59 (BMI 35) patients.

[†]Specific procedure data was available for 246 (BMI<30), 99 (30 BMI<35), and 58 (BMI[3]35) patients.

[§]No cases were reported of aspiration into the respiratory tract, vascular injury, nerve root injury, 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, cauda equina injury, nerve root injury, wound dehiscence, 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 2

Degenerative Spondylolisthesis (DS) Operative treatments, complications and events[*]

DS	(BMI<30) (n=233)	(30 BMI<35) (n=90)	(BMI 35) (n=66)	p-value
Specific procedures[†]				0.17
Decompression only	20 (9%)	2 (2%)	2 (3%)	
Non-instrumented fusion	45 (20%)	20 (22%)	16 (25%)	
Instrumented fusion	163 (71%)	67 (75%)	47 (72%)	
Multi-level fusion	51 (22%)	27 (30%)	13 (20%)	0.22
Decompression level				
L2–L3	26 (11%)	13 (15%)	6 (9%)	0.52
L3–L4	119 (52%)	46 (53%)	24 (38%)	0.099
L4–L5	225 (97%)	88 (100%)	61 (94%)	0.076
L5-S1	71 (31%)	26 (30%)	16 (25%)	0.61
Levels decompressed				0.35
None	1 (0%)	2 (2%)	1 (2%)	
1	91 (39%)	34 (38%)	34 (52%)	
2	85 (36%)	32 (36%)	21 (32%)	
3+	56 (24%)	22 (24%)	10 (15%)	
Operation time, minutes (SD)	197.2 (78.5)	218.4 (91.6)	222.7 (85.8)	0.028
Blood loss, cc (SD)	545.4 (474.6)	644.9 (492.7)	624.5 (407.2)	0.17
Blood Replacement				
Intraoperative replacement	70 (30%)	35 (39%)	27 (41%)	0.14
Post-operative transfusion	52 (23%)	14 (16%)	15 (23%)	0.40
Length of hospital stay, days (SD)	4.4 (2.6)[**]	5 (3.5)	5.3 (3.9)	0.069
Intraoperative complications[§]				
Dural tear/ spinal fluid leak	33 (14%)	5 (6%)	3 (5%)	0.017
Vascular injury	1 (0%)	0 (0%)	0 (0%)	0.71
Other	7 (3%)	2 (2%)	0 (0%)	0.36
None	194 (83%)	83 (92%)	63 (95%)	0.009
Postoperative complications/events[¶]				
Nerve root injury	1 (0%)	0 (0%)	0 (0%)	0.72
Wound dehiscence	0 (0%)	1 (1%)	0 (0%)	0.19
Wound hematoma	0 (0%)	0 (0%)	1 (2%)	0.085
Wound infection	3 (1%)	3 (3%)	5 (8%)	0.023
Other	20 (9%)	11 (12%)	6 (9%)	0.58
None	165 (71%)	62 (70%)	40 (62%)	0.30
Post-operative mortality (death within 6 weeks of surgery)	1 (0.4%)	0 (0%)	0 (0%)	0.72
Post-operative mortality (death within 3 months of surgery)	1 (0.4%)	0 (0%)	1 (1.5%)	0.40

DS	(BMI<30) (n=233)	(30 BMI<35) (n=90)	(BMI 35) (n=66)	p-value
Additional surgeries (1-year rate)[//]	10 (4%)	8 (9%)	7 (11%)	0.08
Additional surgeries (2-year rate) [//]	23 (10%)	14 (15%)	11 (17%)	0.15
Additional surgeries (3-year rate) [//]	24 (10%)	18 (20%)	12 (18%)	0.04
Additional surgeries (4-year rate) [//]	27 (11%)	19 (21%)	13 (20%)	0.04
Recurrent stenosis / progressive listhesis	14 (6%)	3 (3%)	3 (5%)	
Pseudarthrosis / fusion exploration	0	2 (2.2%)	2 (3.1%)	
Complication or Other	9 (3.9%)	9 (10.1%)	7 (10.9%)	
New condition	4 (1.7%)	4 (4.5%)	1	

[*] Surgical information was available for 233 (BMI<30), 90 (30 BMI<35), and 66 (BMI 35) patients.

[†] Specific procedure data was available for 228 (BMI<30), 89 (30 BMI<35), and 65 (BMI 35) 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, cauda equina 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.

[**] One of the patients in BMI<30 group had a length of hospital stay of 372 days—not counting that case the average length of hospital stay for the BMI<30 group would be 4.4 (2.6).

Table 3

Change Scores and Treatment Effects for Primary and Secondary Outcomes in the Randomized and Observational DS Cohorts Combined, According to BMI and Treatment Received*

DS		1-Year			2-Year			3-Year			4-Year		
Outcome	BMI	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)
SF-36 Bodily Pain (BP) (0–100) (SE)[††]	BMI < 30	32.4 (1.6)	15.7 (1.7)	16.7 (12.4, 21)	32.6 (1.6)	15.1 (1.9)	17.5 (13, 22)	33 (1.6)	17.4 (2)	15.6 (10.8, 20.4)	30.7 (1.7)	16.9 (2.2)	13.8 (8.7, 19)
	30 ≤ BMI < 35	29.2 (2.7)	10.8 (3.1)	18.4 (11, 25.8)	29.3 (2.5)	9.6 (3.4)	19.6 (11.9, 27.4)	30.8 (2.5)	12.4 (3.7)	18.4 (10.1, 26.6)	31.6 (2.6)	15.7 (4)	15.9 (6.9, 24.8)
	BMI ≥ 35	34.4 (3)	11 (3.8)	23.5 (14.6, 32.3)	30.4 (2.9)	10.1 (4.1)	20.4 (11.1, 29.7)	31.3 (3)	9.8 (4.7)	21.5 (11, 32)	29.6 (3.1)	10.7 (4.6)	19 (8.5, 29.5)
	pvalue	0.40	0.26	0.39	0.47	0.26	0.80	0.72	0.23	0.55	0.89	0.48	0.67
SF-36 Physical Function (PF) (0–100) (SE)[††]	BMI < 30	31 (1.5)	15.1 (1.7)	15.9 (11.9, 20)	29.9 (1.5)	14.1 (1.8)	15.8 (11.5, 20.1)	28.1 (1.5)	13.8 (1.9)	14.4 (9.8, 18.9)	27.9 (1.6)	14 (2.1)	13.9 (9, 18.8)
	30 ≤ BMI < 35	23.3 (2.6)	5 (3)	18.3 (11.3, 25.2)	19.8 (2.5)	2.1 (3.3)	17.8 (10.4, 25.1)	19.3 (2.4)	−0.4 (3.5)	19.7 (11.9, 27.5)	22.8 (2.5)	−2.6 (3.8)	25.4 (16.9, 33.8)
	BMI ≥ 35	23.4 (2.9)	−0.7 (3.6)	24.1 (15.8, 32.5)	18.2 (2.8)	0.1 (4)	18 (9.2, 26.9)	21.1 (2.9)	1.6 (4.8)	19.5 (9.1, 29.8)	21.2 (3)	−4.8 (4.5)	26 (15.9, 36.1)
	pvalue	0.009	<0.001	0.22	<0.001	<0.001	0.84	0.003	<0.001	0.40	0.069	<0.001	0.016
Mental Component Summary (MCS) (0–100) (SE)[††]	BMI < 30	2.2 (0.7)	1.8 (0.7)	0.4 (−1.4, 2.2)	2.3 (0.6)	1 (0.8)	1.3 (−0.6, 3.2)	2.5 (0.7)	0.6 (0.8)	1.9 (−0.2, 3.9)	2.6 (0.7)	−0.2 (0.9)	2.8 (0.5, 5.1)
	30 ≤ BMI < 35	1.8 (1.1)	0.6 (1.3)	1.2 (−1.9, 4.4)	2.9 (1)	1 (1.4)	1.9 (−1.4, 5.2)	2.3 (1)	−1.4 (1.5)	3.7 (0.2, 7.2)	1.9 (1.1)	1 (1.7)	0.9 (−3, 4.7)
	BMI ≥ 35	7.4 (1.2)	0.9 (1.6)	6.5 (2.7, 10.3)	3.5 (1.2)	−0.2 (1.7)	3.7 (−0.3, 7.6)	3.5 (1.2)	0 (2.1)	3.5 (−1.1, 8.1)	2.3 (1.3)	−0.7 (2.1)	3 (−1.7, 7.8)
	pvalue	<0.001	0.66	0.015	0.60	0.82	0.55	0.72	0.52	0.59	0.88	0.76	0.67
Oswestry Disability Index (ODI) (0–100) (SE)[‡‡]	BMI < 30	−25.2 (1.2)	−9.8 (1.3)	−15.4 (−18.5, −12.2)	−24.7 (1.2)	−10.2 (1.4)	−14.5 (−17.8, −11.1)	−22.7 (1.2)	−11 (1.5)	−11.7 (−15.2, −8.2)	−23.2 (1.3)	−10.5 (1.6)	−12.6 (−16.4, −8.8)
	30 ≤ BMI < 35	−23.1 (2)	−5.8 (2.3)	−17.3 (−22.7, −11.9)	−22.5 (1.9)	−6 (2.6)	−16.5 (−22.2, −10.8)	−19.3 (1.9)	−7.8 (2.8)	−11.6 (−17.7, −5.5)	−22 (2)	−5.3 (3)	−16.8 (−23.3, −10.2)
	BMI ≥ 35	−25 (2.3)	−2 (2.9)	−23 (−29.5, −16.5)	−22 (2.2)	−0.5 (3.1)	−21.5 (−28.3, −14.6)	−21.3 (2.3)	−2.4 (3.5)	−18.9 (−26.6, −11.2)	−21.3 (2.4)	−2.4 (3.4)	−18.8 (−26.5, −11.2)
	pvalue	0.66	0.027	0.11	0.42	0.012	0.18	0.31	0.068	0.22	0.75	0.055	0.26
Stenosis Bothersomeness Index (0–24) (SE)[§§]	BMI < 30	−9.5 (0.4)	−4.3 (0.5)	−5.2 (−6.4, −4)	−9.4 (0.4)	−4.3 (0.5)	−5.1 (−6.3, −3.8)	−9.4 (0.4)	−4.7 (0.6)	−4.7 (−6, −3.3)	−9.7 (0.5)	−4.6 (0.6)	−5.1 (−6.5, −3.7)
	30 ≤ BMI < 35	−9 (0.7)	−3.1 (0.8)	−5.9 (−7.8, −3.9)	−8.2 (0.7)	−2.6 (0.9)	−5.6 (−7.7, −3.5)	−8.5 (0.7)	−2.6 (1)	−5.9 (−8.2, −3.7)	−8.3 (0.7)	−1.5 (1.1)	−6.8 (−9.2, −4.3)
	BMI ≥ 35	−10.2 (0.8)	−2.6 (1)	−7.6 (−10, −5.2)	−9.1 (0.8)	−3.6 (1.1)	−5.5 (−8.1, −2.9)	−9.1 (0.8)	−4.5 (1.3)	−4.5 (−7.5, −1.6)	−8.2 (0.9)	−1.7 (1.3)	−6.5 (−9.4, −3.6)
	pvalue	0.55	0.22	0.21	0.27	0.23	0.90	0.47	0.15	0.62	0.12	0.012	0.41
Low Back Pain Bothersomeness (0–6)	BMI < 30	−2.4 (0.1)	−1.2 (0.1)	−1.2 (−1.6, −0.8)	−2.2 (0.1)	−1.3 (0.2)	−0.8 (−1.2, −0.4)	−2.1 (0.1)	−1.4 (0.2)	−0.7 (−1.1, −0.3)	−2.1 (0.1)	−1.3 (0.2)	−0.8 (−1.2, −0.4)

DS

Outcome	BMI	1-Year Surgical	1-Year Non-operative	1-Year Treatment Effect[†] (95% CI)	2-Year Surgical	2-Year Non-operative	2-Year Treatment Effect[†] (95% CI)	3-Year Surgical	3-Year Non-operative	3-Year Treatment Effect[†] (95% CI)	4-Year Surgical	4-Year Non-operative	4-Year Treatment Effect[†] (95% CI)
(SE)¶¶	30 BMI < 35	−2.1 (0.2)	−1.1 (0.2)	−1.1 (−1.7, −0.5)	−2.1 (0.2)	−1 (0.3)	−1.1 (−1.7, −0.5)	−2.2 (0.2)	−1.2 (0.3)	−1 (−1.7, −0.3)	−2.1 (0.2)	−0.9 (0.3)	−1.1 (−1.8, −0.4)
	BMI 35	−2.4 (0.2)	−0.5 (0.3)	−1.8 (−2.5, −1.1)	−2 (0.2)	−0.9 (0.3)	−1.1 (−1.8, −0.4)	−1.7 (0.2)	−1.5 (0.4)	−0.2 (−1.1, 0.7)	−2 (0.2)	−0.8 (0.4)	−1.2 (−2.1, −0.3)
	pvalue	0.57	0.048	0.18	0.86	0.37	0.70	0.36	0.71	0.34	0.97	0.28	0.51
Very/somewhat satisfied with symptoms (%)	BMI < 30	74.5	31.9	42.7 (33.2, 52.2)	70.2	30.8	39.3 (29.2, 49.4)	65.8	39.4	26.4 (15, 37.8)	62.8	32.5	30.3 (18.2, 42.3)
	30 BMI < 35	70	20.1	49.9 (35.1, 64.8)	67.6	34.2	33.5 (15.6, 51.4)	65.4	25	40.4 (22.6, 58.1)	62.7	25.7	37 (17.3, 56.8)
	BMI 35	67.6	14.7	52.9 (36, 69.8)	67.8	39.6	28.2 (5.7, 50.7)	66.3	39	27.3 (1.7, 52.9)	65.8	14.5	51.3 (31, 71.5)
	pvalue	0.57	0.083	0.49	0.90	0.70	0.64	0.99	0.32	0.47	0.94	0.42	0.43
Self-rated progress: major improvement (%)	BMI < 30	73.2	28.8	44.4 (35, 53.8)	74	26.2	47.9 (38.2, 57.5)	73.8	25.4	48.4 (38.3, 58.5)	65.5	21.9	43.7 (32.6, 54.7)
	30 BMI < 35	73.4	23	50.4 (35, 65.8)	68.5	19.7	48.8 (33, 64.7)	65.2	33.8	31.4 (11.9, 51)	65.8	19.3	46.6 (27.7, 65.4)
	BMI 35	84	12.3	71.7 (57.4, 86.1)	75.9	18.6	57.3 (39, 75.6)	66.8	13.3	53.5 (33.7, 73.2)	69.9	15.5	54.5 (33.5, 75.4)
	pvalue	0.29	0.25	0.087	0.59	0.65	0.75	0.36	0.43	0.29	0.88	0.83	0.74

*
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. 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.

†
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.

§§
The Stenosis 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

Table 4

Intervertebral Disc Herniation (IDH) Operative treatments, complications and events[*]

IDH	(BMI<30) (n=552)	(30 BMI<35) (n=151)	(BMI 35) (n=94)	p-value
Discectomy Level - no. (%)				
L2–L3	11 (2%)	2 (1%)	1 (1%)	0.75
L3–L4	20 (4%)	2 (1%)	5 (5%)	0.21
L4–L5	202 (37%)	71 (48%)	39 (42%)	0.045
L5-S1	323 (59%)	78 (53%)	52 (56%)	0.36
Operation time, minutes (SD)	72.3 (33.5)	84 (39.2)	90.5 (49.6)	<0.001
Blood loss, cc (SD)	56.1 (90.8)	84.8 (137.7)	80.7 (90)	0.002
Blood Replacement - no. (%)				
Intraoperative replacement	5 (1%)	1 (1%)	0 (0%)	0.64
Post-operative transfusion	0 (0%)	0 (0%)	0 (0%)	
Length of hospital stay, days (SD)	0.89 (0.8)	1.2 (1.2)	1.1 (1.2)	<0.001
Intraoperative complications - no. (%)[§]				
Dural tear/ spinal fluid leak	14 (3%)	7 (5%)	3 (3%)	0.41
Nerve root injury	1 (0%)	0 (0%)	1 (1%)	0.23
Other	1 (0%)	1 (1%)	1 (1%)	0.35
None	536 (97%)	144 (95%)	89 (95%)	0.35
Postoperative complications/events - no. (%)[¶]				
Nerve root injury	0 (0%)	0 (0%)	1 (1%)	0.024
Wound hematoma	3 (1%)	1 (1%)	0 (0%)	0.75
Wound Infection	13 (2%)	3 (2%)	2 (2%)	0.96
Other	18 (3%)	7 (5%)	2 (2%)	0.55
None	516 (94%)	141 (93%)	89 (95%)	0.90
Post-operative mortality (death within 6 weeks of surgery) - no. (%)	0 (0%)	0 (0%)	0 (0%)	
Post-operative mortality (death within 3 months of surgery) - no. (%)	1 (0.2%)[‡]	0 (0%)	0 (0%)	0.8
Additional surgeries (1-year rate) - no. (%)[//]	32 (6%)	8 (5%)	6 (6%)	0.93
Additional surgeries (2-year rate) - no. (%)[//]	40 (7%)	15 (10%)	9 (10%)	0.49
Additional surgeries (3-year rate) - no. (%)[//]	43 (8%)	18 (12%)	10 (11%)	0.26
Additional surgeries (4-year rate) - no. (%)[//]	51 (9%)	18 (12%)	13 (14%)	0.31
Recurrent disc herniation	32 (6%)	10 (7%)	7 (8%)	
Complication or Other	13 (2%)	4 (3%)	4 (4%)	
New condition	4 (1%)	4 (3%)	1	

[*] Surgical information was available for 552 (BMI<30), 151 (30 BMI<35), and 94 (BMI 35) patients.

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

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

*//*One-, two-, three- and four-year post-surgical re-operation rates are Kaplan Meier estimates. P-values are based on the log-rank test. Numbers and percentages are based on the first additional surgery if more than one additional surgery.

*‡*Patient died after heart surgery at another hospital, the death was judged unrelated to spine surgery.

Table 5

Change Scores and Treatment Effects for Primary and Secondary Outcomes in the Randomized and Observational IDH Cohorts Combined, According to BMI and Treatment Received*

IDH		1-Year			2-Year			3-Year			4-Year		
Outcome	BMI	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)
SF-36 Bodily Pain (BP) (0–100) (SE)[††]	BMI < 30	47.5 (1.1)	34.1 (1.4)	13.4 (10, 16.7)	48 (1.1)	34.9 (1.4)	13.1 (9.7, 16.4)	48.7 (1.1)	35.8 (1.4)	12.9 (9.4, 16.4)	50 (1.2)	33.4 (1.5)	16.6 (12.9, 20.3)
	30 ≤ BMI < 35	43 (2)	26.4 (2.9)	16.6 (10.1, 23.1)	41.6 (2)	35.1 (3)	6.6 (−0.3, 13.4)	41.7 (2.1)	30.8 (3.2)	11 (3.7, 18.2)	45 (2.2)	34.2 (3.3)	10.8 (3.3, 18.3)
	BMI 35	47.3 (2.5)	28.9 (3.8)	18.3 (9.9, 26.8)	40.7 (2.5)	24.9 (4)	15.8 (7.1, 24.5)	41.6 (2.7)	20.9 (4.2)	20.7 (11.4, 30)	42.8 (2.7)	25.6 (4.3)	17.2 (7.8, 26.7)
	pvalue	0.13	0.031	0.43	0.002	0.051	0.16	0.002	0.002	0.23	0.013	0.19	0.37
SF-36 Physical Function (PF) (0–100) (SE)[††]	BMI < 30	46.2 (1)	31.3 (1.2)	14.8 (11.8, 17.9)	45.7 (1)	32.3 (1.3)	13.4 (10.4, 16.5)	46.4 (1)	33.5 (1.3)	12.9 (9.7, 16.1)	47.7 (1.1)	32 (1.4)	15.7 (12.4, 19)
	30 ≤ BMI < 35	39.1 (1.8)	23.3 (2.6)	15.8 (10, 21.7)	37.5 (1.8)	29.5 (2.8)	8 (1.8, 14.1)	36.9 (2)	26.1 (2.9)	10.8 (4.2, 17.3)	36.5 (2.1)	26.2 (3)	10.3 (3.5, 17.1)
	BMI 35	40.7 (2.3)	17.1 (3.5)	23.6 (16, 31.3)	38.6 (2.3)	17.9 (3.6)	20.7 (12.9, 28.5)	40.7 (2.4)	15.7 (3.8)	25 (16.7, 33.3)	37.9 (2.4)	18.5 (3.9)	19.4 (10.9, 27.9)
	pvalue	<0.001	<0.001	0.10	<0.001	<0.001	0.04	<0.001	<0.001	0.016	<0.001	0.002	0.21
Mental Component Summary (MCS) (0–100) (SE)[††]	BMI < 30	7.7 (0.4)	4.4 (0.6)	3.3 (1.9, 4.7)	6.8 (0.4)	4.2 (0.6)	2.6 (1.2, 3.9)	7 (0.4)	4 (0.6)	2.9 (1.5, 4.4)	6.5 (0.5)	4.6 (0.6)	2 (0.5, 3.5)
	30 ≤ BMI < 35	8 (0.8)	5.6 (1.2)	2.3 (−0.3, 5)	5.8 (0.8)	5.3 (1.2)	0.5 (−2.3, 3.3)	5.4 (0.9)	4.7 (1.3)	0.7 (−2.3, 3.6)	5.2 (0.9)	4 (1.3)	1.1 (−1.9, 4.2)
	BMI 35	7.7 (1)	1.6 (1.6)	6.1 (2.7, 9.6)	5.5 (1)	5.5 (1.6)	0 (−3.6, 3.5)	4.7 (1.1)	3.7 (1.7)	1 (−2.8, 4.7)	4.5 (1.1)	2.2 (1.8)	2.3 (−1.6, 6.2)
	pvalue	0.95	0.11	0.21	0.37	0.57	0.21	0.064	0.87	0.28	0.13	0.44	0.86
Oswestry Disability Index (ODI) (0–100) (SE)[‡‡]	BMI < 30	−38.5 (0.8)	−25.2 (1)	−13.3 (−15.8, −10.8)	−39.2 (0.8)	−25.6 (1)	−13.6 (−16.1, −11.1)	−39.7 (0.8)	−27 (1.1)	−12.7 (−15.3, −10.1)	−40.1 (0.9)	−26.1 (1.1)	−14 (−16.7, −11.3)
	30 ≤ BMI < 35	−34.7 (1.5)	−18.1 (2.1)	−16.6 (−21.3, −11.9)	−32.5 (1.5)	−24.2 (2.3)	−8.3 (−13.4, −3.3)	−31.2 (1.6)	−21.1 (2.4)	−10.1 (−15.4, −4.8)	−33.3 (1.7)	−23.3 (2.5)	−10 (−15.5, −4.5)
	BMI 35	−35.9 (1.9)	−14.5 (2.8)	−21.5 (−27.6, −15.3)	−32.2 (1.9)	−19.3 (2.9)	−12.9 (−19.2, −6.6)	−34.4 (2)	−15.3 (3.2)	−19.1 (−26, −12.3)	−34.1 (2)	−18.3 (3.2)	−15.8 (−22.7, −9)
	pvalue	0.064	<0.001	0.035	<0.001	0.12	0.17	<0.001	<0.001	0.11	<0.001	0.049	0.33
Sciatica Bothersomeness Index (0–24) (SE)[§§]	BMI < 30	−11.3 (0.3)	−8.3 (0.3)	−3.1 (−3.9, −2.2)	−11.3 (0.3)	−8.2 (0.3)	−3.1 (−3.9, −2.2)	−11.5 (0.3)	−8.6 (0.3)	−2.9 (−3.7, −2)	−12.1 (0.3)	−8.3 (0.4)	−3.8 (−4.7, −2.9)
	30 ≤ BMI < 35	−10.8 (0.5)	−6.8 (0.7)	−4 (−5.5, −2.5)	−10 (0.5)	−7.7 (0.7)	−2.3 (−4, −0.7)	−10 (0.5)	−6.8 (0.8)	−3.2 (−4.9, −1.5)	−10 (0.5)	−8.6 (0.8)	−1.5 (−3.3, 0.3)
	BMI 35	−10.8 (0.6)	−6.5 (0.9)	−4.2 (−6.2, −2.2)	−9.8 (0.6)	−6.4 (0.9)	−3.4 (−5.5, −1.4)	−9.9 (0.6)	−6.8 (1)	−3.1 (−5.3, −0.9)	−10.2 (0.6)	−5.6 (1)	−4.6 (−6.8, −2.3)
	pvalue	0.50	0.046	0.36	0.011	0.16	0.64	0.006	0.031	0.93	<0.001	0.037	0.04
Low Back Pain Bothersomeness (0–6)	BMI < 30	−2.2 (0.1)	−1.4 (0.1)	−0.7 (−1, −0.4)	−2.2 (0.1)	−1.4 (0.1)	−0.8 (−1.1, −0.5)	−2.3 (0.1)	−1.5 (0.1)	−0.8 (−1.1, −0.5)	−2.3 (0.1)	−1.4 (0.1)	−0.9 (−1.2, −0.6)

IDH

Outcome	BMI	1-Year Surgical	1-Year Non-operative	1-Year Treatment Effect† (95% CI)	2-Year Surgical	2-Year Non-operative	2-Year Treatment Effect† (95% CI)	3-Year Surgical	3-Year Non-operative	3-Year Treatment Effect† (95% CI)	4-Year Surgical	4-Year Non-operative	4-Year Treatment Effect† (95% CI)
(SE)‡¶	30≤BMI<35	−2 (0.1)	−1.2 (0.2)	−0.8 (−1.3, −0.3)	−1.8 (0.1)	−1.6 (0.2)	−0.2 (−0.7, 0.3)	−1.8 (0.2)	−1.2 (0.2)	−0.6 (−1.1, −0.1)	−1.9 (0.2)	−1.6 (0.2)	−0.2 (−0.8, 0.4)
	BMI≥35	−2.2 (0.2)	−0.7 (0.3)	−1.5 (−2.1, −0.9)	−1.9 (0.2)	−1.3 (0.3)	−0.5 (−1.1, 0.1)	−1.9 (0.2)	−1.2 (0.3)	−0.7 (−1.4, 0)	−1.9 (0.2)	−0.9 (0.3)	−1 (−1.7, −0.3)
	pvalue	0.41	0.022	0.076	0.041	0.72	0.20	0.011	0.27	0.91	0.036	0.19	0.10
Very/somewhat satisfied with symptoms (%)	BMI <30	73.8	46.4	27.4 (19.7, 35.2)	76.9	51.2	25.8 (18, 33.6)	75.7	51.4	24.3 (16.2, 32.4)	78.4	49	29.4 (21, 37.8)
	30≤BMI<35	71	39.3	31.7 (17.1, 46.3)	68.8	46.1	22.7 (6.8, 38.5)	65.9	48.9	16.9 (−0.3, 34.1)	70.4	46.6	23.8 (6.3, 41.3)
	BMI≥35	79	30.5	48.4 (30.6, 66.2)	72.6	32.6	39.9 (20.9, 58.9)	78	38.5	39.5 (19, 60.1)	74.7	24.8	50 (31.3, 68.6)
	p-value	0.44	0.19	0.14	0.16	0.14	0.39	0.10	0.44	0.21	0.23	0.082	0.17
Self-rated progress: major improvement (%)	BMI <30	83.8	57.6	26.2 (18.7, 33.6)	80.1	62.1	18 (10.3, 25.6)	77.3	56.7	20.6 (12.4, 28.8)	80.4	53.8	26.6 (18.2, 35.1)
	30≤BMI<35	82.5	38.8	43.7 (29.8, 57.6)	76.2	54.4	21.8 (6.1, 37.5)	69.8	50.5	19.3 (2.2, 36.5)	72.8	45.1	27.7 (10.4, 45.1)
	BMI≥35	80.6	59.1	21.5 (2.1, 40.9)	70.6	40.1	30.5 (10.2, 50.8)	76.9	43.5	33.4 (11.9, 54.9)	77.3	46.4	31 (8.6, 53.3)
	p-value	0.76	0.044	0.19	0.15	0.045	0.70	0.27	0.36	0.51	0.24	0.53	0.95
Work status: working (%)	BMI <30	85.9	84.1	1.8 (−4.3, 7.8)	86	84.1	1.9 (−4.3, 8.1)	86.6	80.4	6.3 (−0.7, 13.2)	86.9	78.4	8.5 (0.8, 16.2)
	30≤BMI<35	85.9	83.7	2.2 (−9, 13.5)	84.5	87.5	−3 (−13.8, 7.8)	75.2	79.2	−3.9 (−19.6, 11.8)	75.3	82.1	−6.8 (−22.5, 8.9)
	BMI≥35	87.7	85.4	2.3 (−11, 15.5)	84.2	87.1	−2.8 (−16.1, 10.5)	79.5	75.1	4.3 (−15.9, 24.5)	79.8	65.5	14.3 (−9.3, 37.8)
	p-value	0.89	0.96	0.99	0.89	0.77	0.67	0.042	0.82	0.52	0.038	0.41	0.22

*
Adjusted for age, gender, marital status, smoking status, race, compensation, herniation location, working status, stomach comorbidity, depression, other comorbidity, self-rated health trend, duration of most recent episode, treatment preference and baseline score (for SF-36, ODI, and Sciatica Bothersomeness), and center. Other comorbidities include: stroke, diabetes, osteoporosis, cancer, fibromyalgia, chronic fatigue syndrome (CFS), post traumatic stress disorder (PTSD), alcohol, drug dependency, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine, anxiety, stomach, bowel.

†
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.

§§
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