Journal of Surgery
Cornidez E, et al. J Surg 10: 11284
www.doi.org/10.29011/2575-9760.11284
www.gavinpublishers.com
Research Article

A Retrospective, Multicenter, Analysis of a Novel Sacroiliac Joint Fusion Device on Physician Work and Device Safety at 3 and 12 Months

Eric Cornidez[1], Angel Boev[2], Pankaj Mehta[3], Steven Falowski[4], Chau Vu[5], Jason E. Pope[5*]

[1]Pain Institute of Southern Arizona, Tucson, AZ, USA

[2]Boev Clinic, Rochester, NY, USA

[3]Pain Specialists of America, Killeen, TX, USA

[4]Argires-Marotti Neurosurgical Associates of Lancaster, Lancaster, PA, USA

[5]Evolve Restorative Center, Santa Rosa, CA, USA

[*]**Corresponding author:** Jason E. Pope, Pain Institute of Southern Arizona, Tucson, AZ, USA

Citation: Cornidez E, Boev A, Mehta P, Falowski S, Vu C, et al. (2025) A Retrospective, Multicenter, Analysis of a Novel Sacroiliac Joint Fusion Device on Physician Work and Device Safety at 3 and 12 Months. J Surg 10: 11284 DOI: 10.29011/2575-9760.011284

Received Date: 15 March 2025; **Accepted Date:** 20 March 2025; **Published Date:** 22 March 2025

Abstract

Introduction: Sacroiliac joint dysfunction treatment with arthrodesis has changed significantly over the last 5 years with novel therapies focused on posterior approaches. This study examines the safety of a novel sacroiliac joint fusion technique at 3 and 12 months, representing initial data on this posterior approach.

Methods: After an Institutional Review Board exemption, a retrospective analysis was performed on patients that underwent the SiLO TFX sacroiliac joint fusion procedure at 5 sites with data on safety and device integrity recorded at 3- and 12-months post-implant. Safety was assessed by noting the presence of serious adverse events (bleeding, infection, nerve injury, death), and device integrity was assessed by noting broken or dislodged devices.

Results: 91 patients were identified across 5 sites, all of which had complete data sets. There were no adverse events reported, and no device integrity issues noted at time of implant or postoperatively at 3- and 12-month follow-ups. The average operating room time, serving as a measure of physician work, was 59.9 minutes,

Conclusion: The posterior sacroiliac joint fusion system utilizing the SiLO TFX is safe, with device integrity being maintained at 12 months. All surgeries were performed in an outpatient setting with a mean operating room time of 59.9 minutes and blood loss of less than 10 mL. These results suggest that this inline posterior approach has a better safety profile than the historical lateral approach. Further research is needed prospectively to assess efficacy.

Keywords: Arthrodesis; Sacroiliac Joint Fusion; Sacroiliitis; Sacroiliac Joint Dysfunction

Introduction

Sacroiliac joint disease is very common in the United States accounting for an estimated 30% of patients presenting with low back pain. [1] Diagnosis with 3 or more positive SI joint provocative physical exam tests, demonstrates 91% sensitivity and 79% specificity. Diagnostic accuracy can be further improved with diagnostic SI joint blocks with at least 70% pain intensity improvement [2,3]. Historically, sacroiliac joint pain management included conservative approaches, along with lateral

branch radiofrequency, but this treatment modality has become increasingly difficult to perform due to evolving coverage policies [4,5]. When conservative treatments fail, the long-term treatment focus has shifted to fusion. Fusion approaches have undergone a significant change over the last 5 years with increasing posterior and lateral approaches described [6-8] using titanium implant or allograft materials. As one would expect, controversy exists as to which approach is the safest and most effective. Other posterior approaches utilizing a posterior titanium implant with transfixation of the joint (sacrum and ilium) either posteriorly or posterolaterally have been described [8]. Although biomechanical data exists between therapies, there is a paucity of commercial use data or even large retrospective analysis [9-11]. There have been multiple sacroiliac joint fusion therapies that have entered the market, with very little data on safety and efficacy. Although existing biomechanical data substantiates FDA approval as a 510K, there is a growing focus on the approach of fusion (posterior, posterior/lateral, posterior oblique or lateral). To date, there is no such data published, despite being commercially available. The purpose of this study was to determine safety and physician work during commercial use of the inline, posterior transfixation bridge with iliac and sacral screws (SiLO TFX © Aurora Spine, Carlsbad, CA) to treat symptomatic SIJ dysfunction at 3 and 12 months.

Methods

After an IRB exemption was acquired (WCG IRB Work Order # 1-1799976-1), the deidentified data was collected for analysis. This study is the first retrospective, multicenter quantitative safety analysis measured at 3 and 12 months employing an in-line, posterior transfixing bridge with iliac and sacral screws system (SiLO TFX © Aurora Spine, Carlsbad, CA) for the treatment of sacroiliac joint pain. Data was collected from 5 sites. Patients were taken as consecutive implants from each site in which complete data sets could be obtained at 12 months. This included all patients from the inception of the physician employing the therapy. The 3-month endpoint will capture data representing safety of the surgical procedure through adverse events review (infection, nerve injury, bleeding), while the 12-month endpoint will assess durability of the device. All adverse events from time of surgery to 12 months were collected using a retrospective chart review within standard scope of practice with symptom identification. X-rays were obtained by the physicians' standard of care and reviewed by them for device placement and integrity,. Physician work was determined by descriptive statistics of operating room time and necessity for an overnight hospital stay.

The SiLO TFX procedure is performed using an in-line posterior approach using a titanium fixation system. The fusion is accomplished by bridging with use of bone graft material, a sacral screw, and an iliac screw. The patient is placed in the prone position and Monitored Anesthesia Care (MAC) is initiated. After appropriate local anesthesia administration, a guide pin is inserted into the SI joint under fluoroscopic guidance. Placement is confirmed with Anterior Posterior (AP), Contralateral Oblique (CLO), Ferguson, and lateral views on fluoroscopy. A 22mm incision is then made and dissection is carried down to the SI joint (which can be directly palpated and visualized with the fluoroscope). A joint finder is then placed over the guide pin, which is followed by the soft tissue protector. Appropriate placement of the soft tissue protector is confirmed with fluoroscopy utilizing the above-mentioned views, and the joint finder and guide pin are removed. A reamer is then carefully inserted in the soft tissue protector, and the ilium and sacrum are decorticated and recessed in preparation for the implant. Arthrodesis is promoted by the use of the manual hand drill. The proper depth and position of the drill is confirmed with AP and lateral fluoroscopy. The reamings from the drill were harvested for bone grafting. The graft is packed into the SI joint as well as the TFX implant in preparation for fusion. The implant is then carefully placed into proper anatomic position with the use of a mallet. The proper position of the implant is confirmed with AP and lateral fluoroscopy. Next, the trans-sacral and trans-iliac fixation screws are deployed and incision closed. Bracing is commonly utilized post-operatively.

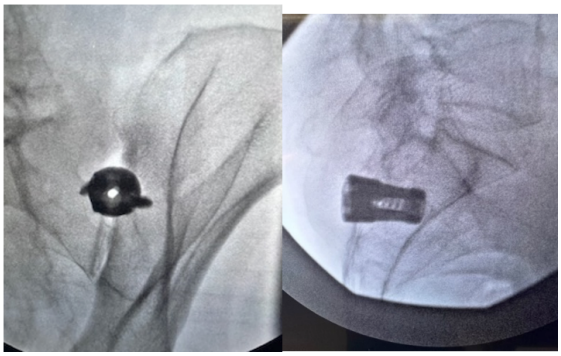

Figure 1: Placement of the SiLO TFX.

Results

91 patients were identified across the 5 centers, with complete data available for both 3- and 12-month endpoints. The data is summarized in the descriptive table below (Table 1).

Demographics	Mean Age in Years (standard deviation))	59 **(13.3)**
	Female n (%)	55 (60%)
Surgical characteristics	Unilateral n (%)	91
	Operating room time (min) mean (standard deviation)	59.9 **(11.32)**
	Procedure related serious adverse events, n (%)	0
	Estimated blood loss (EBL) mean	Less than 10 mL
	Device Complications*	0
	Serious Adverse Events**	0
	Hospital length of stay after the procedure (LOS)	0
3-month safety	Serious Adverse Events**	0
	Device Complications*	0
12-month safety	Serious Adverse Events**	0
	Device Complications*	0
	Xray at 12 months with identified device fracture, malposition or dislocation***	0

* Fracture or dislocation

** Bleeding complications, infection, nerve injury, or death related to the procedure or the device

*** 12 month x-rays were available on n = 85 implanted subjects

Table 1: (n=91).

As seen in the table above, data collected by 91 subjects reveals a population that is 60% female with a mean age of 58 years old. All subjects had a unilateral SI Joint procedure. Physician work, determined by operative time, was qualified with a mean operative time of 59.9 minutes ±2.546 (±4.25%) with a confidence level of 95%. No serious adverse events were noted for any of the 91 subjects at 3 or 12 months postoperatively. Radiographs were available on 93.4% (85/91) of the subjects at 12 months and revealed no device fracture, malposition or dislocation.

Discussion

The approach defined in this retrospective study describes 91 patients treated with a posterior approach with a titanium fixation system using a transfixing bridge with use of bone graft material, a sacral screw, and an iliac screw [9]. This study is the first of its kind to investigate the safety and integrity of an implant at the time of the surgery as well as at 3 and 12 months postoperatively. This data reveals no device malfunction at all endpoints and no adverse events at all endpoints. Female propensity, laterality, and physician work, as defined by operating room times, is consistent with other approaches published [1,5,12,13]. Of note, procedure related adverse events, including unanticipated hospital stay, bleeding complications and nerve injury is better than the lateral approach and comparable to allograft techniques. Of note, similarities exist between the physician work of the procedures as qualified by the mean operating room time, as seen comparing the meta-analysis calculated mean of the lateral approach to the mean of the posterior transfixation approach represented in this cohort, which are not statistically significant (p value 0.364) , respectively, of 59 minutes (n = 432) versus 59.9 minutes (n = 91), using a two sample t-test and a 95% confidence level [13]. This would suggest the physician work and time necessary to accomplish the procedure are not statistically different between these approaches.

However, a few differences are important to note. First, the blood loss for the posterior approach in this manuscript was less than 10 mL, where the blood loss identified in the meta-analysis of the lateral transarticular approach was 36.9mL [13]. Second, the Length of Stay (LOS) within the hospital after the surgery was markedly different. Patients in the posterior cohort had no (0) days within the hospital, while the lateral approach cohort had a mean LOS of 1.7 days [13]. Limitations in this study include the retrospective nature of the study design. Further, the purpose of this manuscript was to ascertain safety and device integrity, and not efficacy of the treatment.

This investigation is timely, however, as the number of commercially available surgical approaches and devices to treat sacroiliac joint dysfunction continues to expand, the need for a large real-world safety assessment is critical and necessary, as there is a paucity of data for a device commercially available. Even more, as with novel device development, efficacy assessment oftentimes lags safety analysis.

Conclusion

As data is emerging on different anatomic approaches to treat sacroiliac joint dysfunction and pain by fusion, reviewing the AO principles of arthrodesis are necessary. These include adequate exposure and preparation of the joint by removing interarticular tissue and decorticating the surfaces, coaptation of the surfaces, and rigid fixation [14,15]. The posterior transfixation system with both iliac and sacral screws achieves these goals and is supported by biomechanical data [9,12]. For the first time, this demonstrates 3 month and 12-month data that the device is safe, as represented by no serious adverse events such as bleeding, infection, or nerve injury. In addition, the device integrity was sound (no fractures or dislodgement) at 12 month follow up. Further, physican work, as defined by operating room time, was not statistically different from the traditional lateral approafh As the treatment of sacroiliac joint dysfunction treatment continues to evolve with different trajectory and anatomic approaches, continued research is needed to investigate their safety and efficacy.

Acknowledgements

All authors took part in data collection, manuscript construction and editorial edits per authorship guidelines.

The authors would like to thank Shawn Tomlinson, Eric Bruntlett and Sarah Martineck for their support of the study.

Ethics/Ethical approval: Exemption determination was received after study review by WCG IRB.

Data Availability: The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Funding: Support was provided by Aurora Spine.

Reference

1. Buchanan P, Vodapally S, Lee DW (2021) Successful Diagnosis of Sacroiliac Joint Dysfunction. J Pain Res 14: 3135-3143.
2. Simopoulos TT, Manchikanti L, Gupta S (2015) Systematic review of the diagnostic accuracy and therapeutic effectiveness of sacroiliac joint interventions. Pain Physician 18: E713-E756.
3. Manchikanti L, Falco FJ, Benyamin RM (2014) A modified approach to grading of evidence. Pain Physician 17: E319-E325.
4. https://www.acr.org/Advocacy-and-Economics/Advocacy-News/Advocacy-News-Issues/In-the-March-11-2023-Issue/ACR-Pain-Management-Societies-Disappointed-in-Coverage-Limitations-for-Sacroiliac-Joint-Injections#:~:text=The%20American%20College%20of%20Radiology,their%20latest%20final%20local%20coverage
5. Daniels AH, Park AM, Lee DJ, Daher M, Diebo BG, et al. (2024) Impact of Sacroiliac Belt Utilization on Balance in Patients with Low Back Pain. Orthop Rev (Pavia) 16: 116960.
6. Polly D, Cher D, Wine K (2015) Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. Neurosurgery 77: 674-691.
7. Calodney A, Azeem N, Buchanan P, et al. (2024) Safety, Efficacy, and Durability of Outcomes: Results from SECURE: A Single Arm, Multicenter, Prospective, Clinical Study on a Minimally Invasive Posterior Sacroiliac Fusion Allograft Implant. Journal of Pain Research 17: 1209-1222.
8. Falowski S, Sayed D, Pope J, et al. (2020) A Review and Algorithm in the Diagnosis and Treatment of Sacroiliac Joint Pain. J Pain Res 13: 3337-3348.
9. Raji OR, Pope EJ, Falowski SM, Stoffman M, Leasure J (2024) Fixation of the Sacroiliac Joint: A Cadaver-Based Concurrent-Controlled Biomechanical Comparison of Posterior Interposition and Posterolateral Transosseous Techniques. Neurospine 2024.
10. Lee DW, Patterson DG, Sayed D (2021) Review of Current Evidence for Minimally Invasive Posterior Sacroiliac Joint Fusion. Int J Spine Surg 15: 514-524.
11. Deer TR, Beall DP, Falowski SM (2022) Revision of Failed Sacroiliac Joint Posterior Interpositional Structural Allograft Stabilization with Lateral Porous Titanium Implants: A Multicenter Case Series [Letter]. Med Devices 15: 365-366.
12. Falowski SM, Valdevit A (2022) Transfixation of the Sacroiliac Joint: Biomechanical Stability of a Dual-Implant Minimally Invasive Procedure. Pain Physician 25: E469-E479.
13. Heiney J, Capobianco R, Cher D (2015) A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. Int J Spine Surg 9: 40.
14. Charnley JC (1948) Positive pressure in arthrodesis of the knee joint. J Bone Joint Surg Br 30B: 478-486.
15. Cunningham JL, Richardson JB, Soriano RM, Kenwright J (1989) A mechanical assessment of applied compression and healing in knee arthrodesis. Clin Orthop Relat Res 1989: 256-264.