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Prospective Study

Minimally Invasive Sacroiliac Joint Fusion Using 3D Printed Implants and a Lateral Approach: Safety and Effectiveness Assessments of Fusion Performed by Interventional Physicians in a Prospective Multicenter Single-Arm Clinical Study (The FICS Study)

Douglas P. Beall, MD[1], Ty Ptacek, MD[2], Ashley M. Classen, CO[3], Michael Jung, MD[4], Matthew Skoblar, MD[5], John Hatheway, MD[6], Olivia A. Beall, MA[1], Ethan Wood, BA[7] Matthew C. Shonnard, MD[1], and Reade DeLeacy, MBBS[8]

From: [1]Comprehensive Specialty Care, Interventional Pain/ Interventional Radiology, Edmond, OK; [2]Rapid City Medical Center Interventional Pain, Rapid City, SD; [3]Trinity Pain Medicine Associates, Ft. Worth, TX; [4]Wisconsin Spine and Pain, West Bend, WI; [5]Spine Nerve and Joint Institute, Clark, NJ; [6]Interventional Pain Physician, Gig Harbor, WA; [7]Oklahoma State University Center for Health Sciences, Tulsa, OK; [8]Department of Neurosurgery, Mount Sinai Health System, New York, NY

Address Correspondence:
Douglas P Beall, MD
Comprehensive Specialty Care
1023 Waterwood Parkway
Edmond, OK 73034
E-mail: db@clinrad.org

Disclaimer: Funding for this study was provided by Genesys Spine, Austin, TX, USA. The datasets generated during and/or analyzed during the current study are not publicly available due to data protection and privacy concerns but are available from the corresponding author on reasonable request. The sacroiliac joint fusion study included 7 total active study sites that utilized the approval process of either the central IRB (the Western-Copernicus Group Institutional Review Board) (n = 6 sites) or their local IRB (n = one site).

Conflicts of Interest: See page 92 for this information.

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Background: Low back pain (LBP) is a widespread and costly condition. Sacroiliac joint (SIJ) dysfunction accounts for 15–25% of chronic LBP cases and is especially common following lumbar spine fusion—affecting up to 75% of such patients within five years. Risk factors include prior spine surgery, pregnancy, obesity, trauma, and inflammatory diseases. For persistent cases, sacroiliac joint fusion (SIJF) is increasingly used, offering better outcomes than conservative treatments. Recent advancements in minimally invasive surgical (MIS) techniques and implant designs have improved the safety and effectiveness of SIJF, making it a reliable option for managing chronic SIJ dysfunction.

Objectives: To examine the effectiveness of a minimally invasive sacroiliac joint approach and fusion device by means of clinical patient reported outcomes (PROs) and radiological outcomes.

Study Design: The design of this clinical trial is a multi-site, prospective, single arm feasibility study.

Setting: The study was conducted in 7 sites located across the United States including both private practices and academic centers from September 19, 2022, to December 6, 2023.

Methods: This study enrolled 37 patients aged 21–80 with chronic SIJ pain or degenerative sacroiliitis unresponsive to conservative care. All underwent SIJF and were followed for six months. PROs on pain, function, opioid use, work status, adverse events, and quality of life were collected via email at 1, 3, and 6 months postoperatively. Diagnostic inclusion required SIJ pain localization, ≥ 3 of 6 positive physical exam tests, 75% pain relief after anesthetic injection, and confirmatory imaging. Exclusions included alternative causes of back pain, trauma, infection, or conditions that could interfere with recovery. Radiologic outcomes were evaluated by a six-month CT. PROs included pain reporting via the Numeric Rating Scale (NRS), function via the Oswestry Disability Index (ODI), and quality of life via PROMIS-10.

Results: The study measured outcomes using NRS, ODI, PROMIS-10, opioid use, pain interventions, work status, and SAEs. Pain scores (NRS) significantly decreased from 6.8 at baseline to 4.1, 4.8, and 4.2 at 1, 3, and 6 months ($P < 0.01$). Disability scores (ODI) also improved significantly from 50.3 to 41.7, 35.6, and 34.9 ($P < 0.05$). PROMIS-10 scores showed slight, non-significant improvements. Opioid use dropped from 26 to 13–16 patients over time, though not statistically significant. No SAEs occurred. CT scans at 6 months showed 96% implant bone apposition and no implant failures; 72% of patients had SIJ bridging.

Limitations: This study is limited by a small sample size, short follow-up, and lack of control group.

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Conclusions: Laterally placed SIJ fusion titanium alloy implants are a safe and effective treatment for patients with refractory SIJ dysfunction, as evidenced by significant improvements in pain and function, high rates of radiological fusion, and a favorable safety profile.

Key words: Low back pain, sacroiliac joint, SI joint dysfunction, SI joint fusion, chronic pain, patient reported outcome measures, radiological outcomes

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Low back pain (LBP) is a common debilitating condition that affects over 70 million Americans and represents annual costs of over 40 billion dollars in health care spending (1,2). Dysfunction in the sacroiliac joint (SIJ) is a common cause of LBP (3,4). According to recent estimates, 15-25% of chronic LBP cases can be attributed to the SIJ (5,6). Risk factors for SIJ dysfunction include pregnancy, obesity, anatomical abnormalities, prior lumbar spine surgery, trauma, and inflammatory arthropathies (7). Prior lumbar fusion is the most significant risk factor for the development of SIJ dysfunction, occurring in 40-75% of post–spine fusion patients after 5 years (7,8).

Although SIJ dysfunction is common, the diagnosis can be challenging. The SIJ has unique anatomy and biomechanics and demonstrates marked anatomic differences between men and women as well as from one individual to another (9). Anatomic variations in the SIJ are seen in over 80% of patients with SIJ dysfunction (12). Symptoms of SIJ dysfunction can present in a variety of ways, often mimicking radicular or discogenic pain, and the pain associated with this SIJ condition can radiate to the buttocks, lower back, and/or groin (5,11,13). Given the difficulties associated with distinguishing SIJ dysfunction from related pathologies, a thorough clinical evaluation is necessary before diagnosing the patient. Definitive diagnosis may be made by eliciting pain with 3 or more tests specific to the SIJ and confirmed via injecting an anesthetic into this joint (13).

Treatment of SIJ dysfunction can include conservative measures such as physical therapy and anti-inflammatory medications but often involves targeted therapies such as corticosteroid injections and radiofrequency ablation (13,14). If these treatment measures fail or do not provide sustained relief, SIJ fusion (SIJF) may be warranted. SIJF has gained popularity in recent years as a treatment for chronic, refractory SIJ dysfunction, and the use of this technique has grown considerably (14,15). For patients who have not responded to conservative management, SIJF has been shown to provide effective pain relief superior to optimized conservative management (4,6,7-15).

Recent developments in implant design and MIS techniques have further enhanced the efficacy of SIJF, allowing for percutaneous arthrodesis (18-21). Improvements in surgical techniques and advances in materials and implant design have led to greater successes in reducing the pain associated with SIJ dysfunction (22). These improvements, combined with favorable safety and efficacy evidence from clinical trials, have solidified SIJF as a viable treatment for SIJD.

The goal of the assessment of fusion from implants placed by Interventional physicians in a prospective multicenter single-arm clinical study (FICS study) using a roughened, self-tapping, self-augering, rifled fusion device (Genesys SIros® Sacroiliac Joint Fusion implants, Genesys Surgical) 3D printed from a titanium alloy (Ti-6Al-4V). The means of assessment were clinical patient-reported outcomes (PROs) and radiological findings. A secondary goal of the study was to inform the design of a larger clinical study in the future.

Methods

In this study, 37 patients between the ages of 21-80 with refractory SIJ pain or degenerative sacroiliitis were enrolled, treated with SIJF, and followed for a total of 6 months after surgery. The data collection was performed with PROs collected by email at one, 3, and 6 months after SIJF. The clinical information recorded included the patients' pain, functioning, work status, use of prescription opioids/pain management, adverse events/serious adverse events (AEs/SAEs), and quality-of-life data. In addition to these PROs, a computed tomography (CT) scan was obtained at 6 months after the procedure. Each CT was assessed for multiple radiographic factors, including sacroiliac bone apposition and bridging, heterotopic ossification, per-implant radiolucency, device failure (e.g., broken device), and device migration or subsidence.

Inclusion and exclusion criteria were informed by current research and chosen based on diagnostic criteria for SIJ dysfunction or degenerative sacroiliitis. At the time of screening, patients aged 21-80 years old were considered eligible if they had over 6 months of

LBP that remained unresponsive to conservative care. Baseline pain had to rate at least 5 out of 10 on the numeric rating scale (NRS). A diagnosis of SIJ dysfunction or degenerative sacroiliitis was considered if the patient had all of the following: (A) pain at or close to the posterior superior iliac spine (PSIS) and the ability to point at the location of pain (aka the Fortin finger test); (B) at least 3 out of 6 the physical-exam maneuvers specific to SIJ dysfunction (distraction, thigh thrust, Patrick/FABER, compression, Gaenslen, and/or sacral thrust); (C) an improvement of at least 75% in NRS score after the injection of local anesthetic into the affected SIJ(s); (D) and one or more imaging findings: (i) asymmetric SIJ widening on x-ray or CT scan, (ii) leakage of contrast on diagnostic arthrography, (iii) SIJ degeneration via sclerosis, osteophytes, subchondral cysts, vacuum phenomenon, or prior lumbosacral spine fusion on x-ray or CT scan. Patients were excluded from the study if they had alterative diagnoses known to contribute to LBP. Additional exclusion criteria included the presence of another known sacroiliac pathology, recent trauma (less than one year old) to the pelvis, local or systemic infections, medications, or diseases or conditions that could impact the procedure, healing process, or physical therapy.

The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice (ICH GCP) and applicable local, state, and federal regulatory requirements. The protocol, informed-consent form(s), recruitment materials, and all patient materials were submitted, reviewed, and approved by the Western-Copernicus Group Institutional Review Board (WCG IRB). Approval of both the protocol and the consent was obtained before any patient was enrolled. All personnel involved in the conducting of the study completed the necessary Human Subjects Protection, ICH GCP, and WCG IRB training. In addition to the data collection training, clinical sites were provided with a narrative that was used to describe the study to their patients, with emphasis on the PRO component.

The PRO data collection was done via automated email surveys to the patient at one month and at 3 and 6 months after their SIJF. At least 4 attempts were made to contact the patient at each time point. The data requirements for the study included the baseline patient characteristics, the type of primary health insurance, brief medical history, spine surgical history, current opioid use, treatments received for LBP, and procedure characteristics. The PROs obtained included pain and functioning, with pain assessed on the Numeric Pain Rating Scale (NRS; 0 = no pain, 10 = most severe pain) and function assessed on the Oswestry Disability Index (ODI; 0-100; 0-20 = minimal disability, 21-40 = moderate disability, 41-60 = severe disability, 61-80 = very severe disability, 81-100 = bedbound). Meanwhile, quality of life was assessed on the Patient-Reported Outcomes Measurement Information System (PROMIS 10; 0 = poor quality of life; 20 = best possible quality of life). Any alternatives to treatment were discussed at the discretion of the treating clinician, and the patients were tracked for adverse events and outcomes.

Study Design and Analysis

The data obtained for this study were collected from 7 sites located across the United States, including both private practices and academic centers, from September 19, 2022, to December 6, 2023. Patients were included in the database if they completed the baseline data collection, finished the follow-up PRO assessments, and/or attended the final 6-month on-site visit after SIJF.

The primary objective was to evaluate the effectiveness of treatment with the SIros® SI Joint Fusion System via PRO and CT scan. Primary endpoints were both clinical and radiologic. Clinical endpoints assessed pain, function, and quality of life by email at one month and at 3 and 6 months. Clinically, pain was assessed on the NRS and by opioids prescribed as well as other pain management interventions before and after SIJF. Each patient's functioning and work status were assessed on the ODI before and after the procedure. Quality of life was assessed on the PROMIS 10. In addition to these clinical endpoints, SAEs were captured. At 6 months after the SIJF, radiographic endpoints were assessed by CT scan . Each CT scan was evaluated by 2 independent radiologists for sacroiliac bone apposition and bridging, heterotopic ossification, per-implant radiolucency, device failure, and device migration or subsidence.

All of the analyses were performed using Stata® version 17 (StataCorp LLC). Descriptive statistics (number, frequency, mean, and standard deviation) were calculated for patient and procedure characteristics. Medication and employment status were assessed at baseline and at each follow-up time point (one month, 3 months, and 6 months). Chi-squared tests were performed to evaluate the significance of differences in medication and employment status over time. Mean pain scores (on the NRS) and function scores (on the ODI and the PROMIS 10 Mental and Physical) were also calculated at baseline and each follow-up time

point. T-tests were used to compare mean scores between 2 time points, while one-way ANOVA tests were utilized to assess the impact of time on mean scores. Chi-squared tests were used to analyze major follow-up assessments, including problems surrounding the procedure, readmissions to the hospital, satisfaction with the outcome of the procedure, and the likelihood of repeating the procedure if the patient was faced with the same diagnosis at each follow-up time point (one month, 3 months, and 6 months).

Results

Demographics

A total of 37 patients with SIJ dysfunction were included in this registry. Two patients withdrew between the one-month and 3-month follow-up, and one patient withdrew between the 3- and 6-month follow-up. All the patients had baseline PROs, and at least one completed follow-up survey. The follow-up surveys were available at one, 3, and 6 months from a respective 23, 25, and 26 patients who had provided their baseline data (Table 1). Women outnumbered men, comprising 73% of the patients. Ages ranged from 33 to 80 years old, with the mean age being 57.5 (Table 1).

Prior spine surgery was common (23 patients [62%]), and of the 23 who had had surgery, most (13 [56.5%] of those 23) had received a prior fusion (Table 1). Most of the patients had used opioids previously (78.4%) and tried different conservative treatments before SIJF (91.9% received physical therapy, 81.1% NSAIDs, 64.9% muscle relaxants, and 43.2% transforaminal epidural steroid injections) (Table 1). Unsurprisingly, most patients described an inadequate response to conservative care (89.2%). In addition to patient characteristics (Table 1), procedure characteristics were documented (Table 2). The latter included the American Society of Anesthesiologists (ASA) classification and the type of graft and product used. All patients underwent fusion, with 3 implants placed laterally using fluoroscopic guidance. There were no SAEs or deaths related to the procedure.

The primary clinical endpoints were measured by the scores on the 11-point NRS, the 100-percentage-point ODI, and the 50-point PROMIS 10 as well as the evaluations of patients' pre- and post-SIJF opioid use, pain management interventions, work status. SAEs were also captured. The mean NRS pain score at baseline was 6.8 (Table 3). Postoperatively, the mean NRS scores were 4.1, 4.8, and 4.2 at one month, 3 months, and 6 months, respectively (Table 3, Fig. 1). The improvement from the baseline for mean NRS scores were statistically significant ($P < 0.01$) at all time points.

The mean ODI percent score at baseline was 50.3% (Table 3). Postoperatively, the mean ODI percent scores were 41.7, 35.6, and 34.9 at the one-month, 3-month and 6-month time points, respectively (Table 3, Fig. 2). The improvements from the baseline for both mean ODI percent scores were statistically significant ($P < 0.05$; was < 0.01 for 3 and 6 months) at all time points.

Quality of life was assessed on the PROMIS 10 PRO. The mean PROMIS 10 scores at baseline were for mental health 12.8 and 10.9 for physical health (Table 3). Postoperatively, the PROMIS 10 scores showed no statistically significant changes. However, the mental health scores did improve slightly to 13.5, 12.9, and 13.5 at the respective one-month, 3-month and 6-month time points, while the physical health scores became 11.7, 11.9, and 12.8 at one month, 3 months, and 6 month, respectively (Table 3, Fig. 3).

Additional clinical endpoints assessing pre- and post-SIJF opioid use, pain management interventions, and work status did not show any statistically significant findings, but some were clinically important (Tables 4 and 5). For example, 26 of the 37 patients were taking pain medications when screened at baseline. Although not statistically significant, this number decreased to 13, 15, and 16 at the one-, 3-, and 6-month time points, respectively (Table 4). SAEs were also assessed, and none was reported.

Twenty-five of the 37 patients obtained CT scans of their pelvises at 6 months after SIJF. Of the 25 patients, 96% exhibited apposition of bone on the iliac sides of at least 2 of the 3 implants (24/25 patients). The same percentage (96%) of patients also exhibited apposition of bone on the sacral sides of at least 2 of the 3 implants (24/25 patients) (Table 6). With one exception, none of the implants exhibited surrounding radiolucency (96%; 24/25 patients), and no implant failed or exhibited subsidence (0/25 patients) (Table 6). At 6 months, 72% of the patients showed bridging across the SIJ (18/25 patients) after SIJF (Table 6).

Discussion

This multi-site, prospective, single-arm feasibility study evaluated the effectiveness of a trio of 3D-printed titanium alloy implants placed by interventional pain management physicians or interventional radiologists via the lateral approach (Fig. 4) to treat 37 patients with refractory SIJ dysfunction or degenera-

Table 1. *Characteristics of patients included in the FICS sacroiliac joint fusion (SIJF) study.*

Characteristics	n = 37
Gender, n (%)	
Female	27 (73.0)
Male	10 (27.0)
Age (years)	
Mean (SD)	57.5 (13.8)
Min-Max	33-80
Height (inches)	
Mean ± SD	66.9 (3.1)
Range	61-73
Weight (lbs)	
Mean ± SD	183.6 (35.5)
Range	118-270
BMI	
Mean ± SD	28.9 (5.4)
Range	17.4-39.6
Primary Insurance Type, n (%)	
Private	13 (35.1)
Medicaid	1 (2.7)
Medicare	19 (51.4)
Other	4 (10.8)
Smoking History, n (%)	
Current (within one month)	5 (13.5)
Former	13 (35.1)
Never	17 (24.0)
Unknown	2 (5.4)
Diabetes Mellitus, n (%)	
No	27 (73.0)
Yes	9 (24.3)
5.7%-6.4%	6 (66.7)
6.5% or higher	3 (33.3)
Unknown	1 (2.7)
Oral Steroid Use, n (%)	
No	36 (97.3)
Yes	1 (2.7)
Hypertension, n (%)	
No	24 (64.9)
Yes	13 (35.1)
Chronic Kidney Disease, n (%)	
No	35 (94.6)
Yes	2 (5.4)
Stroke/Transient Ischemic Attack (TIA), n (%)	
No	35 (94.6)
Yes	2 (5.4)

Table 1 cont. *Characteristics of patients included in the FICS sacroiliac joint fusion (SIJF) study.*

Characteristics	n = 37
Had Previous Spine Surgeries, n (%)	
No	14 (37.8)
Yes	23 (62.2)
Fusion	13 (56.5)
Laminectomy and spine fusion	4 (17.4)
Laminectomy	2 (8.7)
Decompression and laminectomy	1 (4.3)
Decompression and fusion	1 (4.3)
Interspinous spacer	1 (4.3)
Microdiscectomy	1 (4.3)
Previous Use of Any Opioids for Low Back Pain (LBP), n (%)	
No	8 (21.6)
Yes	29 (78.4)
Previous Use of Any Pain Medication for LBP, n (%)	
No	4 (10.8)
Yes	33 (89.2)
Had LBP for More Than 6 Months, n (%)	
No	1 (2.7)
Yes	36 (97.3)
Type of Treatment Received for LBP, n (%) (Patients can have more than one.)	
Physical therapy	34 (91.9)
Intermittent corset	4 (10.8)
NSAIDS	30 (81.1)
Adjuvant analgesics	5 (13.5)
Anxiolytics	1 (2.7)
Neuroleptics	6 (16.2)
Non-opioids	21 (56.8)
Muscle relaxants	24 (64.9)
Short-term opioid	15 (40.5)
Steroid taper	1 (2.7)
Lidoderm patch	10 (27.0)
Transcutaneous electrical nerve stimulation unit	10 (27.0)
Compounded ointments	7 (18.9)
Transforaminal epidural steroid injections (TFESIs)	16 (43.2)
Other	9 (24.3)
Had Inadequate Response to Conservative Care, n (%)	
No	0 (0)
Yes	33 (89.2)
Unknown	4 (10.8)

tive sacroiliitis over a 6-month follow-up period. The results demonstrated that minimally invasive SIJF using this system improves pain and functional outcomes significantly, with promising radiological evidence of fusion, supporting the potential of SIJF as a viable treatment option for patients who have not responded to conservative management. These findings align with the growing body of evidence supporting SIJF as an effective intervention for SIJ dysfunction and has comparable results to other trials evaluating the lateral approach, such as the INSITE, iMIA, LOIS, SALLY and SIFI trials (23-27) and the SECURE trial that evaluated the posterior approach using a cortical allograft implant (28).

Table 2. *Procedure characteristics of the FICS SIJF study.*

Characteristic	n = 37
ASA Classification, n (%)	
ASA I	0 (0)
ASA II	20 (54.1)
ASA III	16 (43.2)
ASA IV	1 (2.7)
ASA V	0 (0)
Type of Graft Used, n (%)	
Autograft	8 (21.6)
DBM	12 (32.4)
Synthetic	10 (27.0)
None	3 (8.1)
Other	4 (10.8)
Procedure-Related Adverse Events	
No	37 (100.0)
Yes	0 (0)
Procedure-Related Deaths	
No	37 (100.0)
Yes	0 (0)

The primary clinical endpoints of this study showed statistically significant improvements at all follow-up time points (one, 3, and 6 months) compared to baseline. The mean NRS score decreased from 6.8 at baseline to 4.2 at 6 months ($P < 0.01$), indicating a substantial reduction in pain intensity. Similarly, the mean ODI score improved from 50.5 (severe disability) at baseline to 34.9 (moderate disability) at 6 months ($P < 0.01$), reflecting a meaningful enhancement in functional capacity. The transition from severe to moderate disability on the ODI scale is particularly noteworthy, since it suggests that patients regained a level of functionality that could exert a positive impact on their daily activities and overall quality of life.

Although quality of life, as measured by the PROMIS 10 scores, did not show statistically significant changes, there was a slight upward trend in both mental and physical health scores over the 6-month period. The lack of statistical significance may be attributed to the small sample size and the relatively short follow-up duration, which might not have been sufficient to capture broader quality-of-life improvements. Additionally, the PROMIS 10 tool, while comprehensive, may be less sensitive to changes specific to SIJ dysfunction than pain- and function-specific measures like NRS and ODI. Future studies with larger cohorts and longer follow-up periods may better elucidate the impact of SIJF on quality of life.

Table 3. *Pain and functioning at baseline and each follow-up time point.*

	Baseline	One Month	3 Months	6 Months	*P*-value*
Number of Patients	**37**	**23**	**25**	**26**	
NRS					
Mean (SD)	6.8 (1.2)	4.1 (2.1)	4.8 (2.5)	4.2 (2.7)	< 0.01
P-value†	—	< 0.01	< 0.01	< 0.01	
ODI Percent Score					
Mean (SD)	50.5 (13.9)	41.7 (18.3)	35.6 (19.2)	34.9 (19.6)	< 0.01
P-value†	—	0.04	< 0.01	< 0.01	
PROMIS 10					
Mental:					
Mean (SD)	12.8 (3.4)	13.5 (4.0)	12.9 (3.3)	13.5 (2.9)	0.79
P-value†	—	0.47	0.88	0.39	
Physical:					
Mean (SD)	10.9 (2.2)	11.7 (2.9)	11.9 (2.5)	12.8 (3.0)	
P-value†	—	0.05	0.19	0.10	

The reduction in opioid use, while not statistically significant, is a clinically relevant finding. At baseline, 64.9% of patients were using opioids for pain management, and this figure decreased to 34.6% by 6 months. This trend aligns with the broader goal of reducing opioid dependency in chronic pain populations, a critical consideration in view of the opioid epidemic. The lack of statistical significance may be due to the small sample size and variability in patient responses to pain manage-

ment strategies. Nevertheless, this reduction underscores the potential of SIJF to address pain at its source, potentially decreasing the need for long-term opioid therapy.

Radiological outcomes at 6 months provided strong evidence of successful fusion with the Genesys SIros® system. Of the 25 patients who underwent CT scans, 96% exhibited bone apposition to both the iliac and sacral sides of at least 2 of the 3 implants, and 28% showed bridging across the SIJ. These findings are encouraging, since bone apposition and bridging are critical indicators of successful arthrodesis and long-term stability of the SIJ and osseous bridging thereof can take one year or longer to appear (16). The absence of implant failure, subsidence, or significant radiolucency further supports the safety and reliability of the device used in the study. These results are comparable to those reported by Hermans et al (17), who found high rates of fusion and low rates of complications in patients undergoing minimally invasive SIJF.

The safety profile of the laterally placed implants was favorable, with no procedure-related AEs, SAEs, or deaths reported during the study period. This outcome aligns with the broader literature on minimally invasive SIJF, which consistently demonstrates lower complication rates than do other minimally invasive surgical techniques (29). The absence of SAEs in this study is particularly reassuring, given the patient population, which included individuals with prior spine surgeries (62%) and comorbidities such as diabetes (24.3%) and hypertension (35.1%), all of which can increase surgical risk. The minimally invasive approach likely contributed to the low complication rate, since minimally invasive procedures are associated with reduced blood loss, shorter hospital stays, and faster recovery times than is open surgery (30).

The findings of this study reinforce the role of minimally invasive SIJF as an effective treatment for patients with refractory SIJ dysfunction, particularly those with a history of prior lumbar fusion—a known risk factor for SIJ dysfunction (7,8). The significant improvements in pain and functioning, coupled with the high rate of radiological fusion, suggest that the 3 laterally placed titanium implants can be a valuable addition to the armamentarium of treatments for SIJ dysfunction when the operation is performed using a minimally invasive technique by physicians who specialize in interventional procedures.

Despite the promising results, this study has several limitations that should be addressed in future research.

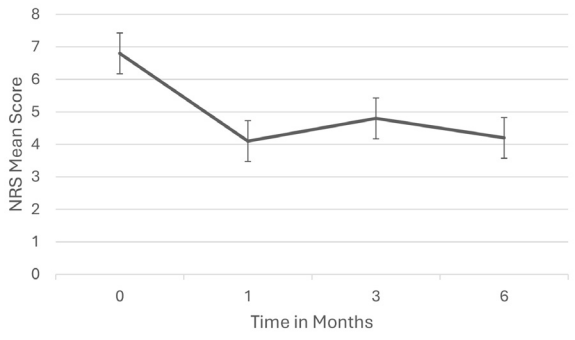

Fig. 1. *Mean NRS scores at baseline and each follow-up time point in the FICS SIJF study.*

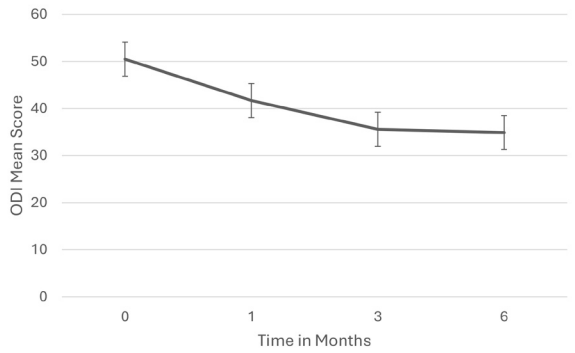

Fig. 2. *Mean ODI scores at baseline and each follow-up time point in the FICS SIJF study.*

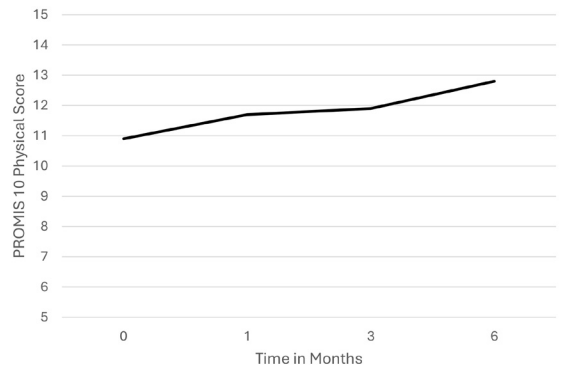

Fig. 3. *Mean PROMIS-10 Mental Health scores at baseline and each follow-up time point in the FICS SIJF study.*

First, the small sample size (n = 37) and relatively short follow-up period (6 months) limit the generalizability of the findings and the ability to assess long-term outcomes. While the 6-month follow-up provided valuable insights into early pain relief and fusion, longer-term studies are needed to evaluate the durability of these outcomes, particularly in terms of sustained pain relief, functional improvement, and implant stability. Second, the single-arm design lacks a control group, making it difficult to directly compare the effectiveness of this system to other SIJF devices placed using a different approach or to nonsurgical management. Additionally, the lack of statistically significant improvements in quality of life (as measured on the PROMIS 10) and opioid use suggests that these outcomes may require a larger sample size or longer follow-up for meaningful changes to be detected.

Conclusion

In conclusion, this feasibility study demonstrates that when used for the purpose of SIJF, the placing of 3 lateral titanium alloy implants by physicians specializing in interventional procedures is a safe and effective treatment for patients with refractory SIJ dysfunction, as evidenced by significant improvements in pain and functioning, high rates of radiological fusion, and a favorable safety profile. The findings support the use of minimally invasive SIJF as a viable option for patients who have not responded to conservative management, particularly those with a history of prior lumbar fusion. However, larger, controlled studies with longer follow-up periods are needed to confirm these results, assess long-term outcomes, and compare this treatment method to other treatment modalities. These efforts will further refine the role of SIJF in the management of SIJ dysfunction and inform clinical decision-making for this patient population.

Author Contributions:

RD: conception and design of the work; acquisition, analysis, or interpretation of the data; drafting and critical review of the manuscript; final approval of the manuscript.

MS: acquisition, analysis, or interpretation

Table 4. *Medication status at baseline and each follow-up point.*

	Baseline/ Screening	PRO Follow-Up (One Month)	PRO Follow-Up (3 Months)	PRO Follow-Up (6 Months)	*P*-value*
Number of Patients	**37**	**23**	**25**	**26**	
Currently Using Opioids for LBP					
No	13 (35.1)	14 (60.9)	15 (60.0)	16 (61.5)	0.12
Yes	24 (64.9)	8 (34.8)	10 (40.0)	9 (34.6)	
Unknown	0 (0)	1 (4.4)	0 (0)	1 (3.9)	
Currently Taking Any Pain Medication for LBP					
No	11 (29.7)	9 (39.1)	10 (40)	9 (34.5)	0.72
Yes	26 (70.3)	13 (56.5)	15 (60.0)	16 (61.5)	
Unknown	0 (0)	1 (4.4)	0 (0)	1 (3.9)	

Table 5. *Employment status at baseline and each follow-up time point.*

	Baseline/ Screening	PRO Follow-Up (One Month)	PRO Follow-Up (3 Months)	PRO Follow-Up (6 Months)	*P*-value*
Employment Status	9 (24.3)	3 (13.0)	4 (16.0)	8 (30.8)	0.17
Employed full-time (> 30 hours)	4 (10.8)	1 (4.4)	4 (16.0)	1 (3.9)	
Employed part-time (< 30 hours	1 (2.7)	4 (17.4)	2 (8.0)	1 (3.9)	
Medical leave/disability	5 (13.5)	5 (21.7)	4 (16.0	6 (23.1)	
Not employed, not seeking employment	0 (0)	1 (4.4)	0 (0)	0 (0)	
Homemaker	9 (24.3)	2 (8.7)	4 (16.0)	5 (19.2)	
Other:	7 (18.9)	7 (30.4)	7 (28.0)	5 (19.2)	
Retired	5 (71.4)	4 (42.9)	5 (71.4)	3 (60.0)	
Disabled	0 (0)	1 (14.3)	1 (14.3)	2 (40.0)	
Disabled/Retired	1 (14.3)	0 (0)	0 (0)	0 (0)	
Caregiver	0 (0)	1 (14.3)	1 (14.3)	0 (0)	
Unknown	1 (14.3)	1 (14.3)	0 (0)	0 (0)	

Table 6. *Imaging assessment of fusion and other radiologic characteristics.*

Radiologic Outcome	N = 25
Apposition of bone to iliac sides of at least 2 of 3 Gensys implants, n (%)	
No	1 (4.0)
Yes	24 (96.0)
Apposition of bone to sacral sides of at least 2 of 3 Genesys implants, n (%)	
No	1 (4.0)
Yes	24 (96.0)
Radiolucency around any of the Genesys implants, n (%)	
No	24 (96.0)
Yes	1 (4.0)
Bridging across the SI Joint either adjacent and/or distant from the Genesys implants, n (%)	
No	18 (72.0)
Yes	7 (28.0)
Evidence of Genesys implant device failure (breakage), n (%)	
No	25 (100.0)
Yes	0 (0)
Evidence of subsidence or migration of any of the Genesys implants apparent, n (%)	
No	25 (100.0)
Yes	0 (0)
Evidence of heterotopic ossification, n (%)	
No	20 (80.0)
Yes	5 (20.0)

of the data; critical review of the manuscript; final approval of the manuscript.

TP: acquisition, analysis, or interpretation of the data; critical review of the manuscript; final approval of the manuscript.

AC: acquisition, analysis, or interpretation of the data; critical review of the manuscript; final approval of the manuscript.

OAB: conception and design of the work; acquisition, analysis, or interpretation of the data; critical review of the manuscript; final approval of the manuscript.

MJ: acquisition and analysis of the data; final approval of the manuscript.

MS: acquisition and interpretation of the data; critical review of the manuscript; final approval of the manuscript.

JH: acquisition of the data; critical review of the manuscript; final approval of the manuscript.

DPB: conception and design of the work; acquisition,

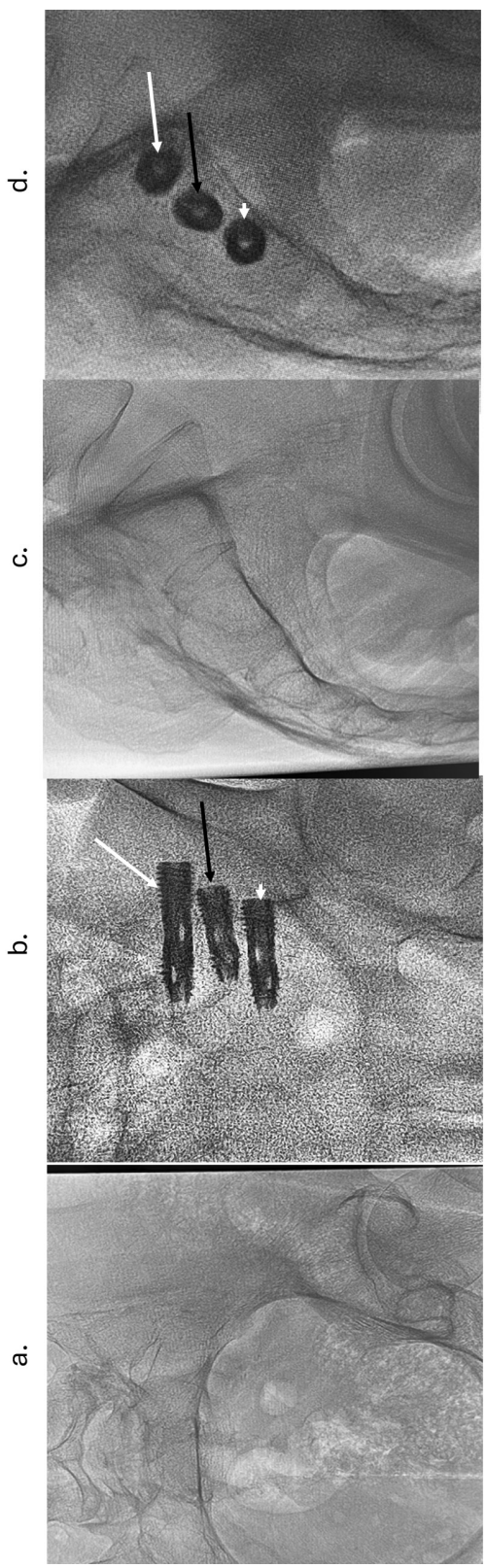

Fig. 4. *a–d. Fluoroscopic anteroposterior (a and b) and lateral (c and d) views showing before and after the placement of a trio of 3D printed titanium implants. The top and bottom screws are placed in the S1 and S2 bone corridors (white arrows and white arrowheads in b and d, respectively), and the middle screw is placed at the level of the S1 neural foramen (black arrows in b and d).*

analysis, or interpretation of the data; critical review of the manuscript; final approval of the manuscript.

Conflicts of Interest

Douglas Beall has been a consultant for and has received grants and research support from ReGelTec, Orthoson, Vivex, Discgenics, Mesoblast, Discure, Tissue Tech, Genesys, Smart Soft, Spine Biopharma. Beall has also received honoraria or consultation fees from ReGelTec, Vivex, Mesoblast, and Discure. Funding for Beall's research was provided by ReGelTec, Orthoson, Vivex, Discgenics, Mesoblast, Discure, Tissue Tech, Spine Biopharma, Kolon TissueGene. Tyler A. Ptacek has received research funding from Genesys and has been a consultant for Genesys and Nevro. Ashley M. Classen has no relevant conflicts of interest to disclose. Michael W. Jung has been a consultant for and received research and meeting support from SI Bone and Genesys. Funding for Matthew Skoblar's research was provided by Genesys, and MS served as the New Jersey Medicare CAC representative as well as on the New Jersey Society of Interventional Pain Physicians. John A. Hatheway has been a consultant for Medtronic and Nalu, and JAH's research funding has been provided by Medtronic, Nalu, and SI Bone. Ethan Wood, Matthew C. Shonnard, and Olivia A. Beall have no relevant conflicts of interest to disclose. Reade De Leacy has been a consultant for Stryker, Medtronic, Imperative Care, Penumbra, Cerenovus, Hyprevention, Vastrax, Synchron, and Precision Recovery.

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