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Prospective Study

Six-Month Interim Outcomes of the SPARTAN Study: A Prospective, Multicenter, Post-Market Surveillance Study on a Modular SI Joint Fusion System

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Background: Low back pain (LBP) is the most common type of pain reported by adults and the leading cause of disability globally. The sacroiliac joint (SIJ)—the large, load-bearing joint that connects the pelvis and lower spine—is one of the most underrecognized causes of LBP and has been determined to be a source of the condition in 10–38% of cases. While SIJ fusion has been shown to be a superior alternative to the long-term conservative management of SIJ dysfunction, many early SIJ fusion techniques have resulted in high incidences of adverse events (AEs) and serious adverse events (SAEs), long recovery times, and, often, the need for revision surgeries.

Objectives: To prospectively assess the effectiveness of a minimally invasive lateral oblique approach to SIJ fusion that uses TransLoc 3D™ Sacroiliac Joint Fusion System (CornerLoc™) compression screws, based on patient-reported outcome measures of pain and functional improvement.

Study Design: Prospective study.

Setting: Seventeen pain centers across the United States.

Methods: Between November 13, 2023, and December 31, 2024, 114 patients underwent SIJ fusion via TransLoc 3D™ SIJ fusion compression screws in a procedure that used a minimally invasive lateral oblique approach. Outcomes for pain and functional improvement were assessed both before the procedure and at 3 (n = 85) and 6 (n = 72) months after it. Those outcomes were measured on the Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), and Quebec Back Pain Disability Scale (QBPDS). Additionally, the safety and efficacy of the procedure were assessed using a composite endpoint comprising improvement in both NRS and ODI scores as well as the absence of AEs or SAEs. Comparisons between the groups of patients were performed using Student's t-test for continuous data or Fisher's exact test for categorical data. Mixed models for repeat measures were used to model factors associated with each endpoint longitudinally and generalized linear models for interim tests. All patients provided consent to participate in the study, and approval was obtained from the institutional review board (approval number 1356747).

Results: The average age of the patients at the baseline was 67.1 ± 10.5 years, and 70.8% were female. Our results show significant improvements in pain and functional outcomes from the baseline, as assessed by both the composite endpoint and individual measures (i.e., NRS, ODI, and QBPDS), 3 and 6 months after the procedure ($P < 2.2$ e-16 for all measures). Furthermore, 72.94% of patients reported improvements in both their NRS pain scores and ODI function scores within 3 months, while 90.3% reported an improvement at 6 months. Additionally, 84.7% of patients reported an improvement in their QBPDS scores within 6 months. A significant majority of patients experienced greater than 20% improvement in all outcome measures at 3 and 6 months ($P <$ 2.16e-16). No AEs or SAEs were reported as results of the SIJ fusion procedure.

Limitations: Patients reported the outcomes, and the analysis had only a single arm.

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Conclusions: The results of the present study show that patients received significant benefits from a minimally invasive lateral oblique approach to SIJ fusion that used 3D-printed titanium compression screws.

Key words: Low back pain, sacroiliac joint, arthrodesis, SIJ fusion, minimally invasive surgery, lateral oblique approach, pain reduction, 3D printed titanium, surface porosity, sacroiliitis, compression, outcome measures

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Low back pain (LBP)—the most common type of pain reported by adults and the leading global cause of years lived with disability—was estimated to affect approximately 619 million people worldwide in 2020 (1). Approximately 75–80% of people in the Western world will develop LBP over the course of their lives (2). LBP is a severe and debilitating condition that poses a similar disability burden to other serious health conditions such stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, and limb loss (3). Despite the global burden and prevalence of LBP, its etiologies can be challenging to determine, resulting in widespread undiagnosed chronic LBP and considerable financial impact (2,4).

Historically, most LBP has been attributed to lower spine– and disc-related issues, often resulting in misdiagnosis of the pain source (4,5). Sacroiliac joint (SIJ) pain is one of the most under-recognized causes of LBP and has been determined to be the source of pain in 10–38% of patients presenting with the condition (4,6-9). Furthermore, the SIJ is suspected to be a source of low back pain in 40–75% of patients with prior lumbar fusion (10-15). The SIJ is a large, irregularly shaped, load-bearing joint that is bordered anteriorly and posteriorly by the sacroiliac ligaments, in which a sacral concave depression interlocks with a corresponding iliac osseous ridge (16). This joint complex—designed for stability—transmits the forces exerted through the spine from the upper body to the lower extremities and is now known to be both a primary and secondary pain generator (16-19).

Sacroiliac joint fusion—the surgical fusion of the ilium in the pelvis to the sacrum in the spine—has emerged as a superior alternative to the long-term conservative management of SIJ-related pain (16,20-22). Traditional methods of SIJ fusion involved open (i.e., invasive) surgery with screws, plates, cages, and often bone grafts, resulting in longer operating times, larger incisions, extended hospital stays, increased blood loss, substantially longer recovery times, and poorer patient outcomes (5,23-28). Over the last 2 decades, minimally invasive surgical (MIS) procedures became the standard of care for SIJ fusion, increasing in prevalence from 39% in 2009 to over 87% in late 2012, while open procedures decreased substantially during that same period (23). A more recent study on the evolving trends of SIJ fusion in a large national dataset found that nearly 87% of SIJ fusions were performed using MIS (29).

Although MIS techniques for SIJ fusion have resulted in improved outcomes for patients compared to open techniques and conservative management (20,30); direct lateral-approach MIS techniques (Fig. 1A) still require long recovery periods; carry substantial anatomical risks to the gluteal artery, gluteal nerve, and gluteal muscle structures; and have a high rate of adverse outcomes (28,31-39). In a randomized controlled trial that assessed a direct lateral, minimally invasive approach to SIJ fusion with triangular metal implants (n = 52), the authors observed 39 severe adverse events (AEs) 24 months after the patients received their surgery (34). Moreover, at least 91.16% of the 1103 AEs associated with SIJ fixation devices reported in the US FDA Manufacturer and User Facility Device Experience (MAUDE) database between the dates of January 1, 2014, and December 31, 2024, were associated with direct lateral approach SIJ procedures (28).

Over the last decade, a small number of manufacturers have introduced implant systems intended to fixate and fuse the sacroiliac joint using a lateral oblique implant trajectory (also referred to as posterior lateral, posterior oblique, posterolateral, and posterolateral transiliac) (36,39-42). These implant systems—each

with its own specialized design features—transfix the SIJ by placing screws through the posterolateral aspect of the cortical bone of the ilium, just posteromedial to the gluteal muscles, directing the screws anteromedially to pass across the sacroiliac joint and piercing both the medial cortex of the iliac bone and lateral cortex of the sacrum (Fig. 1B). As noted in an early study that documented the use of the lateral oblique approach (43), these lateral oblique trajectory implant systems avoid the gluteal artery and nerve and muscle structures, making this type of implant system a safer option than direct lateral implant systems and resulting in greater clinical benefits than those associated with the lateral approach (35,39,42,44). Despite better clinical outcomes and fewer complications than other methods, relatively few studies to date have focused on the safety and efficacy of lateral oblique SIJ fusion techniques.

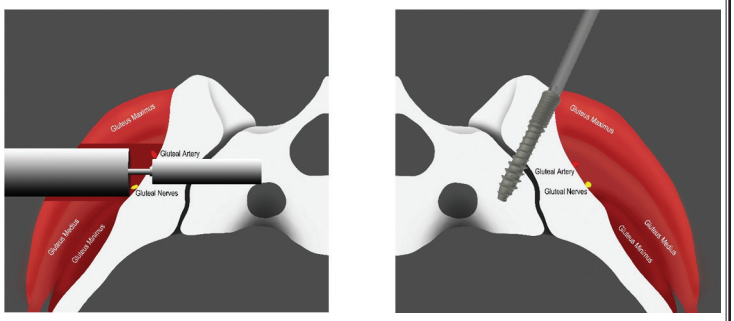

Fig. 1. *Comparison of direct lateral and lateral oblique sacroiliac joint fixation techniques. A) Direct lateral approach, passing through the gluteus maximus and minimus and near the gluteal artery and nerves. B) Lateral oblique approach, avoiding major muscles and the gluteal artery and nerves.*

To address prevailing issues with existing SIJ fusion techniques and the data gap for patient outcomes using lateral oblique approaches, we utilized an evidence-informed, minimally invasive, and low-impact lateral oblique approach to SIJ fusion spanning the SIJ (TransLoc 3D™, Foundation Fusion Solutions, LLC) that used the placement of 2 uniquely designed 3D printed titanium screws with high surface porosity and special lagging features, thereby facilitating compression of the joint (Fig. 2). To determine the safety and efficacy of this system, we performed a prospective, 12-month multicenter study to assess changes in pain and functional outcomes. This interim analysis reports on, firstly, patients' pain and functional outcomes at the baseline and at 3 and 6 months after the procedure and, secondly, a sensitivity analysis to assess the suitability of the scales.

Methods

This prospective study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (45). The STROBE Checklist is included in the Supplemental Material.

Patient Population

Of the 165 patients screened, 122 patients were consecutively enrolled in the study. Patients who met the inclusion criteria were assigned a unique ID number, and all patient data were de-identified. All patients provided consent to participate in the study, and institutional review board (IRB) approval was obtained (IRB approval number 1356747). The inclusion criteria for the study are listed in Table 1, and the exclusion criteria are listed in the Supplemental Material. Information on patient age, gender, height, weight, BMI, employment status, history of lumbar fusion and other comorbidities (Table 2), and history of relevant SIJ treatments were collected from coded data in the patient record at the baseline (i.e., prior to surgery). Baseline measures of self-described pain or disability (described below) were collected prospectively from patients scheduled for SIJ fusion using the FDA-Cleared TransLoc 3D™ SIJ fusion system (K211496; CornerLoc™) and at 3- and 6-month post-surgical follow-up appointments between November 13, 2023, and December 31, 2024. Treatment centers provided data on procedural details, procedure side, revisions of failed prior fusions, AEs and SAEs, and blood loss.

Measures

Patients' pain was assessed pre-procedurally and postoperatively using the following validated measures: i) the Numeric Rating Scale (NRS) for pain, a scale of 0 to 10 on which 0 represented no pain and 10 represented the worst possible pain; ii) functional outcomes as assessed on the Oswestry Disability Index (ODI) (46), a scale of 0–100 calculated as a raw score [0-50]÷50 x 100); and the Quebec Back Pain Disability Score (QBPDS) (47), another scale of 0–100, to measure the level of functional disability for patients with LBP. Patients were instructed to report only pain relating to their SIJ pathology.

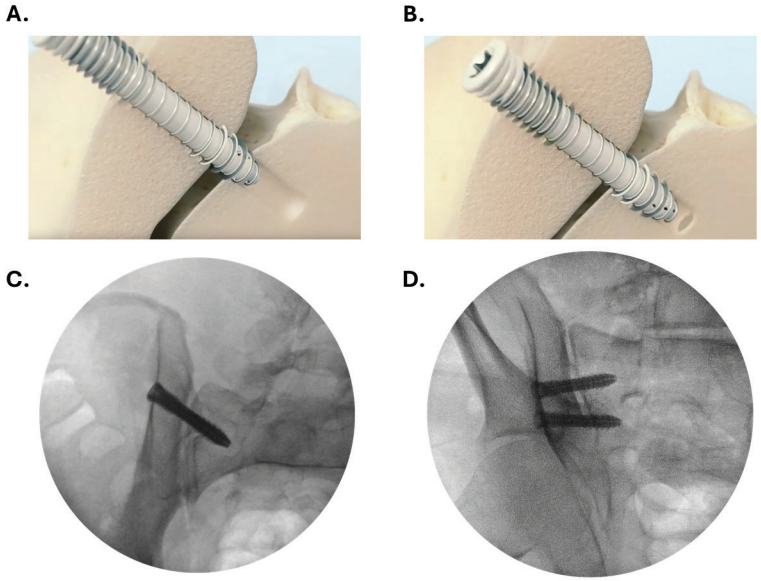

Fig. 2. *TransLoc 3D™ printed titanium screws with high surface porosity and special lagging features facilitate compression* of the sacroiliac joint (SIJ). A) Graphic illustrations of the placement of the TransLoc 3D™ printed titanium screw across the SIJ. B) SIJ compression using the TransLoc 3D™ screw. C) Fluoroscopic image showing the inlet view of TransLoc 3D™ screws across the SIJ at the level of the S1 foramen. D) Fluoroscopic image showing the outlet view of the TransLoc 3D™ screws.*
*Compression data available at CornerLoc™ (72).

Table 1. *Inclusion criteria for the prospective, multicenter, post-market surveillance study on a modular SI joint (SIJ) fusion system (SPARTAN) study.*

Inclusion Criteria for the SPARTAN Study
• Aged 18–85 (over 85 considered with history and physical assessment screening upon approval by medical monitor)
• Absent condition of high-risk surgical candidate
• Moderate to severe pain with functional impairment and persistent pain despite a minimum of 6 months of intensive non-operative treatment and can point with a single finger at the location of pain (Fortin finger test)
• ≥ 75% pain reduction for the expected duration of the anesthetic used, following an image-guided, contrast-enhanced SIJ injection on 2 separate occasions
• Positive response to 3 of 5 provocative tests (i.e., FABER, Gaenslen, thigh thrust or posterior shear, SI compression, and SI distraction)
• Asymmetric SIJ widening on x-ray or CT scan, or degenerative sacroiliitis with radiographic evidence of SIJ degeneration as evidenced on CT or x-ray image
• Baseline ODI score of at least 30% (i.e., raw score of 15)
• Baseline SIJ pain score of at least 6 on the NRS
• Provision of informed consent

ODI: Oswestry Disability Index, NRS: Numeric Rating Scale

Statistical Analyses

No imputations were made for missing data, since all cases were complete (i.e., they contained no missing data; Table S1). We created mixed-model repeated measures (MMRMs), a type of repeated ANOVA, to follow individual patient progression in key outcome measures—NRS, ODI and QBPDS—through the 3 checkpoints (baseline, 3 months, and 6 months) while simultaneously adjusting for confounding demographic, clinical, and procedural variables (Table S2). MMRMs are particularly suitable for longitudinal data because these analyses account for both between-patient variability (differences across patients) and within-patient variability (changes within a patient over time). MMRMs were constructed using the R package mmrm (48), allowing data from visits at the baseline and at 3 and 6 months after the procedure to be modelled longitudinally while adjusting for nonnormal distributions and avoiding assumptions of linearity. Predictive covariates considered in each model included potential sources of bias, such as visit number, age, gender, height, BMI, race, procedure side, revision surgery, employment status, clinical site, and intraoperative blood loss. Quantitative variables—including age, height, BMI, blood loss, and outcome scores (i.e., NRS, ODI, QBPDS)—were treated as continuous variables, without binning, to preserve information and retain statistical power. More detail on the statistical models used in the present study can be found in the Supplemental Materials and Table S2.

Student's t-test was used to assess changes from the baseline to both the 3-month and 6-month follow-ups for each of the patient measures (i.e., NRS, QBPDS, and ODI) and any other pairwise comparisons between the groups. Fisher's exact test was used to compare categorical (i.e., count) data, and binomial tests were used to compare outcomes to a zero-change null hypothesis. Correlations were assessed using Pearson's test. Descriptive statistics were used to summarize quantitative variables, including means and standard deviations, medians and interquartile ranges for continuous data and counts, and percentages for categorical data. Power calculations for sample size are described in detail in the Supplemental Material.

Table 2. *Characteristics of patients enrolled in the prospective, multicenter, post-market surveillance study on a modular SIJ fusion system (SPARTAN) study at the time of interim analysis.*

Category	Subcategory	n (%)	Median (IQR)	Mean (SD)	Min, Max
Total enrolled patients		122 (100)			
Total discontinued patients		3			
	< 2 weeks	0			
	> 2 weeks < 3 months	2			
	> 3 months < 6 months	1			
Interval between treatment and visits (days)	Visit 2	85 (73.68)	80 (70, 91)	73.91 (± 41.9)	17, 117
	Visit 3	72 (63.16)	169.5 (156.75, 181.25)	172.03 (± 23.62)	137, 269
Gender	Male	21 (29.17)			
	Female	51 (70.83)			
Age (yrs)			68.49 (60.97, 74.52)	67.1 (± 10.45)	29.89, 90.11
	≥ 65 at baseline	75 (61.48)			
	≥ 65 at 3m visit (n = 85)	59 (48.36)			
	≥ 65 at 6m visit (n = 72)	48 (39.34)			
Height (cm)			154.37 (153.58, 155.94)	155.69 (± 7.63)	125.86, 183.67
BMI			29.41 (25.82, 33.95)	30.31 (± 5.63)	20.8, 43.4
BMI Category	Underweight (< 18.5)	0 (0)			
	Normal (≥ 18.5, < 25)	23 (18.85)			
	Overweight (≥ 25, < 30)	46 (37.70)			
	Obese Class I (≥ 30, < 35)	27 (22.13)			
	Obese Class II (≥ 35, < 40)	20 (16.39			
	Obese Class III (> 40)	8 (6.56)			
Race	Black/AA	2 (1.64)			
	Hispanic	5 (4.10)			
	White	116 (95.08)			
	Other	1 (0.82)			

IQR: interquartile range, BMI: body mass index, CRD: chronic respiratory disease, HLVD: heart/lung valve disease; PVD: peripheral vascular disease, CVD: cardiovascular disease, COPD: chronic obstructive pulmonary disease.

Safety and efficacy were assessed using a composite endpoint that comprised the following 3 key binomial indicators: any reduction in NRS as a measure of pain (yes/no), any reduction in ODI representing disability/loss of function (yes/no), and the absence of adverse events (yes/no; Table S2). Lastly came the completion of a sensitivity analysis that substituted QBPDS for ODI as an alternative measure for back pain in the composite response variable to determine whether the choice of scale created bias in the composite endpoint. Differences were deemed significant at a *P*-value of ≤ 0.05, in which *P* was reported as < 2.2 e-16, if *P* fell below the calculable value threshold. Statistical analyses were performed using R v.4.4.2 (Posit Software).

Results

Patient Population

A total of 165 patients were screened for inclusion, and 122 were enrolled (Table 2, Fig. 3). Of the enrolled patients, 114 had received surgery at the point of this interim analysis, with 85 patients having progressed past the 3-month visit and 72 patients having progressed past the 6-month visit (data pulled on January 29, 2025). From enrollment to the 6-month visit, only 2 patients had been discontinued from the study. The majority of patients who underwent surgery were female (70.18%; n = 80), 64.04% were 65 or older (n = 73), and 81.58% (n = 93) were considered overweight or above according to body mass index (BMI) measurements (BMI ≥ 25).

Table 2 cont. *Characteristics of patients enrolled in the prospective, multicenter, post-market surveillance study on a modular SIJ fusion system (SPARTAN) study at the time of interim analysis.*

Category	Subcategory	n (%)	Median (IQR)	Mean (SD)	Min, Max
Patient History	CRD	49 (40.16)			
	Kidney disease	8 (6.56)			
	Advanced age (≥ 65 yrs)	75 (61.48)			
	PVD	8 (6.56)			
	Myocardial infarction	4 (3.28)			
	Stroke	6 (4.92)			
	CVD	21 (17.21)			
	HLVD	7 (5.74)			
	Heart failure	1 (0.82)			
	Diabetes type I	1 (0.82)			
	Diabetes type II	22 (18.03)			
	Hypertension	59 (48.36			
	Arthritis	70 (57.38)			
	Asthma	20 (16.39)			
	COPD	6 (4.92)			
	Cancer	11 (9.02)			
	Substance abuse	0 (0)			
	Autoimmune disorder	6 (4.92)			
	Coagulation disorder	2 (1.64)			
	Chronic renal disease	6 (4.92)			
	Liver disease	2 (1.64)			

IQR: interquartile range, BMI: body mass index, CRD: chronic respiratory disease, HLVD: heart/lung valve disease; PVD: peripheral vascular disease, CVD: cardiovascular disease, COPD: chronic obstructive pulmonary disease.

Patient Outcomes

Scores improved significantly in all 3 patient outcome measures—NRS, ODI, and QBPDS—at both 3 and 6 months after the procedure ($P < 2.2e-16$ for all measures; Fig. 4). Mean and median changes over time for all outcome measures are summarized in Table S3. Odds ratios/estimates, confidence intervals, and *P*-values for all 6- and 3-month models are detailed in Tables S4 and S5, respectively. Significant improvements in each measure occurred within the first 3 months after surgery, with improvement continuing between 3 and 6 months in all measures (NRS: $P = 0.45$; ODI: $P = 0.27$; QBPDS: $P = 0.32$). The average time elapsed between the procedure and 6-month visit was 172 ± 24 days. Three months after the procedure, NRS pain scores improved by an average of 4.63 points, demonstrating an average improvement of 56.94% over the baseline score (8.25 ±1.2), ODI scores improved by an average of 21.42 points (43.69% improvement over baseline [49.03 ±12.64]), and QBPDS scores improved by an average of 27.18 points (44.93% improvement over baseline [63.45 ±14.8]; Fig. 4, Table S3). Six months after the SIJ fixation, NRS scores improved by an average of 4.99 points (59.90% improvement over baseline), ODI scores improved by an average of 24.03 points (49.01% improvement over baseline) and QBPDS scores improved by an average of 29.03 points (48.14% improvement over baseline; Fig. 4; Table S3).

Furthermore, a significant number of patients experienced improvements of 20% or better in each of the 3 measures at both 3 and 6 months ($P < 2.16e-16$ for all measures and time points; Table 3). Most notably, 92.94% and 88.89% of patients experienced improvements of ≥20% from their baseline NRS scores at 3 and 6 months after the procedure, respectively (Table 3). A more in-depth analysis of NRS outcomes revealed that the majority of the patients achieved ≥50% improvement from their baseline NRS scores at both 3 months (62.35%) and 6 months (70.83%) (Table 4).

The composite endpoint (improvement in ODI, QBPDS, and NRS scores) showed that pain and function improved in a significant number of patients at 3

and 6 months after the procedure ($P < 2.2$ e-16, Tables S4-5), and 91.67% of patients experienced improvement in both function and pain at the 6-month time point (Table S3). Additionally, at 6 months (n = 72), the composite endpoint model revealed a significant negative association between recovery and BMI, in which increased BMI decreased the likelihood of noticeable improvement in both SIJ pain and disability at 6 months ($P = 0.04$, Model 1, Table S5). A higher BMI was also associated with a higher starting ODI score ($P < 0.05$).

The 3-month interim model (n = 85, Model 5, Table S4) showed that the matter of whether the surgery was a revision of a previous unrelated SIJ surgery was significant. Specifically, patients undergoing revisions were less likely to see positive outcomes within 3 months ($P < 0.01$). However, this effect was absent from the 6-month data, suggesting that revision surgeries had longer initial recovery periods but equally favorable long-term outcomes. Additionally, one site was a significant outlier after the 3-month visit ($P = 0.04$), and we observed significantly improved outcomes for patients undergoing right-sided procedures ($P = 0.01$) after 6 months. Removing the anomalous site from the 3-month model did not change the main outcomes, and the differences were still statistically significant. Therefore, the site was retained in the model. A sensitivity analysis that removed the single anomalous site also removed the effect of right-sidedness, implying that this factor was nongeneralizable.

We incorporated a sensitivity analysis that explored the potential of using ODI and QBPDS interchangeably to quantify disability resulting from back pain. In this analysis, an MMRM was constructed that substituted change in QBPDS score for change in ODI score as the response (n = 72), and the results showed that no additional covariates moderated the change in functional disability as measured by QBPDS. Additionally, we found that ODI and QBPDS were correlated only moderately (r = 0.43), despite both being measures of pain-related disability, indicating that the tools were related but not interchangeable. Notably, at higher pain levels (≥ 50%), QBPDS scores tended to be higher than ODI scores (Fig. 5).

Modeling predictors of NRS via the same methods revealed a significant positive interaction between male gender and reduction in pain reported at the 6-month visit ($P = 0.01$, n = 72). The reduction in reported pain over time was lower at one site at both the 3- and 6-month visits ($P < 0.02$ and $P = 0.05$, respectively) than at other sites. A sensitivity analysis removing this site from the model retained the significant effect of gender ($P = 0.02$) and did not change any of the outcomes, and thus the site was retained in the model.

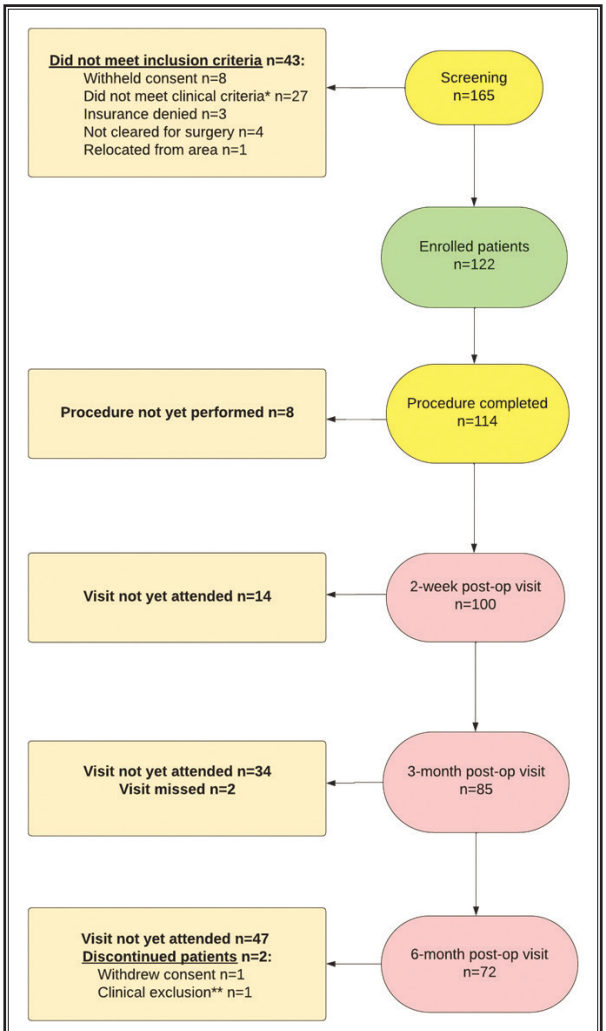

Fig. 3. *Flowchart demonstrating patient enrollment at each study checkpoint and patient withdrawals. At the time of this interim analysis (6 months), 47 recently enrolled patients were not yet within the timeline window for their 6-month visit as of January 29, 2025.*
*Twenty-seven patients did not meet the clinical criteria for medical necessity for SI joint fusion.
**One patient was clinically excluded after their 3-month visit, since they proceeded with a spinal cord stimulator and could not discern pain areas from one another.

Surgical Outcomes

All surgeries used a lateral oblique approach, 9.65% (11/114) of which were revision surgeries of prior unrelated SIJ systems (Table 5). There were no reported pro-

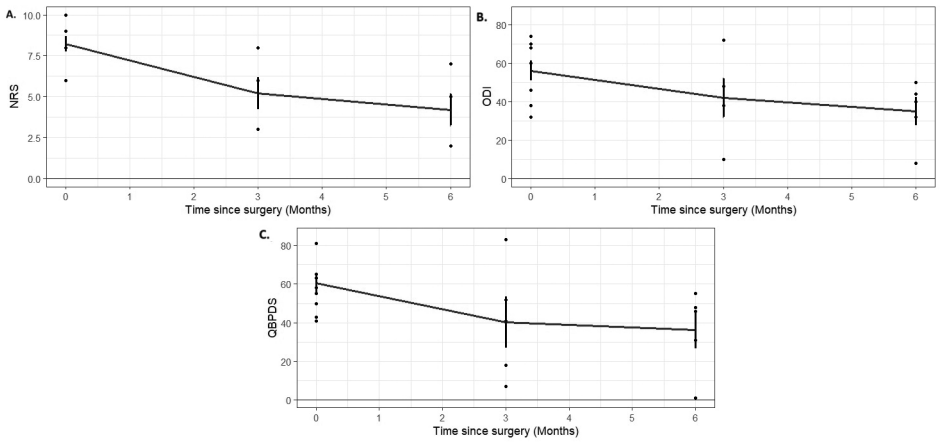

Fig. 4. *Changes in patient-reported pain and disability indexes between baseline and follow-up visits after sacroiliac joint (SIJ) fixation with the TransLoc 3D™ system. A) Oswestry Disability Index (ODI) score. B) Numeric Rating Scale (NRS) score. C) Quebec Back Pain Disability Scale (QBPDS) score. Data are shown with standard error bars at 95% confidence intervals.*

Table 3. *Numbers of patients who experienced ≥ 20% improvement in outcome measures following SIJ using the TransLoc 3D™ Sacroiliac Joint Fusion System at the time of the interim analysis.*

Time Frame	Reporting Patients (n)	≥ 20% Improvement in NRS: n (%)	≥ 20% Improvement in ODI: n (%)	≥ 20% Improvement in QBPDS: n (%)
3 months	85	79 (92.94%)*	63 (74.12%)*	61 (71.76%)*
6 months	72	64 (88.89%)*	50 (69.44%)*	50 (69.44%)*

*Asterisks indicate statistical significance at a threshold of $P < 2.16e\text{-}16$.

Table 4. *Numeric rating scale (NRS) outcomes 3 and 6 months following SIJ fusion using the TransLoc 3D™ Sacroiliac Joint Fusion System.*

NRS Outcomes	3 Months (n = 85)	6 Months (n = 72)
≥ 30% improvement from baseline, n (%)	71 (83.53%)	58 (80.56%)
≥ 50% improvement from baseline, n (%)	53 (62.35%)	51 (70.83%)
≥ 80% improvement from baseline, n (%)	22 (25.88%)	19 (26.39%)

cedural complications (Table 5). Each patient received 2 screws. Importantly, there were no reported AEs or SAEs related to the procedure or device during the study.

Discussion

The present study describes an evidence-informed, minimally invasive, lateral oblique transarticular approach to SIJ fusion that uses an FDA-510(k)-cleared device to fuse the SIJ by providing transarticular fixation and compression across the joint. The results of the present post-market study show that the patient-reported measures—NRS, ODI, and QBPDS scores—decreased significantly after the procedure from the baseline values, highlighting that a broad cross-section of patients experienced significant improvements in pain and function at 3 and 6 months after surgery. Furthermore, the data also show the following: that 100% of the patients experienced improvement in either pain or function following the SIJ fusion procedure, which used TransLoc 3D™ implants, 91.67% of patients reported improvements in both pain and function, a significant percentage of patients experienced a 20% or better improvement in all measures at 3 and 6 months, and that no procedure- or device-related AEs or SAEs were reported.

Previous studies on LBP and SIJ fixation have determined clinical improvement using thresholds for minimal clinically important difference (MCID) and substantial clinical benefit (SCB) (5). The range of MCID values for ODI reported in the literature about LBP is a 12–15-point reduction (5,32,49,50), or a 30–51% reduction in ODI score from the baseline (51,52). Glassman et al (53) define SCB for ODI as an improvement of 18.8 points, a 36.8% improvement, or a final score of < 31.3 points. In the present study, the average change in ODI score from the baseline within 6 months (–24.03 ± 16.61) and the average final score (27.56) are within the range of the proposed minimum SCB and MCID thresholds. Moreover, the improvements observed in the present study are similar to or better than those reported in other studies on SIJ fusion (24,54,55). Additionally, in the present study, the average change in NRS scores from the baseline during the first 6 months (4.99 ± 2.63) exceeds the MCID thresholds reported in the literature (1.4–2.3) (32,56,57).

The success of the procedure described in the pres-

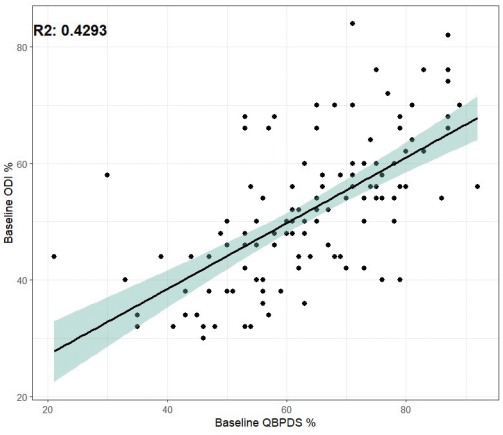

Fig. 5. *Correlation between QBPDS score and ODI score in baseline patient data.*

Table 5. *Summary of patient procedure details for patients who underwent SIJ fusion using the TransLoc 3D™ Sacroiliac Joint Fusion System.*

Category	Subcategory	n (%)	Median (IQR)	Mean (sd)
Total surgeries completed		114 (100)		
Procedure feature	Total blood loss (mL)		10 (5,15)	14.6 (±16.75)
	Side = left	50 (43.86)		
	Side = right	64 (56.14)		
	Complications	0 (0)		
Revision of prior unrelated systems	Completed surgery	11 (9.65)		
	Attended 3-m visit (n = 85)	8 (9.41)		
	Attended 6-m visit (n = 72)	8 (11.11)		

ent study may be attributed to several factors. First, although hardware implanted using a direct lateral approach is associated with a high rate of failure and adverse events (e.g., device migration and failure to osseointegrate) (5,28,34,39), lateral oblique implant systems avoid risky neurovascular anatomy and can provide mechanical stability upon insertion (58) and eventual fusion along the implant and across the SIJ, owing to decortication inside the joint. This phenomenon increases the local bone healing response and facilitates long-term bone formation and fusion within the joint space (21,59–62). Notably, previous studies have compared the direct lateral approach to SIJ fixation to a lateral oblique approach and demonstrated increased clinical benefit and fewer complications associated with the latter (35,36,39,43,44). Additionally, the recent increase in the use of the lateral oblique approach coincides with a precipitous drop in reported AEs associated with SIJ fixations in the MAUDE database during the last several years (28).

The moderate correlation observed between ODI and QBPDS in the sensitivity analysis, in which the QBPDS score was greater at higher levels of pain, may be related to the ODI's focus on pain intensity and functional limitations and the QBPDS's focus on movement- and posture-related activity limitations rather than on pain itself, which may be inherently higher in older populations. Our findings are consistent with the literature, which shows that scores on the QBPDS are consistently higher than the ODI (63). This observation indicates that these measures can be used in tandem, though not interchangeably, to capture useful information from patients that pertains to LBP-related outcomes. Furthermore, the gender-based differences in NRS outcomes seen in the present study reflect a tendency among female patients to report higher levels of postoperative pain in previous findings (64,65).

The placement of 2 compressive screw implants resists joint movement and creates immediate joint stability. A healthy SIJ has only 2–4° of rotation, in which the greatest range of motion has been shown to appear at both sides of the joint, at the farthest points from the point of axial rotation (18). Thus, evidence shows that multiple points of fixation effectively reduce the range of motion in flexion, extension, lateral bending, and axial rotation (66). The use of an implant system consisting of 2 or more parts has been traditionally used in the stabilization of pelvic fractures and has been shown to provide substantial fixation benefits over techniques that use a single point of fixation (67-70). Lastly, our findings of rapid pain relief and functional improvements (i.e., at ≤ 3 months) are in agreement with early relief observed in other studies that have used compressive screws (71).

In contrast to other studies that have evaluated patient outcomes after direct lateral SIJ fixation (31,32,34), there were no procedure-related AEs or SAEs or revision surgeries required in the present study. However, we do note that NRS, ODI, and QBPDS are patient-reported measures and thus create the potential for recall and/or reporting bias. Additionally, because this study is an interim analysis, longer-term data will be necessary to confirm that patients continue to experience the benefits of the procedure. Despite these limitations, this interim analysis of patient outcomes exhibits clear utility in serving as a founda-

tion for longer-term analyses and provides a road map for clinical practice.

Conclusions

The patients enrolled in the present study experienced significant improvements in LBP and functional outcomes after SIJ fusion with the TransLoc 3D™ system. Moreover, our findings showed that patients experienced rapid relief from pain and functional limitations (3 months)—possibly owing to immediate joint stability created by compressive screws—and durable improvements (6 months) as assessed by all outcome measures. Thus, the TransLoc 3D™ system, using a lateral oblique approach, provides patients with a safe and effective option for SIJ fusion that yields immediate and extended relief from LBP.

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Supplemental Methods

Exclusion Criteria

The exclusion criteria for the SPARTAN study are as follows: Current severe back pain due to other causes (e.g., lumbar disc degeneration, lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, lumbar facet degeneration, lumbar radicular pain that extends beyond the mid-thigh, and lumbar vertebral body fracture); SIJ pain secondary to inflammatory conditions or other known sacroiliac pathology (e.g., sacral dysplasia, inflammatory sacroiliitis such as ankylosing spondylitis or other HLA-associated spondylo-arthropathy), tumor or infection in the SI joint, acute fracture or crystal arthropathy; history of recent (< 1 year) major trauma to pelvis (moving vehicle or significant accident that results in acute injury to pelvis requiring hospitalization or surgery; previously diagnosed osteoporosis (defined as prior T-score < -2.5 or history of osteoporotic fracture), and if patient meets the osteoporosis screening criteria identified by the National osteoporosis foundation, they should be screened for osteoporosis with DEXA; autoimmune patient who is currently not maintained on a medication regimen for treatment, and not stable (< 6 months without exacerbation); any condition or anatomy that makes treatment with the TransLoc 3D Sacroiliac Joint Fusion System infeasible; current local or systemic infection that raises the risk of surgery; patient currently receiving disability remuneration, and/or involved in injury litigation; patient is undergoing treatment under Workman's Compensation under a claim or injury greater than one year; patient is participating in an investigational study or has been involved in an investigational study within 3 months prior to evaluation for participation; known to be pregnant, suspected pregnant, or planning to be pregnant prior to SIJ surgery; patient is incarcerated or a ward of the state; known or suspected drug or alcohol abuse; known allergy to titanium or titanium alloys; diagnosed psychiatric disease (e.g., schizophrenia, major depression, personality disorders) that is not well controlled for a minimum of two years and could interfere with study participation; patients who are not covered by an insurer, or unable to pay for the procedure.

Study Size

Power calculations (power = 0.8, $P \leqq 0.05$) indicated a sample size of 41 would be necessary to detect significant reductions in NRS, ODI, and QBPDS, assuming thresholds equivalent to a 30% decrease in score (30 points for ODI, 30 points for QBPDS, 2 points for NRS) and predicting maximum potential baseline standard deviation (5 for NRS, 20 for ODI, 20 for QBPDS).

Using SDs in the NRS, ODI, and QBPDS data at 3 months, the updated estimate of the required sample size was 13, which was within the number of patients who had completed their 3-month visit (n = 85).

Statistical Analyses

Descriptions of the statistical models used in the present study are listed in Table S2. Model 1 is a generalized linear mixed model (GLMM) and models 2–4 are mixed models repeat measures (MMRM). Models 1–4 include data from three time points: baseline, 3 months post-surgery and 6 months post-surgery. Visit number and patient ID are included to indicate the order of grouped values. Each model includes the same covariates: visit number, age, gender, height, BMI, race, procedure side, revision surgery, employment status, clinical site.

Response variables varied as shown in the table below. Patient improvement (models 1 and 5) was assessed using a binomial composite indication to summarize the following key indicators: any reduction in NRS as a quantitative measure of pain (yes/no), any reduction in ODI (%), representing disability/loss of function (yes/no), and the absence of adverse effects (yes/no). MMRM models were constructed using the R package mmrm.

Models 5–8 are generalized linear models (GLMs), which contain the same covariates as models 1-4. These models were used for the interim data analysis at 3 months, when fewer than 3 time points of data were available. Family was specified based on the nature of the response variable. One GLM was constructed corresponding to each MMRM.

Supplemental Results

Table S1. *Summary of patient cohort data completeness, detailing missing data frequencies for patients who underwent surgery at the time of the interim analysis.*

	Patients having completed surgery			Patients with completed 3 m checks (analyzed)			Patients with completed 6 m checks (analyzed)		
	n, Missing rows*	Total	% Missing rows	n, Missing rows*	Total	% Missing rows	n, Missing rows	Total	% Missing rows
Age (yrs)	0	114	0	0	85	0	0	72	0
Height (cm)	0	114	0	0	85	0	0	72	0
Gender	0	114	0	0	85	0	0	72	0
BMI	0	114	0	0	85	0	0	72	0
Center number	0	114	0	0	85	0	0	72	0
Procedure date	0	114	0	0	85	0	0	72	0
Enrollment date	0	114	0	0	85	0	0	72	0
Race	0	114	0	0	85	0	0	72	0
Baseline ODI	0	114	0	0	85	0	0	72	0
3 month ODI	29	114	25.44	0	85	0	0	72	0
6 month ODI	42	114	36.84	13	85	15.29	0	72	0
Baseline NRS	0	114	0	0	85	0	0	72	0
3 month NRS	29	114	25.44	0	85	0	0	72	0
6 month NRS	42	114	36.84	13	85	15.29	0	72	0
Baseline QBPDS	0	114	0	0	85	0	0	72	0
3 month QBPDS	29	114	25.44	0	85	0	0	72	0
6 month QBPDS	42	114	36.84	13	85	15.29	0	72	0
Number of screws	0	114	0	0	85	0	0	72	0
Procedural complications	0	114	0	0	85	0	0	72	0
Blood loss	0	114	0	0	85	0	0	72	0
Procedure side	0	114	0	0	85	0	0	72	0
Revision surgery		114		0	85	0	0	72	0
Socioeconomic status	0	122	0	0	85	0	0	72	0
Race	0	122	0	0	85	0	0	72	0
Gender	0	122	0	0	85	0	0	72	0

*Missing rows with values > 0 indicate patients who completed surgery but had not completed 3- and 6-month follow-up visits at the time of the interim analysis. ODI: Oswestry Disability Index; NRS: Numeric Rating System for pain; QBPDS: Quebec Back Pain Disability Score.

Table S2. *Descriptions of statistical models used in the present study.*

Model number	Model type	Data included	Response variable	Family (distribution)
1	GLMM	Composite endpoint: Baseline, 3 months, and 6 months	Binary variable- patient improvement (Y/N)	Binomial
2	MMRM	Baseline, 3 months, and 6 months	ODI	Poisson
3	MMRM	Baseline, 3 months, and 6 months	QBPDS	Poisson
4	MMRM	Baseline, 3 months, and 6 months	NRS	Poisson
5	GLM	Composite endpoint: Baseline and 3 months	Binary variable- patient improvement (Y/N)	Binomial
6	GLM	Baseline and 3 months	ODI	Poisson
7	GLM	Baseline and 3 months	QBPDS	Poisson
8	GLM	Baseline and 3 months	NRS	Poisson

GLMM: generalized linear mixed model; MMRM: mixed-effects model for repeated measures.

Table S3. *Summary of reported patient outcomes of pain and disability for patients after sacroiliac joint (SIJ) fixation with the TransLoc 3D™ system.*

Category	Subcategory	n (%)	Median (IQR)	Mean (sd)	min, Max	*P*-value
Total patients who completed surgery	Of 122 patients enrolled	114 (100)				
Baseline QBPDS (Scale of 0–100)		114 (100)	64 (54,75)	63.45 (±14.8)	21,92	
Baseline NRS (Scale of 0–10)		114 (100)	8 (7,9)	8.25 (±1.2)	6,10	
Baseline ODI (Scale of 0–100)		114 (100)	50 (38.0,58.0)	49.03 (±12.64)	30,84	
Change in QBPDS (Scale of 0–100)	3 months	85 (73.68)	-25 (-41,-12)	-27.18 (±19.53)	-79,2	< 2.2e-16
	6 months	72 (58.06)	-26.5 (-41.5,-15)	-29.03 (±19.83)	-73,8	< 2.2e-16
Change in NRS (Scale of 0–10)	3 months	85 (73.68)	-5 (-6,-3)	-4.63 (±2.31)	-10,0	< 2.2e-16
	6 months	72 (58.06)	-5 (-7,-3)	-4.99 (±2.63)	-10,1	< 2.2e-16
Change in ODI (Scale of 0–100)	3 months	85 (73.68)	-20 (-32,-9.5)	-21.42 (±15.44)	-68,6	< 2.2e-16
	6 months	72 (58.06)	-23 (-34,-12)	-24.03 (±16.61)	-52,12	< 2.2e-16

ODI: Oswestry Disability Index; NRS: Numeric Rating System for pain; QBPDS: Quebec Back Pain Disability Score.

Table S4. *Estimated effect sizes at 3 months among covariates from MMRMs.*

Factor	Level	Model 1 (GLMM composite endpoint)				Model 2 (MMRM ODI)				
		OR	**CI 2.5%**	**CI 97.5%**	***P* value**	**Estimate**	**Std.Error**	**df**	**t.value**	***P* value**
(Intercept)		412.883	0.006	329761.000	0.290	-6.808	24.306	46.641	-0.280	0.781
3 month visit		1.399	0.605	3.328	0.436	-0.899	0.941	63.337	-0.955	0.343
Age (yrs)		0.997	0.949	1.046	0.910	0.003	0.125	47.199	0.028	0.978
Height (cm)		0.978	0.916	1.047	0.501	-0.056	0.136	46.445	-0.410	0.684
BMI		0.919	0.847	0.993	**0.037**	0.341	0.179	47.329	1.905	0.063
Center number	2	2.698	0.199	78.877	0.508	2.228	4.715	46.623	0.472	0.639
	3	2.115	0.403	15.962	0.402	-5.203	3.303	47.216	-1.575	0.122
	6	NA	0.000	NA	0.993	-4.320	4.846	46.794	-0.891	0.377
	7	0.733	0.119	5.392	0.745	-0.601	3.782	46.669	-0.159	0.875
	8	0.538	0.116	2.578	0.422	-4.739	3.616	46.305	-1.311	0.196
	9	NA	0.000	NA	0.991	-3.646	3.933	46.453	-0.927	0.359
	10	0.256	0.055	1.229	0.079	2.781	3.899	49.952	0.713	0.479
	11	NA	0.000	NA	0.993	-0.794	5.553	49.388	-0.143	0.887
	14	0.696	0.23709087650-	1.894	0.488	NA	NA	NA	NA	NA
Blood loss		0.971	0.892	1.052	0.474	-0.220	0.171	46.647	-1.289	0.204
Procedure side right		1.046	0.007	0.255	**0.010**	3.689	2.051	47.641	1.799	0.078
Revision surgery		0.957	0.195	7.076	0.959	-0.724	3.209	46.387	-0.226	0.823
Disabled		NA	NA	NA	NA	9.096	7.985	48.416	1.139	0.260
Not working		NA	NA	NA	NA	3.974	3.999	47.221	0.994	0.325
Retired		NA	NA	NA	NA	1.919	2.989	49.113	0.642	0.524
Hispanic		NA	NA	NA	NA	-4.074	8.857	46.298	-0.460	0.648
Other Race		1.022	0.062	13.000	0.052	0.519	10.497	46.300	0.049	0.961
Black		0.062	0.003	0.928	0.054	-6.507	8.260	46.292	-0.788	0.435
Male		0.977	0.294	3.519	0.962	-0.338	2.382	46.551	-0.142	0.888
6 month visit: Male		0.932	0.837	1.039	0.211	NA	NA	NA	NA	NA

GLMM: generalized linear mixed model; MMRM: mixed-effects model for repeated measures; OR: odds ratio; CI: confidence interval; ODI: Oswestry Disability Index; NRS: Numeric Rating Scale; QBPDS: Quebec Back Pain Disability Scale; BMI: body mass index; SE: standard error; df: degrees of freedom; NA: not applicable or not estimable.

Table S4 con't. *Estimated effect sizes at 3 months among covariates from MMRMs.*

Factor	Level	Model 3 (MMRM NRS)					Model 4 (MMRM QBPDS)				
		Estimate	Std. Error	df	t.value	*P* value	Estimate	Std. Error	df	t.value	*P* value
(Intercept)		-7.607	6.904	48.274	-1.102	0.276	9.220	61.791	46.589	0.149	0.882
3 month visit		-0.746	0.358	66.669	-2.086	**0.041**	-1.967	2.275	63.596	-0.865	0.390
Age (yrs)		-0.037	0.035	49.195	-1.039	0.304	0.074	0.317	46.994	0.235	0.815
Height (cm)		0.020	0.039	47.384	0.500	0.619	-0.125	0.347	46.350	-0.359	0.721
BMI		0.062	0.049	50.325	1.259	0.214	0.288	0.455	47.417	0.633	0.530
Center number	2	-1.377	1.359	47.293	-1.013	0.316	7.580	11.984	46.533	0.632	0.530
	3	-0.054	0.943	48.788	-0.057	0.955	-11.625	8.385	46.962	-1.386	0.172
	6	-0.024	1.397	47.545	-0.018	0.986	-14.055	12.311	46.648	-1.142	0.259
	7	0.143	1.090	47.688	0.131	0.896	-5.301	9.603	46.419	-0.552	0.584
	8	-0.473	1.041	47.363	-0.454	0.652	-12.327	9.188	46.138	-1.342	0.186
	9	-2.276	1.133	47.512	-2.009	**0.049**	-6.876	9.990	46.245	-0.688	0.495
	10	0.607	1.097	47.716	0.553	0.583	4.036	10.026	51.312	0.403	0.689
	11	-0.019	1.568	47.900	-0.012	0.990	-18.288	14.229	50.517	-1.285	0.205
	14	0.413	1.720	51.997	0.240	0.811	NA	NA	NA	NA	NA
Blood loss		0.021	0.049	47.203	0.431	0.668	-0.460	0.435	46.636	-1.059	0.295
Procedure side right		-0.687	0.587	48.088	-1.171	0.247	7.779	5.219	47.773	1.491	0.143
Revision surgery		0.701	0.925	47.259	0.757	0.453	-1.785	8.153	46.227	-0.219	0.828
Disabled		-0.852	2.270	47.331	-0.375	0.709	8.928	20.425	49.337	0.437	0.664
Not working		0.241	1.091	50.871	0.221	0.826	12.025	10.175	47.354	1.182	0.243
Retired		0.882	0.851	50.312	1.037	0.305	-0.102	7.576	48.764	-0.013	0.989
Hispanic		0.386	2.550	47.145	0.151	0.880	-18.889	22.516	46.208	-0.839	0.406
Other Race		2.480	3.024	47.161	0.820	0.416	-22.898	26.679	46.182	-0.858	0.395
Black		0.170	2.381	47.098	0.072	0.943	-30.594	20.996	46.186	-1.457	0.152
Male		0.045	0.719	48.611	0.062	0.951	6.131	6.058	46.511	1.012	0.317
6 month visit:Male		1.651	0.645	66.250	2.558	**0.013**	NA	NA	NA	NA	NA

GLMM: generalized linear mixed model; MMRM: mixed-effects model for repeated measures; OR: odds ratio; CI: confidence interval; ODI: Oswestry Disability Index; NRS: Numeric Rating Scale; QBPDS: Quebec Back Pain Disability Scale; BMI: body mass index; SE: standard error; df: degrees of freedom; NA: not applicable or not estimable.

Table S5. *Estimated effect sizes at 6 months among covariates from GLMs.*

Factor	Level	Model 5 (GLM 3m composite endpoint)				Model 6 (GLM ODI)				
		OR	CI 2.5%	CI 97.5%	*P* value	Estimate	Std. Error	t.value	*P* value	Estimate
(Intercept)		6.683	0.001	425587.630	0.898	-40.106	42.851	-0.936	0.353	-8.371
Age (yrs)		0.955	0.816	1.063	0.484	0.074	0.235	0.315	0.754	-0.072
Height (cm)		1.020	0.894	1.215	0.817	0.035	0.252	0.141	0.888	0.032
BMI		1.051	0.869	1.335	0.633	0.630	0.324	1.942	0.057	0.039
Center number	2	8.036	5.578	10.142	0.274	-9.278	6.950	-1.335	0.187	-1.908
	3	1.100	0.807	2.356	0.678	-14.751	10.270	-1.436	0.156	-0.789
	6	NA	0.000	NA	0.996	0.041	12.442	0.003	0.997	2.402
	7	0.832	0.656	1.098	0.542	-9.879	7.002	-1.411	0.163	-1.471
	8	0.587	0.234	1.998	0.997	-1.843	7.686	-0.240	0.811	-0.546
	9	1.220	0.955	1.558	0.112	5.062	8.545	0.592	0.556	-0.770
	10	0.209	0.045	1.320	0.039	-10.487	6.866	-1.527	0.132	-0.041
	11	NA	0.000	NA	0.991	6.004	8.039	0.747	0.458	1.723
	14	0.699	0.318	2.760	0.746	4.381	10.287	0.426	0.672	1.673
Blood loss		0.905	0.786	3.456	0.518	-0.076	0.244	-0.312	0.756	0.005
Procedure side right		1.001	0.322	1.560	0.798	7.788	3.893	2.000	0.050	-0.340
Revision surgery		0.627	0.440	0.891	0.009	-2.119	6.621	-0.320	0.750	0.526
Disabled		NA	NA	NA	NA	3.188	9.243	0.345	0.731	0.105
Not working		NA	NA	NA	NA	2.343	7.814	0.300	0.765	-0.579
Retired		NA	NA	NA	NA	0.666	6.071	0.110	0.913	0.707
Hispanic		NA	NA	NA	NA	-2.950	18.508	-0.159	0.874	3.049
Other Race		0.980	0.071	1.267	0.997	6.080	22.295	0.273	0.786	4.520
Black		0.398	0.223	1.760	0.916	-12.000	17.397	-0.690	0.493	2.061
Male		0.965	0.665	2.134	0.897	-4.308	4.296	-1.003	0.320	0.602

GLM: generalized linear model; OR: odds ratio; CI: confidence interval; ODI: Oswestry Disability Index; NRS: Numeric Rating Scale; QBPDS: Quebec Back Pain Disability Scale; BMI: body mass index; SE: standard error; NA: not applicable or not estimable.

Table S5 con't. *Estimated effect sizes at 6 months among covariates from GLMs.*

	Model 7 (GLM NRS)				Model 8 (GLM QBPDS)			
Factor	**Level**	**Std.Error**	**t.value**	***P* value**	**Estimate**	**Std.Error**	**t.value**	***P* value**
(Intercept)		6.395	-1.309	0.196	-23.027	55.187	-0.417	0.678
Age (yrs)		0.035	-2.042	0.046	-0.065	0.302	-0.214	0.831
Height (cm)		0.038	0.857	0.395	0.130	0.324	0.401	0.690
BMI		0.048	0.814	0.419	0.220	0.418	0.527	0.600
Center number	2	1.037	-1.840	0.071	-14.170	8.951	-1.583	0.119
	3	1.533	-0.515	0.608	-18.400	13.226	-1.391	0.169
	6	1.857	1.294	0.201	5.962	16.023	0.372	0.711
	7	1.045	-1.408	0.164	-15.283	9.018	-1.695	0.095
	8	1.147	-0.476	0.636	-4.133	9.899	-0.417	0.678
	9	1.275	-0.604	0.548	8.293	11.005	0.754	0.454
	10	1.025	-0.040	0.968	-13.141	8.843	-1.486	0.143
	11	1.200	1.436	0.156	0.269	10.353	0.026	0.979
	14	1.535	1.090	0.280	-7.611	13.248	-0.574	0.568
Blood loss		0.036	0.132	0.895	-0.174	0.314	-0.554	0.582
Procedure side right		0.581	-0.585	0.561	7.094	5.014	1.415	0.162
Revision surgery		0.988	0.533	0.596	2.082	8.527	0.244	0.808
Disabled		1.379	0.076	0.940	2.045	11.903	0.172	0.864
Not working		1.166	-0.497	0.621	4.948	10.064	0.492	0.625
Retired		0.906	0.780	0.439	1.083	7.819	0.138	0.890
Hispanic		2.762	1.104	0.274	-5.410	23.836	-0.227	0.821
Other Race		3.327	1.359	0.179	-20.205	28.713	-0.704	0.484
Black		2.596	0.794	0.431	-26.521	22.406	-1.184	0.241
Male		0.641	0.939	0.352	1.009	5.533	0.182	0.856

GLM: generalized linear model; OR: odds ratio; CI: confidence interval; ODI: Oswestry Disability Index; NRS: Numeric Rating Scale; QBPDS: Quebec Back Pain Disability Scale; BMI: body mass index; SE: standard error; NA: not applicable or not estimable.