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Who should have Surgery for an Intervertebral Disc Herniation?:

Comparative Effectiveness Evidence from SPORT

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Abstract

Study Design—Combined prospective randomized controlled trial and observational cohort study of intervertebral disc herniation (IDH), an as-treated analysis.

Objective—To determine modifiers of the treatment effect (TE) of surgery (the difference between surgical and nonoperative outcomes) for intervertebral disc herniation (IDH) using subgroup analysis.

Summary of Background Data—SPORT demonstrated a positive surgical TE for IDH at the group level. However, individual characteristics may affect TE. No prior studies have evaluated TE modifiers in IDH.

Methods—IDH patients underwent either discectomy (n=788) or nonoperative care (n=404) and were analyzed according to treatment received. Thirty-seven baseline variables were used to define subgroups for calculating the time-weighted average TE for the Oswestry Disability Index (ODI) over 4 years ($TE = \Delta ODI_{\text{surgery}} - \Delta ODI_{\text{nonoperative}}$). Variables with significant subgroup by* treatment interactions ($p < 0.1$) were simultaneously entered into a multivariate model to select independent TE predictors.

Results—All analyzed subgroups improved significantly more with surgery than with nonoperative treatment ($p < 0.05$). In minimally adjusted univariate analyses: being married, absence of joint problems, worsening symptom trend at baseline, high school education or less, older age, no worker's compensation, longer duration of symptoms, and an SF-36 mental component score (MCS) less than 35 were associated with greater TEs. Multivariate analysis demonstrated: being married (TE −15.8 vs. −7.7 single, $p < 0.001$), absence of joint problems (TE −14.6 vs. −10.3 joint problems, $p = 0.012$), and worsening symptoms (TE −15.9 vs. −11.8 stable symptoms, $p = 0.032$) were independent TE modifiers. TE's were greatest in married patients with worsening symptoms (−18.3) vs. single patients with stable symptoms (−7.8).

Conclusions—IDH patients who met strict inclusion criteria improved more with surgery than with nonoperative treatment, regardless of specific characteristics. However, being married, without joint problems, and worsening symptom trend at baseline were associated with a greater treatment effect.

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INTRODUCTION

The Spine Patient Outcomes Research Trial (SPORT) demonstrated a clear benefit of surgery compared to nonoperative treatment for lumbar intervertebral disc herniation (IDH) over four years.¹⁻³ However, these findings were at the group level, and it has been shown that demographic, radiographic, clinical, and psychological characteristics can affect individual outcomes.⁴⁻¹³ The Institute of Medicine and Congress have defined comparative effectiveness research as a top priority with a goal of “assisting consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.”¹⁴ As such, we wanted to determine which *individuals* were the best candidates for surgical and nonoperative treatment. Most prior studies evaluating potential predictors of outcomes have focused on surgical outcomes only.^{5,8,12,13} While these studies were helpful, the decision between surgical and nonoperative treatment should be based on the relative benefit of one treatment compared to the other (i.e. the treatment effect of surgery, TE). By considering only predictors of surgical outcome rather than factors that affect TE in making treatment decisions, surgeons may erroneously suggest nonoperative treatment to patients likely to fail without surgery and surgical treatment to patients who could succeed nonoperatively. In an ideal setting, physicians would be able to predict the likely TE for an individual patient based on their specific characteristics in order to make their treatment decision a truly *informed choice*. To do this, the predicted surgical and nonoperative outcomes must be known. While the Maine Lumbar Spine Study (MLSS) compared surgical and nonoperative outcomes for IDH patients, it did not focus on subgroup analyses to determine TE modifiers.^{6,15,16} As such, SPORT is the first large-scale trial with both surgical and nonoperative arms that is able to evaluate a large number of potential TE modifiers.

Previous SPORT investigations have focused on subgroups that authors selected *a priori* as potential TE modifiers.^{9,10,17,18} We felt that a systematic analysis of all potential TE modifiers would be beneficial in order to determine which patient characteristics were associated with TE and could be used to counsel IDH patients making informed treatment decisions. As such, the goals of this study were to 1) perform subgroup analyses for all potential TE modifiers, and 2) develop a multivariate model to determine independent TE modifiers.

MATERIALS AND METHODS

Study Design

SPORT consisted of a randomized controlled trial with a concurrent observational cohort study conducted in 11 states at 13 institutions with multidisciplinary spine practices.¹⁹ In the first year of follow-up in the randomized trial, 43% of patients assigned to surgery did not have surgery, and 41% of patients assigned to non-operative treatment did have surgery.³ By 4 years, 41% of the patients randomized to surgery had still not undergone surgery, and 45% of the patients assigned to non-operative treatment had received surgery.² Given this rate of protocol nonadherence and the consistency of the findings between the randomized and the observational cohorts, the data were combined in an as-treated analysis in this study.^{1,2} The rationale for this decision has been discussed previously.²⁰

Patient Population

Patients were considered for inclusion in the study if they were over 18 years old, had radicular pain with a positive nerve root tension sign or neurologic deficit, a confirmatory imaging study demonstrating IDH corresponding to their symptoms, and presence of symptoms for at least six weeks. Exclusion criteria included cauda equina syndrome,

malignancy, significant deformity, prior back surgery and other established contraindications to elective surgery.¹⁹

Study Interventions

Surgery consisted of a standard open disectomy with examination and decompression of the involved nerve root.^{21,22} Surgeons were encouraged to use loupe magnification or a microscope. The non-operative treatment group received “usual care”—defined as including at least physical therapy, education and counseling with home exercise instruction, and non-steroidal anti-inflammatory drugs if tolerated. Physicians were instructed to individualize non-operative treatment and explore a wide range of non-operative options.¹⁹

Imaging Studies

Imaging studies included MRI in 97% of the patients and CT scan in the remaining 3%. Radiographic assessment was performed by the treating physician at the time of initial evaluation. Herniation location was classified as central, posterolateral, foraminal, or far lateral.²³ Herniation morphology was classified as a protrusion, extrusion or sequestration.²³

Baseline Characteristics and Primary Outcome Measure

At baseline, patients and clinicians answered questionnaires evaluating demographic, socioeconomic, clinical, and radiographic characteristics.^{1,3} Baseline scores on the Short-Form 36 (SF-36),²⁴ AAOS/Modems version of the Oswestry Disability Index (ODI),²⁵ Sciatica Bothersomeness Index,^{26,27} and Leg and Back Pain Bothersomeness (0–6 point Likert-type scale) were also recorded. The ODI was also recorded at 6 weeks, 3 months, 6 months, 1 year and yearly thereafter out to 4 years. Thirty-seven variables were selected as potential modifiers of the treatment effect of surgery. Continuous variables were converted to categorical variables as follows: ODI defined by quartiles; Sciatica Bothersomeness and Age by the median; Duration of Symptoms categorized as 6 weeks, 6 weeks to 6 months, or greater than 6 months; Income as greater than \$50,000, less than \$50,000 or not working; and the SF-36 Mental Component Score (MCS) as less than or equal to 35 or greater than 35.²⁸ Herniation Location was classified as posterolateral versus other (central, foraminal or far lateral), and Herniation Level was defined as upper lumbar (L2–3 and L3–4), L4–5 or L5–S1.

Statistical Considerations

The primary aim of the analysis was to identify baseline variables that were significant indicators of differential treatment effects of surgery (i.e. variables with significant subgroup by*treatment interactions). The treatment effect (TE) of surgery was defined as:

$$\text{Treatment Effect} = \text{Change in ODI}_{\text{surgery}} - \text{Change in ODI}_{\text{nonoperative}}$$

In all analyses, TE was calculated as the time-weighted average (area under the curve) over 4 years. Note that a negative TE indicated that surgery was more effective than nonoperative treatment. To identify candidate variables, a “minimally-adjusted” analysis (controlling only for age, gender, center, and baseline ODI score) was performed for each of the thirty-seven variables to identify those that had substantial TE differences across subgroups. Those that were identified as potential TE modifiers ($p < 0.1$) were then entered along with their treatment interaction terms into a longitudinal regression model that controlled for factors predicting treatment received or missing data in order to control for selection and attrition bias (age, gender, marital status, smoking status, race, compensation, herniation location, working status, stomach comorbidity, other comorbidity, self-rated health trend, duration of most recent episode, treatment preference, and baseline ODI score).² Variables with significant treatment interaction terms ($p < 0.05$) were identified as independent TE modifiers

and included in the final multivariable mixed effects longitudinal regression model including a random individual effect to account for correlation between repeated measurements within individuals. The outcomes were stratified by modifiers and overall comparisons of area-under-the-curve across the four-year follow-up were made using a Wald test.²⁹ This analytical approach, starting with “minimally adjusted” analyses with a less stringent ($p < 0.1$) criterion for significance, was performed in order to ensure that no potential independent modifiers were missed in the first stage. In the second stage, the complete multivariate model was used with the traditional threshold of significance ($p < 0.05$) in order to definitively identify independent TE modifiers.

RESULTS

Patient Distribution and Follow-Up

There were 1,244 patients enrolled overall, with 501 in the randomized trial and 743 in the observational cohort. By 4 years, 805 (65%) had undergone surgery. Ninety-six percent of patients (1,196) had completed at least one follow-up visit and were included in the analysis. Completeness of follow-up ranged from 87% at 6 weeks to 65% at 4 years. Details can be found in the primary analysis.²

Minimally Adjusted Analyses

All examined subgroups with the exception of patients without insurance had a significant surgical TE (Table 1). While patients without insurance had a TE of -7 , indicating surgery was more effective than nonoperative treatment, this subgroup was quite small ($n=38$) and its TE was associated with a broad confidence interval that crossed zero ($-16.9 - 2.9$). The majority of variables were significantly associated with both surgical and nonoperative outcomes, with the direction of the association always being the same for both treatments (e.g. smokers had worse surgical and nonoperative outcomes but similar TE as non-smokers, Figure 1). Age greater than 41 years (TE -13.3 vs. -10.6 for age less than 41 years, $p = 0.06$), the absence of joint problems (TE -12.6 vs. -8.2 for the presence of joint problems, $p = 0.01$), a high school education or less (TE -16.1 vs. -10.7 vs. for at least some college, $p = 0.001$), no worker's compensation (TE -12.6 vs. -9.0 for receiving or applying for worker's compensation, $p = 0.06$), duration of symptoms for over 6 months (TE -14.7 vs. -11.5 for 6 weeks to 6 months vs. -9.9 for 6 weeks, $p = 0.09$, Figure 2), being married (TE -14.2 vs. -10.3 for divorced vs. -5.2 for single, $p < 0.001$), worsening symptom trend at baseline (TE -15.4 vs. -12.4 for getting better vs. -10.7 for unchanging, $p = 0.02$), and an MCS score of less than 35 (TE -13.9 vs. -11.0 for MCS above 35, $p = 0.1$) were associated with greater treatment effects of surgery.

Multivariate Analyses

The above variables that were associated with TE and their treatment interaction terms were added to a previously published model predicting the time-weighted average treatment effect over four years of follow-up.² Being married, the absence of joint problems, and worsening symptom trend at baseline remained significant indicators of greater TE in this model ($p < 0.05$, Table 2, Figures 3–5). Age, education, worker's compensation status, duration of symptoms, and baseline MCS scores were not significant independent TE modifiers in the multivariate model. To illustrate the range of TEs across subgroups, we compared outcomes among the various groups defined by marital status and symptom trend. Married patients with worsening symptoms ($n=327$) improved 37.9 points with surgery and 19.6 points with nonoperative treatment, yielding a TE of -18.3 (95% CI -21.3 to -15.2). In contrast, single patients with unchanging symptoms ($n=107$) improved 34.8 points with surgery and 27 points with nonoperative treatment, a TE of -7.8 (95% CI -12.2 to -3.4). This difference in TE (-18.3 vs. -7.8) was clinically and statistically significant ($p < 0.001$). Comparing

subgroups defined by all three independent modifiers (i.e. marital status, joint problems, and symptom trend) was not possible due to the small number of single patients with joint problems and unchanging symptoms (n=15).

DISCUSSION

In order for discectomy candidates to make informed treatment decisions, they must have an estimate of the likely benefit of surgery compared to nonoperative treatment. While SPORT and the MLSS have demonstrated the long-term benefit of discectomy compared to nonoperative treatment for the “average” patient meeting the specific inclusion criteria of these studies, the associations between specific individual characteristics and TE have not been formally evaluated.^{2,16} Consistent with the aims of comparative effectiveness research laid out by the Institute of Medicine, we shifted our focus from the population to the individual level.¹⁴ The current study demonstrated that patient characteristics consistently predicted both surgical and nonoperative outcomes in the same direction (i.e. smokers did worse with both surgical and nonoperative treatment compared to nonsmokers). These variables are useful for patient counseling about likely outcomes but are less useful for selecting treatment since they are not associated with differential TEs (i.e. smokers and nonsmokers had comparable TEs).

Similar to prior studies, we found that general health characteristics (e.g. comorbidities, body mass index, mental health problems, smoking, etc.) and socioeconomic factors (e.g. work status, insurance status, worker’s compensation, marital status, education, race, etc.) tended to be the strongest predictors of both surgical and nonoperative outcomes.^{4,6,8,12,16} Some disease specific findings like baseline ODI score, duration of symptoms, predominant pain location, and treatment with opioids were also relatively strong predictors of outcomes. Interestingly, specific physical exam findings such as a positive straight leg raise test, motor weakness, and asymmetric reflexes, which have been found to be associated with surgical outcomes in the past,⁴ were not associated with surgical or nonoperative outcomes in the current study. While evaluation of these individual characteristics can be useful for advising patients of their likely surgical and nonoperative outcomes, most of these variables do not assist in decision making since they are not associated with TE.

Thirty-seven variables were evaluated as TE modifiers in minimally adjusted, univariate analyses. These analyses revealed only eight characteristics that modified TE, even with a threshold of $p < 0.1$. The majority of these factors were general health (joint problems and MCS score) and socioeconomic (age, education, worker’s compensation, and marital status) factors, though the symptom trend at baseline and the duration of symptoms also modified TE. Multivariate analysis that simultaneously included all of the significant factors from the univariate analyses yielded only three independent TE modifiers (marital status, joint problems, and symptom trend at baseline). However, TE did vary markedly across these subgroups, ranging from -7.7 for single patients to -15.8 for married patients and from -7.8 for single patients with unchanging symptoms to -18.3 for married patients with worsening symptoms at baseline. While nearly all subgroups improved significantly more with surgery than with nonoperative treatment, the magnitude of this benefit varied significantly depending on individual patient characteristics.

The current analysis showed that marital status, joint problems, and health trend independently modified TE. It is well known that marriage is associated with positive health outcomes in many conditions, including cancer and heart failure.^{30–33} The literature on the role of marital status in spine outcomes is relatively sparse. Boos et al. found that patients with symptomatic disk herniations were more likely to be married than asymptomatic controls, and Lehman et al. reported that married patients with low back pain returned to

work sooner than similar single patients.^{34,35} We found that married and single patients had similar surgical outcomes, but single patients improved significantly more with nonoperative treatment, leading to a significantly higher TE for married patients. The current study does not provide an explanation for why single patients did better with nonoperative treatment, though marital status is likely a marker for other characteristics that were responsible for these outcomes. In considering the role of joint problems, our findings are consistent with the those of Slover et al. who reported that the presence of comorbidities resulted in less improvement on the ODI following lumbar spine surgery.^{36,37} The current data showed that while the presence of joint problems reduced the improvement following both surgical and nonoperative treatment, this effect was more pronounced for surgical outcomes, resulting in a diminished TE for these patients. This may have represented a ceiling effect in that the degree of ODI improvement experienced by patients with joint problems could have been limited by their non-spine joint problems, even if their spine symptoms were completely resolved. The greater treatment effect observed for patients with worsening baseline symptoms was not surprising given that these patients were worsening with nonoperative treatment at baseline yet had surgical outcomes that were nearly as good as patients who were getting better at baseline.

Many prior studies have evaluated potential predictors of discectomy outcomes, though none have evaluated TE modifiers. Abramovitz and Neff found that predominant leg pain, the absence of worker's compensation, the presence of leg but not back pain on straight leg raising, a radicular distribution of pain, and reflex asymmetry predicted better surgical outcomes.⁴ We also found that predominant leg pain and the absence of worker's compensation were associated with better surgical outcomes, though we did not find such associations with the straight leg raise test or reflex asymmetry. The MLSS also found that worker's compensation was associated with worse outcomes at 10 years, though that analysis did not separate surgical and nonoperative outcomes and did not evaluate TE.^{16,17} In Peul et al.'s randomized trial comparing early discectomy to initial nonoperative care, no TE modifiers were found.¹¹ However, this trial did not compare surgical and nonoperative outcomes but rather an early surgery group to a group consisting of a combination of patients treated with delayed surgery or continued nonoperative treatment. As such, direct comparison to the current study is difficult. Additional studies have also demonstrated the associations between clinical, psychological, and socioeconomic factors with discectomy outcomes, though these studies did not evaluate nonoperative outcomes and were thus unable to evaluate TE modifiers.^{8,12}

There are a number of limitations of this study. While SPORT was designed with a randomized IDH cohort, the high rate of protocol non-adherence precluded meaningful interpretation of those data on an intent-to-treat basis alone.³ This phenomenon underscores the difficulty of conducting and analyzing a randomized trial of an elective surgical procedure that is primarily performed for pain relief. Additionally, the subgroup analyses used to evaluate potential TE modifiers were possibly underpowered for some variables (as indicated by broad confidence intervals around the TEs), and this may have resulted in the failure to detect some meaningful modifiers (Type II error). On the other hand, thirty-seven potential TE modifiers were evaluated, which put the study at risk for finding spurious associations due to chance alone (Type I error). We intentionally performed the initial analyses with minimally adjusted models to generate a list of potential TE modifiers that could be tested in the complete multivariate model. As such, the findings of these minimally adjusted analyses were subject to confounding and could yield slightly different results from those reported previously using the complete model.^{9,18} Five of eight variables found to be associated with TE in the minimally adjusted analyses did not remain significant in the multivariate model, indicating they were not independent TE modifiers. However, details from these analyses were included as clinicians might still find these relationships helpful in

counseling patients. In order to improve the generalizability of our findings, nonoperative treatment was specified as “usual care”. Nonoperative treatment resulted in greater improvement in the current study compared to the MLSS, suggesting that it was generally effective.^{6,16} However, a specified, intensive program of nonoperative treatment may have been more effective for some patients. In addition, 35% of patients were lost to follow-up by four years, and this could have contributed to attrition bias if outcomes among those lost to follow-up were different from those who remained in the study. To address this, we did control for variables associated with missing data in the statistical model. Finally, we used the AAOS/Modems modified version of the ODI. This may give slightly different absolute results than either the original or the latest version (2.1a); however since our analysis was concerned with relative differences between treatment groups all using the same instrument, this is unlikely to have substantially affected the results.

Among patients meeting the strict inclusion criteria of SPORT, essentially all subgroups improved significantly more with surgery than with nonoperative treatment. This underscores the importance of ensuring that patients meet well-defined indications for surgery (i.e. duration of symptoms for at least 6 weeks, imaging consistent with clinical findings, and the presence of neurological signs) prior to undergoing discectomy. Though patients improved more with surgery than nonoperative treatment regardless of individual characteristics, the magnitude of benefit associated with surgery (i.e. TE) varied significantly across some subgroups. While the current study supported prior literature reporting the powerful effects of certain psychological, socioeconomic, and clinical factors on discectomy outcomes, only three variables (marital status, the presence or absence of joint problems, and symptom trend) were found to be significant independent TE modifiers.

How should these data be used in treatment decision making? We feel that the treatment decision in IDH should be based on the comparison of likely surgical and nonoperative outcomes (i.e. TE) rather than on the overall magnitude of change associated with either type of treatment. This is illustrated by the fact that patients with lower educational attainment, longer duration of symptoms, and lower MCS scores, characteristics associated with worse overall outcomes, actually had higher surgical TEs. Based on prior studies and anecdotal evidence, surgeons might be reluctant to offer surgery to these patients.^{4,8,12} However, the current data suggest these patients might benefit more from surgery (relative to their likely nonoperative outcomes) despite not improving to the same degree as patients without these characteristics. In the shared decision making process, this information should be used to create realistic expectations for surgical and nonoperative outcomes and allow patients to make well-informed decisions consistent with their values.^{38,39}

So who should have surgery for intervertebral disk herniation? These data suggest discectomy is appropriate treatment for all patients who meet the strict inclusion criteria of SPORT and select surgery after going through a thorough shared decision making process educating them about the risks, benefits and likely outcomes of surgical and nonoperative treatment. Future work will involve the creation and evaluation of real time computer models that can be used by individual patients with their providers in the clinical setting to predict their likely surgical and nonoperative outcomes.⁴⁰

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KEY POINTS

- Disc herniation patients who met strict inclusion criteria improved more with surgery than with nonoperative treatment, regardless of specific characteristics.
- Being married, without joint problems, and worsening symptom trend at baseline were associated with a greater treatment effect of surgery.
- Some characteristics associated with worse overall outcomes were associated with greater surgical treatment effects (i.e. low education, low MCS score, longer duration of symptoms).

Figure 1.

This graph demonstrates that non-smokers improved more with surgery and non-operative treatment than smokers though had a similar TE. This pattern was observed for the majority of variables in the minimally adjusted analyses.

Figure 2.

This graph demonstrates that patients with a longer duration of symptoms improved less with surgery and non-operative treatment than those with a shorter duration of symptoms but had a greater TE (minimally adjusted analysis).

Figure 3.

This graph demonstrates that patients without joint problems improved more with surgery and non-operative treatment than those with joint problems and also had a greater TE (multivariate analysis).

Figure 4.

This graph demonstrates that married patients improved more with surgery and less with non-operative treatment than single patients and also had a greater TE (multivariate analysis).

Figure 5.

This graph demonstrates that patients getting worse at baseline improved less with surgery and non-operative treatment than patients getting better or with stable symptoms and also had a greater TE (multivariate analysis).

Table 1

Area under curve subgroup results for Oswestry Disability Index (ODI) change scores, adjusted for age, gender, center, and baseline ODI score (Time weighted average 4 years treatment effects).

	N	Surgical (n = 788)	Non-operative (n = 404)	Treatment Effect [†] (95% CI)
Baseline ODI ≤ 31	258	-21.4 (1.5)	-5.2 (1.2)	-16.1 (-19.1, -13.1)
31 < Baseline ODI ≤ 45	252	-29.4 (1.3)	-14.9 (1.4)	-14.5 (-17.5, -11.4)
45 < Baseline ODI ≤ 60	293	-39.2 (1.1)	-23.1 (1.6)	-16 (-19.3, -12.8)
Baseline ODI > 60	386	-50.8 (1)	-39.1 (1.6)	-11.7 (-14.9, -8.4)
p-value		<0.001	<0.001	0.18
Sciatica Bothersomeness ≤ 16	625	-37.3 (0.8)	-25.4 (0.9)	-11.9 (-13.7, -10)
Sciatica Bothersomeness > 16	556	-33.7 (0.8)	-21.5 (1.1)	-12.2 (-14.5, -10)
p-value		0.001	0.006	0.82
Age ≤ 41	644	-35.6 (0.7)	-25 (1)	-10.6 (-12.6, -8.6)
Age > 41	548	-35.7 (0.8)	-22.5 (0.9)	-13.3 (-15.3, -11.2)
p-value		0.89	0.06	0.06
Female	507	-35 (0.8)	-22.3 (1)	-12.7 (-14.9, -10.5)
Male	685	-36.1 (0.7)	-24.7 (0.9)	-11.4 (-13.2, -9.5)
p-value		0.31	0.068	0.35
Body Mass Index < 30	854	-38.1 (0.6)	-25.6 (0.8)	-12.4 (-14.1, -10.7)
Body Mass Index ≥ 30	336	-29.9 (1)	-18.1 (1.3)	-11.9 (-14.5, -9.2)
p-value		<0.001	<0.001	0.71
Reflex Asymmetry	481	-36 (0.8)	-25.1 (1.1)	-10.9 (-13.1, -8.6)
No Reflex Asymmetry	710	-35.4 (0.7)	-22.8 (0.9)	-12.6 (-14.4, -10.7)
p-value		0.60	0.095	0.24
Positive Straight Leg Raise	970	-35.8 (0.6)	-24.2 (0.8)	-11.6 (-13.2, -10)
Negative Straight Leg Raise	221	-34.4 (1.4)	-22.9 (1.4)	-11.4 (-14.7, -8.2)
p-value		0.35	0.42	0.93
No Joint Problem	963	-37.1 (0.6)	-24.5 (0.8)	-12.6 (-14.2, -11)
Joint Problem	221	-28.2 (1.3)	-20 (1.4)	-8.2 (-11.3, -5.1)
p-value		<0.001	0.005	0.01
Not Depressed	1044	-36.5 (0.6)	-24.5 (0.7)	-12 (-13.5, -10.4)
Depressed	141	-28.9 (1.6)	-16.4 (1.9)	-12.5 (-16.4, -8.5)
p-value		<0.001	<0.001	0.82

	N	Surgical (n = 788)	Non-operative (n = 404)	Treatment Effect [†] (95% CI)
No Other Comorbidities **	666	-38.1 (0.7)	-25.8 (0.9)	-12.3 (-14.2, -10.4)
Other Comorbidities	526	-32.3 (0.8)	-21.2 (1)	-11.2 (-13.2, -9.1)
p-value		<0.001	<0.001	0.41
No Missed Work	318	-37.9 (1)	-26.9 (1.3)	-11 (-13.7, -8.4)
Missed Work	724	-34.8 (0.7)	-23.7 (0.9)	-11.1 (-13, -9.3)
p-value		0.015	0.04	0.96
No Opioid Use	520	-38.6 (0.9)	-27 (1)	-11.6 (-13.7, -9.5)
Opioid Use	542	-34.8 (0.8)	-22.8 (1.1)	-12 (-14.3, -9.8)
p-value		0.001	0.005	0.80
No Prior Injections	625	-37.7 (0.8)	-25.7 (0.9)	-12 (-13.9, -10.1)
Prior Injections	567	-33.5 (0.8)	-21.3 (1)	-12.2 (-14.3, -10)
p-value		<0.001	0.001	0.91
No Insurance	38	-20.1 (3.1)	-13.1 (4.7)	-7 (-16.9, 2.9)
Insured	1151	-36.1 (0.5)	-24.1 (0.7)	-12 (-13.4, -10.5)
p-value		<0.001	0.019	0.33
No Litigation	1110	-36.9 (0.5)	-24.9 (0.7)	-11.9 (-13.4, -10.4)
Litigation Pending/Resolved	81	-17.4 (2)	-7.7 (2.7)	-9.7 (-15, -4.4)
p-value		<0.001	<0.001	0.42
Dissatisfied with Symptoms	1134	-35.7 (0.6)	-23.7 (0.7)	-12 (-13.5, -10.5)
Satisfied with Symptoms or Neutral	57	-33.4 (2.9)	-24.7 (2.6)	-8.7 (-14.8, -2.6)
p-value		0.44	0.69	0.30
Predominant back pain	221	-31.9 (1.3)	-21.8 (1.4)	-10.1 (-13.1, -7.1)
Predominant leg pain	962	-36.4 (0.6)	-24 (0.8)	-12.4 (-14, -10.8)
p-value		0.002	0.18	0.18
High school education or less	287	-32.2 (1.1)	-16.1 (1.4)	-16.1 (-19, -13.2)
At least some college or more	884	-36.8 (0.6)	-26.1 (0.8)	-10.7 (-12.3, -9)
p-value		<0.001	<0.001	0.001
Sensory Deficit	603	-34.6 (0.7)	-22.3 (1)	-12.3 (-14.3, -10.3)
Sensory Intact	588	-36.8 (0.8)	-24.9 (0.9)	-11.9 (-13.9, -9.9)
p-value		0.046	0.055	0.78

	N	Surgical (n = 788)	Non-operative (n = 404)	Treatment Effect [†] (95% CI)
Motor Deficit	501	-35.3 (0.8)	-23.8 (1.1)	-11.5 (-13.8, -9.2)
Motor Intact	690	-35.9 (0.7)	-23.8 (0.9)	-12.2 (-14, -10.4)
p-value		0.56	1	0.66
Other Herniation Location	272	-32 (1.2)	-21.6 (1.3)	-10.4 (-13.3, -7.4)
Posterolateral Herniation	919	-36.6 (0.6)	-24.5 (0.8)	-12.1 (-13.7, -10.4)
p-value		<0.001	0.055	0.31
No Stomach Problem	1042	-36.5 (0.6)	-24.4 (0.7)	-12.2 (-13.7, -10.6)
Stomach Problem	142	-28 (1.6)	-17.3 (1.9)	-10.7 (-14.6, -6.7)
p-value		<0.001	<0.001	0.49
No Hypertension	1022	-36 (0.6)	-24.1 (0.7)	-11.9 (-13.5, -10.3)
Hypertension	163	-33.4 (1.5)	-20.3 (1.7)	-13.1 (-16.6, -9.5)
p-value		0.11	0.042	0.55
No Antidepressants Use	1011	-37.3 (0.6)	-25.6 (0.7)	-11.8 (-13.3, -10.2)
Taking Antidepressants	51	-22.1 (2.6)	-14.1 (3.6)	-8 (-15.3, -0.7)
p-value		<0.001	0.002	0.32
No NSAID Use	578	-36 (0.8)	-24.9 (1)	-11.1 (-13.3, -9)
Taking NSAID	484	-37.4 (0.9)	-25.3 (1)	-12.1 (-14.3, -9.9)
p-value		0.23	0.78	0.52
No Physical Therapy	314	-37.6 (1.1)	-24.7 (1.2)	-12.9 (-15.6, -10.2)
Had Physical Therapy	878	-35 (0.6)	-23.4 (0.8)	-11.6 (-13.3, -9.9)
p-value		0.036	0.35	0.42
No Lifting at Work	497	-39.7 (0.8)	-27.7 (1)	-12 (-14.2, -9.8)
Lifting at Work	694	-32.8 (0.7)	-20.6 (0.9)	-12.2 (-14.1, -10.3)
p-value		<0.001	<0.001	0.89
Worker's Compensation	208	-27.2 (1.2)	-18.2 (1.8)	-9 (-12.5, -5.5)
No Worker's Compensation	981	-37.5 (0.6)	-24.9 (0.7)	-12.6 (-14.2, -11)
p-value		<0.001	<0.001	0.06
L2-L3 / L3-4 Herniation	88	-32.7 (2.3)	-22.7 (2.2)	-10.1 (-15.6, -4.5)
L4-L5 Herniation	456	-36.8 (0.9)	-23.7 (1.1)	-13 (-15.3, -10.8)
L5-S1 Herniation	647	-35.1 (0.7)	-24.2 (0.9)	-10.9 (-12.8, -8.9)
p-value		0.14	0.80	0.30

	N	Surgical (n = 788)	Non-operative (n = 404)	Treatment Effect [†] (95% CI)
Protruding Herniation	322	-34.3 (1)	-21.6 (1.2)	-12.8 (-15.3, -10.3)
Extruded Herniation	783	-35.5 (0.7)	-24.6 (0.9)	-11 (-12.8, -9.1)
Sequestered Herniation	86	-41.9 (2.1)	-25.6 (2.4)	-16.4 (-21.6, -11.2)
p-value		0.004	0.084	0.11
6 Weeks or Less Duration	165	-40.6 (1.5)	-30.7 (1.7)	-9.9 (-13.6, -6.2)
1.5 to 6 Months Duration	765	-36.3 (0.7)	-24.8 (0.8)	-11.5 (-13.2, -9.7)
More than 6 Months Duration	262	-30.5 (1.1)	-15.8 (1.4)	-14.7 (-17.7, -11.7)
p-value		<0.001	<0.001	0.09
Non-Smoker	607	-37.8 (0.8)	-25.7 (0.9)	-12.2 (-14.1, -10.2)
Ex-Smoker	298	-35.1 (1.1)	-24.1 (1.3)	-11.1 (-13.8, -8.3)
Smoker	282	-31.2 (1.1)	-17.9 (1.4)	-13.3 (-16.3, -10.3)
p-value		<0.001	<0.001	0.57
White	1033	-36.2 (0.6)	-24.9 (0.7)	-11.4 (-12.9, -9.8)
Black	75	-28 (2.5)	-12.8 (2.4)	-15.2 (-21, -9.4)
Other Race	84	-34.1 (2)	-21 (2.6)	-13.1 (-18.4, -7.8)
p-value		0.004	<0.001	0.40
Married	835	-36.9 (0.6)	-22.7 (0.8)	-14.2 (-15.9, -12.5)
Divorced/Widowed	130	-29.1 (1.6)	-18.9 (2.1)	-10.3 (-14.5, -6)
Single	212	-35.4 (1.4)	-30.1 (1.6)	-5.2 (-8.5, -2)
p-value		<0.001	<0.001	<0.001
Not working	206	-33.5 (1.3)	-18.8 (1.5)	-14.7 (-18, -11.4)
Income Over \$50,000	446	-38.7 (0.9)	-28.3 (1.1)	-10.4 (-12.8, -8.1)
Income Under \$50,000	535	-34 (0.8)	-22.2 (1)	-11.9 (-14, -9.8)
p-value		<0.001	<0.001	0.11
Problem getting better	179	-42.3 (1.6)	-29.8 (1.4)	-12.4 (-15.8, -9.1)
Problem staying about the same	534	-35.8 (0.8)	-25.1 (1)	-10.7 (-12.8, -8.6)
Problem getting worse	472	-32.9 (0.8)	-17.5 (1.3)	-15.4 (-18, -12.9)
p-value		<0.001	<0.001	0.02
Baseline MCS <= 35	263	-30.2 (1.2)	-16.4 (1.4)	-13.9 (-16.9, -10.8)
Baseline MCS > 35	927	-37 (0.6)	-26 (0.8)	-11 (-12.6, -9.4)
p-value		<0.001	<0.001	0.10

[†]Treatment effect is the difference between the surgical and non-operative mean change from baseline.

^{**} Other comorbidities include: stroke, diabetes, osteoporosis, cancer, fibromyalgia, cerebrospinal fluid leak, PTSD, alcohol, drug dependency, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine, anxiety, stomach, or bowel problems.

Table 2

Area Under Curve subgroup results from the adjusted ^{*} as-treated Oswestry Disability Index (ODI) outcome analysis for the three significant treatment effect predictors (joint, marital status, baseline health trend) (*Time weighted average 4 years treatment effects*)

Predictors	N	Surgical (n = 788)	Non-operative (n = 404)	Treatment Effect [†] (95% CI)
No Joint Problem	963	-37.9 (0.6)	-23.3 (0.7)	-14.6 (-16.3, -12.9)
Joint Problem	221	-30.8 (1.2)	-20.5 (1.4)	-10.3 (-13.4, -7.3)
p-value		<0.001	0.062	0.012
Married	835	-37.4 (0.6)	-21.5 (0.8)	-15.8 (-17.6, -14)
Divorced/Widowed	130	-33.1 (1.5)	-21.6 (2)	-11.5 (-15.7, -7.3)
Single	212	-36.2 (1.3)	-28.5 (1.5)	-7.7 (-10.9, -4.5)
p-value		0.023	<0.001	<0.001
Problem getting better	179	-39.9 (1.5)	-27.3 (1.3)	-12.6 (-15.9, -9.3)
Problem staying about the same	534	-36.4 (0.8)	-24.6 (0.9)	-11.8 (-13.8, -9.7)
Problem getting worse	472	-34.8 (0.8)	-18.9 (1.2)	-15.9 (-18.5, -13.4)
p-value		0.013	<0.001	0.032

^{*} 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 and ODI), and center.

[†] Treatment effect is the difference between the surgical and non-operative mean change from baseline.

^{**} Other comorbidities include: stroke, diabetes, osteoporosis, cancer, fibromyalgia, cerebrospinal fluid leak, PTSD, alcohol, drug dependency, heart, lung, liver, kidney, blood vessel, nervous system, hypertension, migraine, anxiety, stomach, or bowel problems.