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SACROILIAC JOINT FUSION USING THE SILO TFX™ TRANSFIXING BRIDGE TITANIUM DEVICE: TWO CASE REPORTS FROM THE UNITED STATES

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Background: Sacroiliac joint (SIJ) pain is a common source of chronic low back pain, accounting for 15% to 30% in patients without disc herniation or radicular pain. Multiple advances have been made in managing SIJ pain with the development of minimally invasive SIJ fusion devices. Minimally invasive SIJ fusion with a posterior approach has shown promising results in recent literature. One of the newly developed SIJ fusion devices utilizing a posterior approach is SiLO TFX™, Transfixing Bridge, a titanium device. The device uses a posterolateral approach with a single transfixing cone and ancillary ilium and sacrum screws.
The case reports presented herein are the first cases of SIJ fusion performed with SiLO TFX™ Transfixing Bridge in the United States.

Case Report: Two patients with chronic bilateral sacroiliitis refractory to conservative management with greater than 75% short-term relief with sacroiliac injections, underwent SIJ fusion surgery with a novel transfixing bridge titanium device, the SiLO TFX™.
Both patients showed resolution of the SIJ pain.

Conclusion: These case reports discuss the unique aspects of the novel device, procedural steps, and early postoperative results, filling a gap in the current literature on titanium-based SIJ fusion.

Key words: Sacroiliac joint pain, sacroiliac joint fusion, low back pain, minimally invasive surgery, SiLO TFX™

BACKGROUND

Sacroiliac joint (SIJ) dysfunction is a common cause of chronic lower back pain, often refractory to nonsurgical interventions (1-6). Published literature utilizing controlled comparative local anesthetic blocks shows that SIJ dysfunction accounts for 15% to 30% of the reported cases of low back pain in patients without disc herniation or radiculitis (1,2). Advancements in the treatment of SIJ pain have led to the development of minimally invasive SIJ fusion devices (6,7). These devices work by stabilizing the joint and preventing movement. The procedure offers a solution for managing chronic pain without requiring extensive surgery or dependence on medications like opioids, which carry risks of addiction and abuse (7-11). Traditionally, SIJ fusion has been performed using various allograft-based spacers or other synthetic implants (12).

Minimally invasive SIJ fusion via the posterior approach has shown promising results in recent retrospective and prospective trials. The posterior or posterior oblique approach can be performed via either surgical screw fixation or percutaneous graft placement(s) with the guidance of fluoroscopy (12). This posterior approach aims away from the sacral neural foramen and avoids deep (~4 inches) insertion into the gluteus medius or maximus before reaching the ilium portion of the

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joint, a technique utilized in some lateral approaches to minimally invasive SIJ fusion (13-15).

As there is a growing database of evidence for posterior SIJ fusion showing substantial reductions in pain and disability, new devices are developing at a rapid pace. Some devices that have been used in trials evaluating the efficacy and safety of posterior fusions include the LinQ Allograft Device from PainTEQ (Tampa, FL) and the PsiF Sacroiliac Joint System from Omnia Medical (Morgantown, WV). The LinQ posterior SIJ fusion system utilizes trans fixation with a unique drill-free method and patented cortical allograft. In contrast, the PsiF system utilizes an inferior, intraarticular surgical approach with positioning of the implant below the posterior superior iliac spine (PSIS). This location is theorized to provide robust stabilization and decreased biomechanical forces acting on the implant due to its location lying close to the sacral axis of rotation (12,16). The device used in the following case reports, the SiLO TFX™ Transfixing SIJ Fusion System, utilizes a posterolateral approach with a single transfixing cone and ancillary ilium and sacrum screws (17).

These case reports, therefore, presents the first 2 U.S. cases of SIJ fusion performed with the SiLO TFX™ Transfixing Bridge, a titanium implant designed to provide robust mechanical stability and facilitate fusion via lateral bone graft openings. This device represents an alternative to traditional allograft spacers, offering distinct biomechanical properties (13).

Informed Consent

Informed consent was obtained from both patients for publication of these case reports.

CASE PRESENTATIONS

Patient 1

A 78-year-old woman with a medical history of osteoarthritis with bilateral knee replacement, restless leg syndrome, prediabetes, and stage 3b chronic kidney disease presented with chronic lower back pain radiating to the hips. The pain began 5 years ago, following years of employment as a supermarket stocker, and had progressively worsened. She described the pain as tight and squeezing, with severity rated at 8/10, interfering significantly with daily activities and sleep. Conservative treatments, including physical therapy and medications, were ineffective. The patient was diagnosed with sacroiliitis and underwent 2 bilateral SIJ injections using guided fluoroscopy with > 75% relief post-injection. The patient reported ~2 months of pain relief with gradual return to baseline.

Bilateral SIJ fusion was performed using the SiLO TFX™ Transfixing Bridge titanium device (Fig. 1). The patient reported significant improvement in pain and functional status during the one-week follow-up, rating her discomfort as minimal and expressing satisfaction with the outcome.

Patient 2

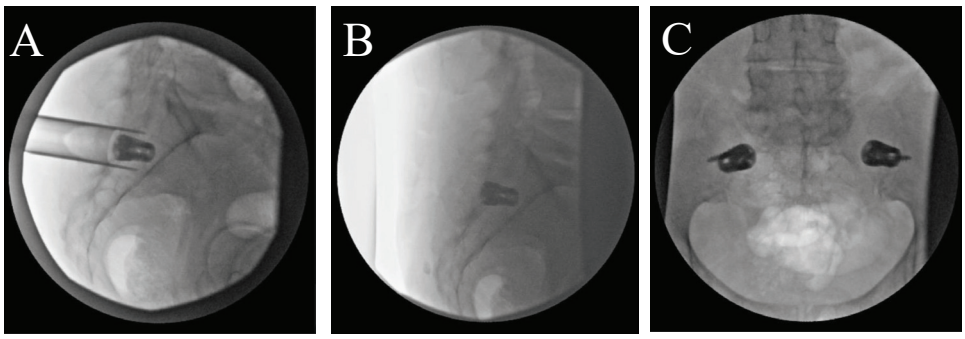
A second woman presented with chronic lower back pain localized to the lumbosacral region. The pain began in 2013 without an inciting event and progressively worsened over the past year. She described it as a constant, deep ache (7/10) that interfered with daily activities and sleep. The pain was partially alleviated with heat, lying supine, and medications like gabapentin. The patient was diagnosed with sacroiliitis and underwent 2 bilateral SIJ injections under guided fluoroscopy with > 60% reported pain relief.

Bilateral SIJ fusion using the SiLO TFX™ Transfixing Bridge titanium device was performed (Figs. 2,3). During the 2-week follow-up, the patient reported an improvement in her SIJ pain from 10/10 preoperatively to minimal post-surgical incision discomfort, which resolved in the next 2-3 weeks.

Both procedures followed a standardized technique under general anesthesia with the patient positioned prone. After sterile preparation, fluoroscopic guidance was used to confirm correct placement of spinal needles into the SIJ. Guide pins were advanced, followed by sequential dilation and decortication. The SiLO TFX™ device was then tapped into place with demineralized bone matrix (DBM). Proper placement was verified on contralateral oblique and lateral views. Once the SiLO TFX transfixing bridge is in the appropriate position 2 color-coded screws, the ilium screw (yellow) and sacrum screw (green) were inserted in designated ports within the tranxfixing bridge and then tightened (Figs. 4,5). Postoperative pain control utilized a bupivacaine injection into the wound region.

DISCUSSION

These cases represent the first documented use of the SiLO TFX™ Transfixing Bridge for SIJ fusion in the U.S. The device's titanium construction and unique design provide potential advantages over traditional allograft spacers, including enhanced mechanical stability (17).



Figs. 1. Intraoperative images for posterior SIJ fusion using SiLO TFX™ Transfixing Bridge titanium device in Patient 1. A) Lateral view of the SiLO TFx Implant after insertion through the working cannula in Patient 1. B). Lateral view of the SiLO TFX Implant in its final position in the sacroiliac joint between S1 and S2 in Patient 1. C) Anteroposterior view of bilateral SiLO TFX implants in the final position in Patient 1.

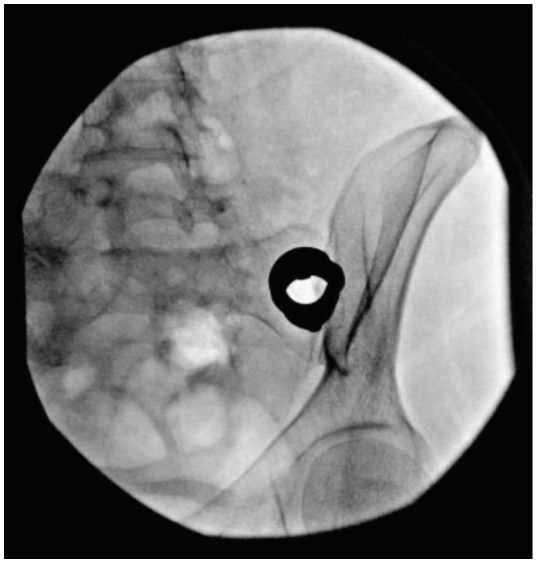


Fig. 2. Anteroposterior view of the cannula before insertion of the SiLO TFX implant (barrel shot demonstrating the sacroiliac joint in the middle of the cannula) in Patient 2.

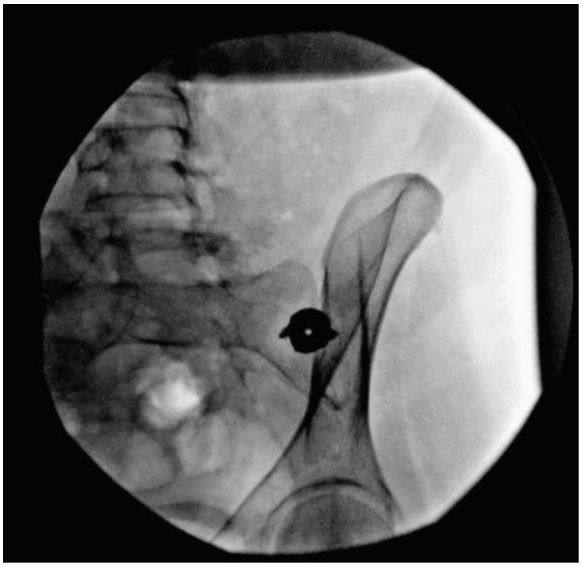


Fig. 3. Anteroposterior view of final position of SiLO TFX Implant in Patient 2.

Both patients experienced significant improvement in pain and functionality within the early postoperative period, demonstrating the potential effectiveness of this novel approach. The SiLO TFX™ device offers an alternative for patients with contraindications to traditional allograft implants or those seeking durable, metal-based solutions. According to a white paper study by Raji (18), the SiLO TFX™ Transfixing SIJ Fusion System, which incorporates a single transfixing-cone along with supplementary ilium and sacrum screws, delivers comparable or even better results than lateral fusion systems. This minimally invasive posterolateral technique minimizes bone removal while optimizing the surface area for bony fusion. Additionally, the conical implant's design enhances its contact with the SI joint, potentially improving fusion outcomes while maintaining a smaller footprint within the joint (18). Further studies are needed to compare the long-term outcomes of titanium-based implants with existing options (13).

CONCLUSION

The SiLO TFX™ Transfixing Bridge represents a promising innovation in SIJ fusion. These 2 cases highlight its potential effectiveness in treating bilateral SIJ pain. The SiLO TFX™ The Transfixing Bridge effectively alleviated pain in both patients, demonstrating its ability

Fig. 4. Picture demonstrating a standard set including all the equipment used to perform the procedure.

Fig. 5. Picture demonstrating the SiLO TFX implant from 2 different angles with and without the screws used from the transfixion.

to provide reliable stabilization and promote healing. Compared to other devices, its innovative design minimizes complications, improves patient outcomes, and ensures a quicker return to daily activities. As the first U.S. patients to undergo this procedure, the favorable outcomes underscore the need for further research and clinical adoption of this novel device.

Author Contributions

The article was designed by ADK, AC, and AN.

Statistical analysis was performed by ADK.

All authors contributed to the preparation of this article, reviewed and approved the content with the final version (Fig. 6).

Fig. 6. Dr. Patel (left) and Dr. Kaye (right) featured with patient, one week post-operatively who received implant of SiLO TFX™ Transfixing Bridge.

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