White Paper

SACROILIAC JOINT FUSION:

Improving Surgical Outcomes Through an Inferior-Posterior Approach with the Tenon Medical Catamaran™ SI Joint Fusion System

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Introduction

The sacroiliac (SI) joint is gaining recognition as the source of chronic low back and posterior pelvic pain in up to 30% of patients presenting with this complaint.[1,2] Painful SI joint dysfunction is thought to occur from joint disruption commonly arising from joint degeneration resulting from osteoarthritis, pregnancy, infection, inflammatory arthritis, trauma, and tumor.[3] SI joint pain can be debilitating, with patients reporting Oswestry Disability Index (ODI) scores as high as 50 and poor quality of life.[4,5] The prevalence and intensity of sacroiliac joint pain points to the need for efficacious, efficient, and long-lasting therapeutic measures.

The medical community is shifting away from conventional, non-surgical therapies such as the use of opioids and other oral analgesics, physical therapy, radiofrequency denervation, and chiropractic methods due to underwhelming treatment durability and minimal pain relief.[6, 7, 8] Surgical fusion of the sacroiliac joint is becoming more widely adopted, due in part to the increasing numbers of patients diagnosed with sacroiliac dysfunction along with poor response to conservative therapies. Traditional SI joint surgery is performed via a large open incision, and the SI joint is immobilized with the objective of achieving bony fusion. The goal is to eliminate motion at the joint thought to be the cause of inflammation and resulting pain.[9]

The traditional open SI joint fusion technique is highly invasive and should be reserved for major disruption of the joint such as trauma, infection, or tumor, as it has been found to result in generally poor clinical outcomes, a variety of post-surgical complications, and long recovery periods.[8] Newer percutaneous surgical techniques have emerged that are designed to reduce many of the complications associated with the procedure and improve postoperative outcomes. These techniques may include the use of screws and/or dowels to achieve fixation of the joint. Because of the anatomy of the joint, these techniques often require the use of multiple devices to achieve adequate joint immobilization.

The clinical results of using these percutaneous techniques have been mixed, with as many as 30% of patients reporting poor results or no improvement following surgery.[10] The majority of the complications resulting from these techniques have resulted from entry of the device into the neuroforamen.[11] Some surgeons have attempted a posterior approach by delivering graft material across the joint in an area of the joint that is not part of the articulation. In this region of the sacroiliac joint, the bony surfaces of the sacrum and the ilium are separated by several millimeters of connective tissue. Therefore, this area is not optimal for placement of graft material or a fixation device. Despite the limited success of these minimally invasive techniques, they have highlighted the role sacroiliac dysfunction plays in minor trauma, degenerative spine disease, and adjacent level disease in lumbar fusion.

Figure 1. The Catamaran Fixation Device

Introduction *(Cont.)*

This paper describes an Inferior-Posterior approach to the sacroiliac joint using the Catamaran SI Joint Fusion System (Tenon Medical, Inc., Los Gatos, CA). The system is indicated for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The Catamaran SI Joint Fusion System includes the Catamaran Fixation Device and the surgical instruments required to perform the Inferior-Posterior sacroiliac arthrodesis. The Catamaran Fixation Device is manufactured from medical grade titanium alloy and consists of two hollow pontoons connected by a bridge. The Catamaran Fixation Device pontoons are available in two lengths: 30mm and 40mm. The surgical technique allows for direct visualization of the SI joint for decortication, grafting with reserved autograft bone, and fixation with a single device.

Rationale for an Inferior-Posterior Approach to the Sacroiliac Joint

The sacroiliac joint is a bilateral, diarthrodial joint that connects the sacrum to the ilium. The joint is shaped like an "L" lying on its side (rather than a triangle), with the long arm lying along the posterior wall of the pelvis and relatively straight through its entire course. The joint floor slopes downward and laterally at an approximately 30% grade. The short arm of the "L" is parallel to L5-S1 and is limited superiorly by the sacral ala. Based on the understanding of the anatomy of the joint and surrounding anatomical structures, the Inferior-Posterior approach enters the sacroiliac joint at approximately the S3 level, which is the top of the long arm of the "L". At this location, there are no vital structures in the soft tissues obstructing the SI joint entry point.

A 4 cm incision allows visualization of the joint for decortication, grafting, and placement of the fixation device. A guide pin is placed at the SI joint entry point in the same trajectory as the joint space, along the long arm of the "L" and parallel to the floor of the pelvis. It is important to note that the joint space, and therefore the guide pin, are directed away from the neuroforamina. The use of the guide pin serves two purposes: a landmark for joint decortication and a trajectory guide to position the Catamaran Fixation Device. This approach is designed to reduce risk of entry into a neuroforamen or injury to a nerve root. The parallel path to the floor of the sacrum can be identified on fluoroscopy or guided along its trajectory with 3D navigation, thereby avoiding risk of anterior breach into the pelvis.

The guide wire marks the trajectory for an osteotome, curette, and pituitary rongeur, allowing for decortication of the SI joint under direct visualization. The guide instrumentation is angled at 30 degrees, to facilitate placement of the Catamaran Fixation Device in a plane parallel to the floor of the sacrum. Radiation exposure is limited, as only a single fixation device is required. With 3D navigation, the imaging used for diagnosis may be used intraoperatively, further reducing radiation exposure to both the patient and the surgical team.

Surgical Technique

The Catamaran Fixation Device entry point into the sacrum/ilium is through the posterior sacroiliac ligaments at the inferior-posterior of the SI Joint (*Figure 2*).

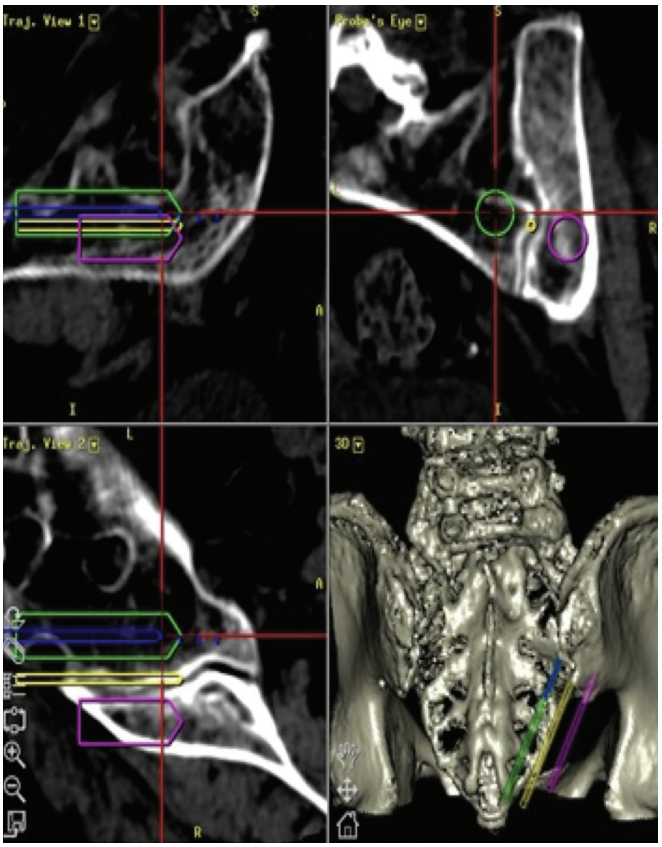

Figure 2. Navigation planning demonstrates the Catamaran Fixation Device successfully placed in cortical bone, below the dorsal recess

The trajectory of the Catamaran Fixation Device is towards the midpoint of the S1 end plate and the sacral promontory (*Figure 2*). Successful delivery of the device is based on establishing anatomic landmarks for the Graduated Guide Wire placement. A placement protocol has been developed using 2D fluoroscopy to establish the landmarks of skin incision, SI joint entry point, instrumentation trajectory, and drilling depth to facilitate successful delivery of the Catamaran Fixation Device.

Surgical Steps:

1. Follow the surgical protocol to place the graduated guide wire at the SI joint entry point (*Figure 3*)
2. Determine the correct device length (30mm or 40mm)
3. Assemble the access sleeve and drill guide
4. Insert and stabilize the access sleeve and drill guide
5. Drill the implant holes and reserve the autologous bone for graft material
6. Prepare the Catamaran Fixation Device for delivery
7. Deliver the device via the holes drilled (*Figure 4*)
8. Pack additional autologous bone graft into the Fixation Device barrels
9. Confirm the device position (*Figure 5*)
10. Close the surgical wound using standard technique

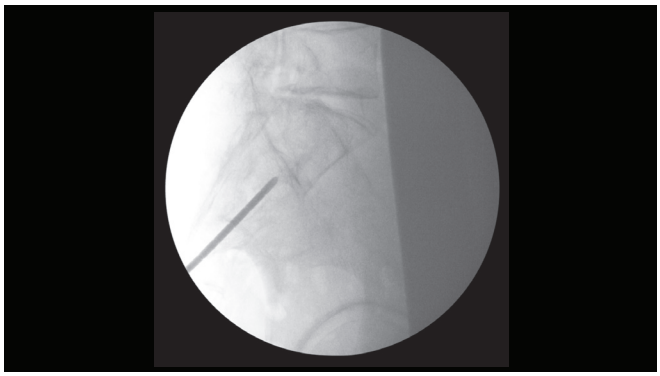

Figure 3. Graduated guide wire marking the trajectory of the Catamaran Fixation Device

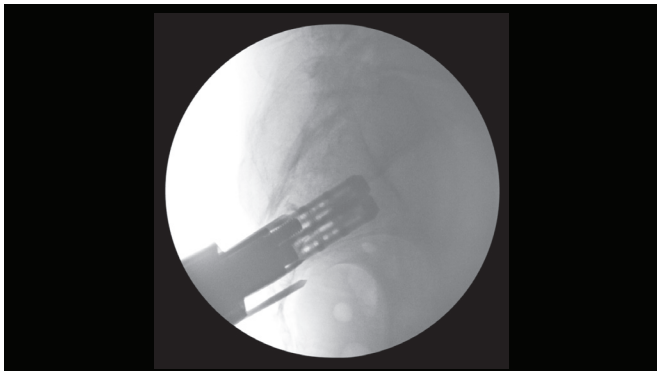

Figure 4. Delivery of Catamaran Fixation Device with Instrumentation

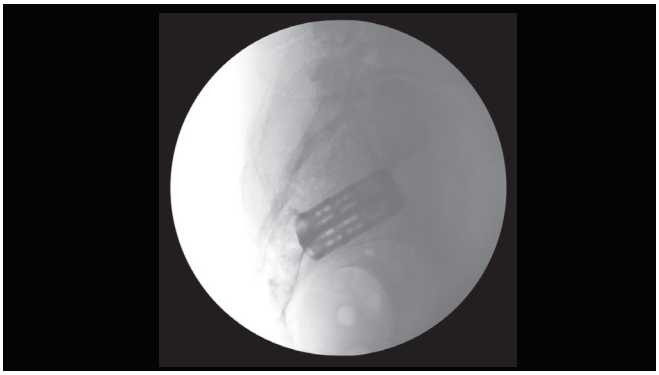

Figure 5. Catamaran Fixation Device showing accurate trajectory, bridging the sacrum and ilium

Early Results of Patients Undergoing Fusion with the Catamaran SI Joint Fixation Device: A Case Series

METHODS

We collected early results of patients who underwent SI joint fusion with the Catamaran SI Joint Fusion System in our clinic. Patients were included in the surgical cohort if they met the following criteria:

1. Pain compatible with sacroiliac dysfunction
2. Positive result for at least three of the following five provocative tests: thigh thrust, distraction, compression, FABER (Flexion, Abduction, and External Rotation), and Gaenslen's test
3. Degenerative changes in the SI joint confirmed on imaging
4. At least 70% pain reduction following intra-articular instillation of 1.5 cc of 1% lidocaine (confirmed by arthrogram) and return of pain to baseline within 12 hours

Patients with any of the following were excluded:

1. Use of tobacco or other nicotine product within 6 weeks preoperative
2. Active Infection
3. Neoplasm involving the affected sacroiliac joint

All surgical procedures were performed in the outpatient setting, except for Medicare patients, who required a minimum two-night hospital stay for the procedure. Patients were instructed to refrain from bearing weight on the involved limb for at least six weeks postoperative. All patients were seen at two weeks post-op for follow-up, wound check, and suture removal. They returned at six weeks for plain x-rays. Per hospital protocol, patients were cleared to resume weight bearing if there was no radiographic evidence of loosening (migration or bone absorption). Patients continued to be evaluated every three months with a clinical examination and plain x-rays for up to one year.

Results

To date, 16 patients (2 bilateral) underwent a total of 18 SI joint fusion surgeries in this clinic using the Inferior-Posterior approach with the Catamaran Fixation Device. This case series includes eight males (50%) and eight females (50%) with a mean age of 47.4 +/-11.4 years (22-68). One female had contralateral SI joint fusion two years after the initial surgery; one male had contralateral SI joint fusion one year after the initial surgery. The mean Visual Analog Score (VAS) for all patients prior to surgery was 8.6 +/- 1.1 (7-10). Patients reported duration of symptoms for as long as 72 months prior to SI joint surgery with a mean duration of 16.1 +/- 18.3 months (1-72). Prior to SI joint surgery, ten patients (62.5%) underwent an L5/S1 fusion surgery, and 12 patients (75%) had previous spinal surgery above the L5/S1 level. Seven patients (38.9%) had a prior history of relevant trauma. (*Table 1*)

Prior to SI joint surgery, 94.4% of patients received some form of physical therapy to attempt pain relief; 4 (22.2%) received intra-articular steroid injections. Two patients (11.1%) underwent rhizotomy. The majority (87%) took NSAIDs for pain control and 81% used opiates. All patients demonstrated tenderness over the sacroiliac joint on the affected side. On physical examination, all patients tested positive to the Fortin FPT and flexion abduction and external rotation (FABER) tests. The majority of patients responded to positive test for thigh thrust (N=15 SIJs, 83.3%), compression (N=14 SIJs, 77.8%), and Gaenslen's (N=17 SIJs, 94.4%) tests. (*Table 2*)

The average surgical time using 3D navigation was 106.6 minutes (61-220 minutes) with an average fluoroscopy time of 66.4 seconds and an average surgical blood loss of 35.6 ml. No intraoperative or immediate postoperative complications were recorded. (*Table 3*) One small hematoma (1 cm) was noted at 6 weeks postoperatively and resolved by the 3 month follow up.

Postoperatively, all patients showed successful placement of the Catamaran Fixation Device (confirmed via plain x-ray). VAS pain scores dropped dramatically following surgery, with an average score of 1.7 after two weeks and 1.3 after 6 weeks. (*Figure 5*) At 6 weeks and 12 months post-operative, 81% and 90% of patients, respectively, required no narcotic pain medications.

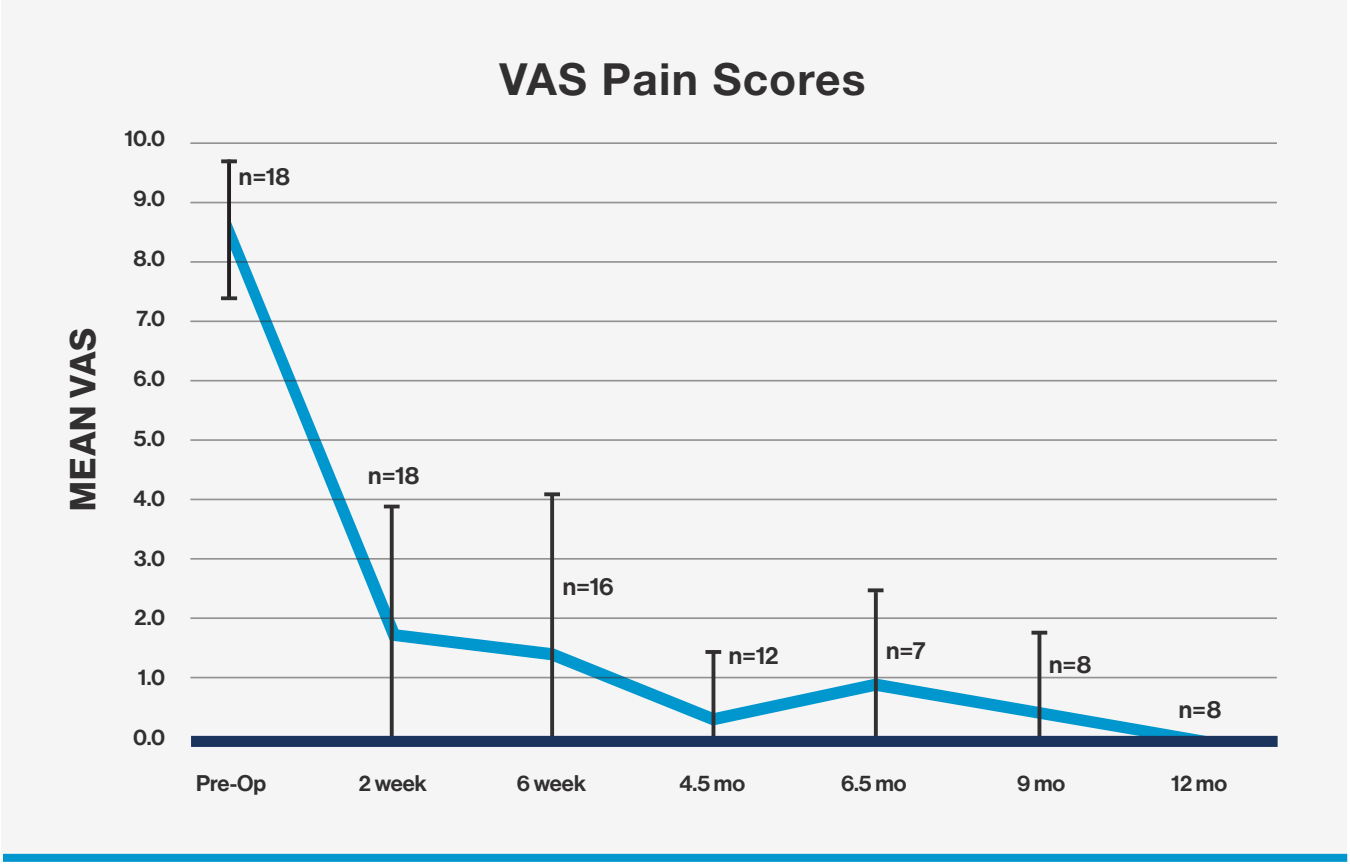

Figure 5. Average pain scores preoperatively and postoperatively, from 2-weeks to 12 months following surgery. VAS: Visual Analog Score.

Radiologic Assessment

CT Scans at six months postoperative show the Catamaran Fixation Device placed across the joint in the correct position. Axial and sagittal plane sections through a region of the sacroiliac joint confirmed solid bridging bone relative to the anatomy and ossification around the Catamaran Fixation Device (*Figure 6*).

X-ray imaging at six months postoperative demonstrates maintenance of device placement across the SI joint space with no breach into the pelvis (*Figure 7*). At twenty months postoperative, one patient underwent CT scan for a reason unrelated to SI joint surgery, and we were able to observe bony ongrowth with bridging at the Catamaran Fixation Device (*Figure 8*).

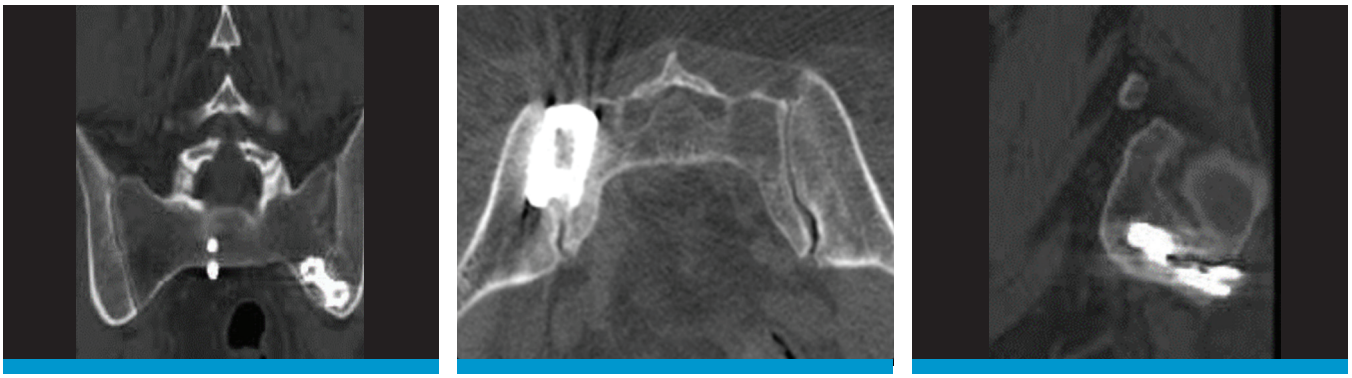

Figure 6. Axial and sagittal plane sections through a region of the sacroiliac joint shows adequate placement in cortical bone, inferior to the dorsal recess and demonstrating bridging bone around the Catamaran Fixation Device

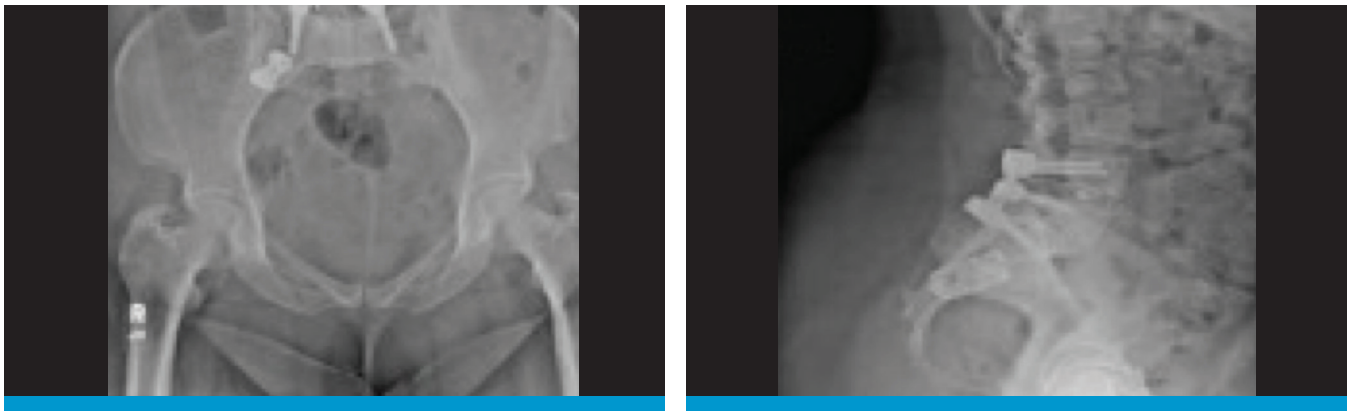

Figure 7. X-ray images show the Catamaran Fixation Device maintenance of placement

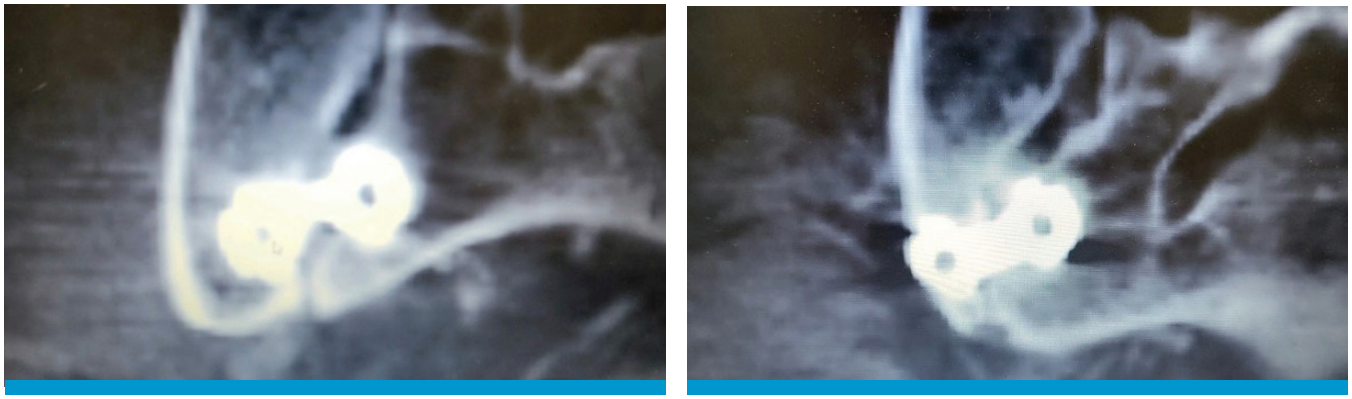

Figure 8. CT Images showing bony ingrowth at 20 months postop

Discussion

Sacroiliac joint fusion has become a common and successful procedure, providing excellent, sustained relief of pain caused by sacroiliac dysfunction. Traditional open SI joint fusion techniques have the disadvantages of prolonged intraoperative x-ray exposure, more than 10% postoperative complication rate,[12] high rates of immediate postoperative pain, and delayed device migration.

On the other hand, minimally invasive approaches do not permit sufficient visualization of the joint, allow for adequate preparation of the joint space, or enable effective delivery of bone graft material to the joint space. With these techniques, the trajectory for placement of the fixation devices is towards the sacral neuroforamina, and adequate fixation requires placement of two or three fixation devices. Each fixation device placed is an opportunity for misplacement and complication. The Inferior-Posterior approach with the Catamaran SI Joint Fusion System is designed to address these challenges.

In carrying out the Inferior-Posterior approach using the Catamaran Fixation Device, the trajectory of the device during placement is directed away from the neuroforamina, avoiding the risk of nerve root injury. Furthermore, the technique facilitates direct access to and visualization of the SI joint while facilitating joint debridement and arthrodesis. Unlike other commonly performed SI joint fusion techniques, this procedure requires only one fixation device.

Early results of the Inferior-Posterior approach have demonstrated encouraging initial outcomes with minimal blood loss and fluoroscopy time. Unlike the study by Polly et al[3] in which 91.2% of patients had at least three implants, our experience suggests that it is possible to achieve stabilization using a single device.

With respect to pain control, preliminary results demonstrate excellent outcomes with an average pain score reduction of 85% at 6 weeks. At 6 weeks and 12 months post-operative, 81% and 90% of patients, respectively, required no narcotic pain medications.

Conclusion

The Inferior-Posterior sacroiliac joint approach using the Catamaran SI Joint Fusion System provides encouraging results when compared with traditional open and newer minimally invasive techniques. These early results demonstrated minimal blood loss and fluoroscopy time with this approach and pain resolution associated with sacroiliac dysfunction. The absence of intraoperative or postoperative complications supports the continued application of this procedure in helping patients with sacroiliac joint dysfunction achieve optimal pain control and better quality of life. Additional studies are recommended.

Table 1. Patient Demographics and Baseline Characteristics

CHARACTERISTIC	N = 18*
Male	8 (50%)
Female	8 (50%)
Mean Age *(years)*	47.4 + 11.4 *(Range 22 - 68)*
Mean Weight *(kg)*	96.6 + 20.8
Mean Height *(inches)*	147.4 + 25
Mean BMI *(kg/m2)*	33.5 + 8.1 *(Range 20.7 – 47.4)*
Mean Visual Analog Score (VAS) for SI Joint pain on a scale of 0-10	8.6 + 1.1 *(Range 7-10)*
Mean Duration of Symptoms *(months)*	16.1 + 18.3 *(Range 1 – 72)*
Patient History (N=16)	
Previous L5/S1 Fusion	10 (62.5%)
Other Spinal Surgery	12 (75%)
Trauma	7 (43.75%)
Degenerative	7 (43.75%)
Gait	7 (43.75%)
Congenital Malformation	1 (6.25%)
SI Joint Side (N=18 SIJs)	Left = 11 *(61.1%)*; Right = 7 *(38.9%)*

* One Female and one male had the Catamaran SI Joint Fusion System procedure performed in both SI Joints approximately 2 years and one year apart respectively.

Table 2. **Patient Treatment History**

PREVIOUS CONSERVATIVE TREATMENTS	N = 18
Physical Therapy	17 (94.4%)
Steroid Injections	4 (22.2%)
Rhizotomy	2 (11.1%)
Baseline Meds for SI Joint Pain	
NSAID	14 (77.8%)
Opiate	13 (72.2%)
Oral Steriod	2 (11.1%)
Gabapentinoid	3 (16.7%)
Muscle relaxant	7 (38.9%)
Cannabis	2 (11.1%)
Average % Pain relief with arthrogram guided SI block: 1.5cc 1% lidocaine epi and no intra-articular steroids	91.5 + 13.7 (Range 75 – 100)
Baseline Provocative Tests	
Activity Induced	17 (100%) – n=1 not reported
Fortin FPT	18 (100%)
Thigh Thrust	15 (83.3%)
Compression	14 (77.8%)
Distraction	15 (83.3%
FABER	18 (100%)
Gaenslen	17 (94.4%)

Table 3. **Surgical Procedure Characteristics**

CHARACTERISTIC	N=18
Mean Operative Time (minutes)	106.6 + 45.3 (Range 61 - 220)
Mean Fluoroscopy Time (seconds)	66.4 + 49.5 (Range 25 - 216)
Mean Estimated Blood Loss (mL)	35.6 + 36.1 (Range 5 - 150)
Device Size	N=18 Devices
7.5 x 30	1 (5.6%)
10 x 30	2 (11.1%)
10 x 40	15 (83.3%)
Intra-operative Complications	0 (0%)
Immediate Post-operative Complications	0 (0%)

Table 4. **Post-Operative Positive Provocative Tests**

Positive Provocative Tests	Preop n=18 SIJs	2 weeks n=15	6 weeks n=17	4.5 months n=11	6.5 months n=6	9 months n=5	12 months n=8
Activity Induced	17 (100%)	2 (13.3%)	1 (6.7%)	2 (18.2%)	0 (0%)	1 knee pain	0 (0%)
Fortin FPT	18 (100%)	1 (6.7%)	1 (6.7%)	2 (18.2%)	0 (0%)	0 (0%)	0 (0%)
Thigh Thrust	15 (83.3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Compression	14 (77.8%)	0 (0%)	0 (0%)	1 (9.1%)	1 (16.7%)	0 (0%)	0 (0%)
Distraction	15 (83.3%)	0 (0%)	0 (0%)	1 (9.1%)	0 (0%)	0 (0%)	0 (0%)
FABER	18 (100%)	0 (0%)	2 (13.3%)	1 (9.1%)	0 (0%)	0 (0%)	0 (0%)
Gaenslen	17 (94.4%)	1 (6.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

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