

Two-Year Outcomes of Lateral Transiliac Sacroiliac Joint Fusion with Porous Threaded Implant

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Purpose: Sacroiliac joint (SIJ) pain is a widely recognized source of chronic low back pain. The safety and effectiveness of SIJ fusion is supported by multiple systematic reviews. Most evidence involves lateral transiliac placement of metallic implants. We report two-year outcomes from lateral SIJ fusion using a 3D-printed porous threaded fusion implant (PTI, iFuse TORQ, SI-BONE).

Patients and methods: A retrospective chart review was undertaken at two centers. Medical records of patients who underwent lateral SIJ fusion between January 2022 and May 2023 with at least two years of follow up were reviewed. Data collection included demographics, complications, and postoperative outcomes. The study protocol was reviewed by WCG IRB and was granted exemption authorization.

Results: 49 patients underwent surgery and had two-year outcomes. Mean age was 63.8 and 71% were women. There were no device- or procedure-related adverse events. Pain scores averaged 8.7 at baseline and 2.8 at follow-up (change of 5.8 points, $p < 0.0001$). Pain score improvements were similar across surgeons and were independent of a history of prior lumbar fusion.

Conclusion: In our case series, lateral SIJ fusion with a titanium 3D printed threaded implant was safe and effective at 2 years of follow-up. No implant breakage or migration was observed. Outcomes were consistent with existing studies.

Keywords: sacroiliac joint pain, sacroiliac joint fusion, 3D-printed implants, safety profile, long term outcomes

Introduction

Sacroiliac joint (SIJ) pain is well-recognized as a source of chronic lower back pain. SIJ pain may explain 15–30% of all chronic low back pain.^{1–5} Over the past decade, minimally invasive SIJ fusion has become the mainstay treatment for chronic SIJ pain refractory to non-surgical treatment. A large body of literature supports the safety and effectiveness of SIJ fusion, including two randomized trials^{6,7} and a comprehensive meta-analysis of 37 studies⁸ in accordance with evidence-based guidelines and techniques.⁹

Most published reports describe SIJ fusion procedures performed via a lateral transfixing trajectory with a series of triangular titanium implants (TTI). Recently, additively manufactured porous threaded titanium implants (PTI, iFuse TORQ [Figure 1], SI-BONE, Santa Clara, CA) with similar characteristics but in a screw design have become available. Similar to the TTI, PTI have a lattice surface with a pore size and porosity similar to cancellous bone. Additionally, the implant contains helical flutes that self-harvest bone during insertion, feeding the autograft into the cannulated interior of the implant by way of strategically placed fenestrations. PTI are indicated for fusion of the SIJ as well as pelvic fracture fixation.

While early evidence supports the use of PTI,¹⁰ no long term published data are available for this implant. Herein we present two-year outcomes from a multicenter retrospective study.



Figure 1 Porous threaded implants (PTI) (iFuse TORQ, SI-BONE, Santa Clara, CA).

Methods

A retrospective chart review was conducted at two centers in the US. Consecutive cases of lateral SI joint fusion (Figure 2) that used 2 or more 3D-printed PTI (iFuse TORQ, SI-BONE, Inc., Santa Clara, CA) were identified. Data extracted from the medical record included demographics, history of previous spine or SIJ surgery, procedure characteristics, and outcomes out to two years. Pain scores were reported by patients using the 0–10 NRS (numeric rating score) pain scale. Electronic health records were thoroughly reviewed to identify any complications within the perioperative and postoperative periods, including infection, neurovascular injury, instrumentation failure (eg implant migration or breakage) and reoperation to address the implants. The study protocol was reviewed by WCG IRB and was granted (work order #1-1706534-1) exemption authorization as no PHI was collected. The study complied with the Declaration of Helsinki.

Statistical analysis was conducted using R.¹¹ Fisher's test was used to compare nominal characteristics across sites. T tests were used to compare continuous variables across sites. A paired *t* test was used to evaluate the SIJ pain change scores. An exact binomial test was used to calculate confidence intervals for proportions. No imputation was performed on missing data.

Results

61 patients were treated between January 2022 and May 2023, of which 49 had both baseline and 2-year follow-up data. In these 49, mean patient age was 63.8, 71.4% were women, and all patients were white (Table 1). Demographic characteristics varied across the two centers; prior spine surgery was more common at the surgeon's site and smoking was more common at the interventionalist's site.

The interventionalist used fluoroscopy to guide implant placement; the surgeon used navigation (Table 2). Estimated blood loss was minimal in all cases. In all but 1 case, 3 implants were used across the target SIJ. There were no device- or procedure-related complications.

Pain scores were available in 41 subjects at baseline and 43 at 2 years and 3 for both baseline and 2 years. Pain scores were high at baseline (mean 8.7) and low at follow-up (2.8, Table 3 and Figure 3). Pain scores were slightly higher at baseline and 2 years at the interventionalist's site. Pain improvement from baseline averaged 5.8 points (95% CI 5.0–6.5 points, $p < 0.0001$) with no difference across surgeons ($p = 0.7699$). Pain scores improved by 2 or more points in 37 of 38 patients (97.4%). Patients with a history of prior lumbar fusion showed similar pain improvements compared to those

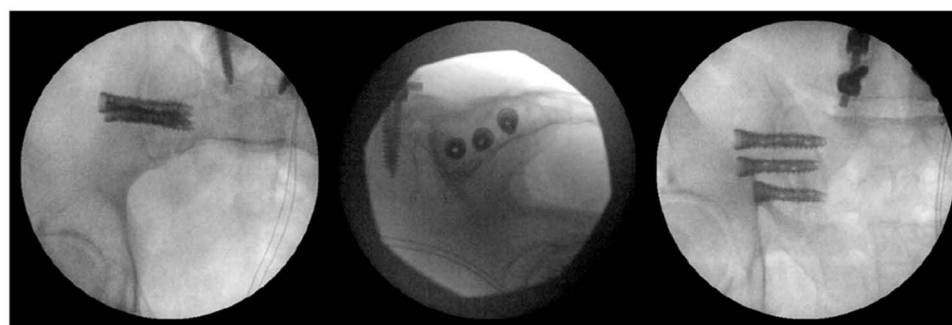


Figure 2 Pelvic inlet, lateral, and outlet intraoperative images showing PTI.

Table 1 Demographic and Medical Characteristics of Study Participants

		Surgeon				Total N=49		P value*
		MJ (interventionalist) (n=27)		CK (surgeon) (n=49)				
		N or mean	Percent or SD	N or mean	Percent or SD	N or mean	Percent or SD	
Age		65.9	9.9	61.2	11.9	63.8	11.0	0.1436
Sex	Male	6	(22.2%)	8	(36.4%)	14	(28.6%)	0.3476
	Female	21	(77.8%)	14	(63.6%)	35	(71.4%)	
Body mass index		33.5	9.5	29.5	4.4	31.7	7.9	0.0580
Race	White	27	(100.0%)	22	(100.0%)	49	(100.0%)	–
Smoker	No	19	(70.4%)	21	(95.5%)	40	(81.6%)	0.0305
	Current	8	(29.6%)	1	(4.5%)	9	(18.4%)	
Prior lumbar fusion	No	23	(85.2%)	14	(63.6%)	37	(75.5%)	0.1037
	Yes	4	(14.8%)	8	(36.4%)	12	(24.5%)	
History of hip procedure	No	24	(88.9%)	22	(100.0%)	46	(93.9%)	0.2423
	Yes	3	(11.1%)	0	(0.0%)	3	(6.1%)	
Prior SIJ fusion	N	22	(81.5%)	21	(95.5%)	43	(87.8%)	0.2044
	Y	5	(18.5%)	1	(4.5%)	6	(12.2%)	
	All	27	(100.0%)	22	(100.0%)	49	(100.0%)	

Notes: *Fisher test or t test.

Table 2 Surgical Characteristics

		Surgeon				Total		P value
		MJ (interventionalist)		CK (surgeon)				
		n	Percent	n	Percent	n	Percent	
Side treated	Left	15	(55.6%)	7	(31.8%)	22	(44.9%)	0.1533
	Right	12	(44.4%)	14	(63.6%)	26	(53.1%)	
	NA	0	(0.0%)	1	(4.5%)	1	(2.0%)	
Imaging type used	Fluoroscopy	27	(100.0%)	0	(0.0%)	27	(55.1%)	<0.0001
	Navigation	0	(0.0%)	22	(100.0%)	22	(44.9%)	
Number of implants placed	2	1	(3.7%)	0	(0.0%)	1	(2.0%)	1.0000
	3	26	(96.3%)	21	(95.5%)	47	(95.9%)	
	NA*	0	(0.0%)	1	(4.5%)	1	(2.0%)	
	All	27	(100.0%)	22	(100.0%)	49	(100.0%)	

Notes: *Not available in 1 case.

Table 3 Pain Scores by Surgeon and Prior Lumbar Fusion

Pain Score	Baseline Mean (SD) (n=41)	2 years Mean (SD) (n=43)	Improvement Mean (95% CI, paired t test p-value) (n=38)
Surgeon			
MJ	9.2 (1.1)	3.4 (1.8)	5.8 (5.0–6.7, <0.0001)
CK	7.7 (1.8)	1.8 (1.9)	5.6 (3.8–7.3, <0.0001)
Prior lumbar fusion			
No	8.6 (1.7)	2.9 (2.0)	5.5 (4.5–6.4, <0.0001)
Yes	8.8 (1.2)	2.2 (2.0)	6.6 (5.7–7.5, <0.0001)
All	8.7 (1.6)	2.8 (2.0)	5.8 (5.0–6.5, <0.0001)

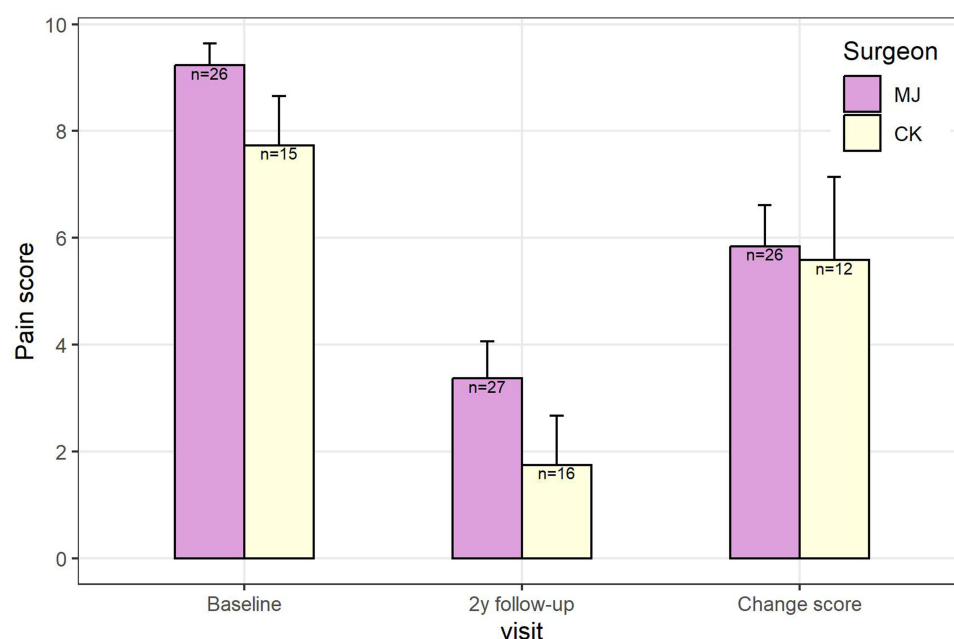


Figure 3 Pain scores at baseline, at 2 years, and change in pain score from baseline to 2 years. Values shown are mean $\pm$ 95% confidence interval. Numbers within bars show sample size at each time point.

without such a history (Table 4). Other variables examined (age, sex, body mass index, smoking status and history of prior hip surgery) were not predictive of SIJ pain improvement.

Satisfaction levels, measured at only one site, were high (96.3%) and did not vary by prior lumbar fusion status (Table 4). One subject underwent revision surgery. The subject, a 60-year-old woman, had a history of trochanteric bursitis, L4/5 foraminal stenosis, L5/S1 degenerative disc disease with right foraminal stenosis. She had multiple falls following SIJ fusion, resulting in lucency around PTI within the sacrum. She underwent revision surgery approximately 24 months after the index procedure with a favorable response. Prior lumbar fusion did not predict revision (Table 4).

Table 4 Threshold Improvements in Pain Scores, Satisfaction and Revision Rates

Pain Score Improvement of 2 or More Points at Follow-up	N/N (rate%)	95% CI
Surgeon		
MJ	26/26 (100%)	86.8–100%
CK	11/12 (91.7%)	61.5–99.8%
Prior lumbar fusion		
Yes	10/10 (100%)	69.2–100%
No	27/28 (96.4%)	81.7–99.9%
Satisfied with procedure		
Surgeon		
MJ	26/27 (96.3%)	81.0–99.9%
CK	ND*	-
Prior lumbar fusion		
Yes	4/4 (100%)	39.8–100.0%
No	22/23 (95.7%)	85.2–100.0%

(Continued)

Table 4 (Continued).

Pain Score Improvement of 2 or More Points at Follow-up	N/N (rate%)	95% CI
Revised by year 2		
Surgeon		
MJ	0/27 (0%)	0–12.8%
CK	1/22 (4.5%)	0.1–22.8%
Prior lumbar fusion		
Yes	0/12 (0%)	(0–26.5%)
No	1/37 (2.7%)	(0.1–14.2%)

Notes: *ND = not done.

Discussion

In our multicenter case series, two-year outcomes from use of PTI for lateral SIJ fusion showed the device and procedure to be safe and effective. We did not observe any cases of adverse events previously reported, such as bleeding from branches of the superior gluteal artery, wound infection or nerve root irritation related to implant malposition. Further, we did not observe implant breakage or migration. One patient underwent revision surgery to address implant loosening following multiple falls.

The body of evidence supporting SIJ fusion has steadily grown over the past decade. Most such evidence reports outcomes from lateral transiliac placement of fusion implants. Initial studies used machined triangular titanium implants (TTI).^{7,12,13} Subsequently a 3D-printed porous version of TTI was made available; this device showed excellent 5-year efficacy with low rates of adverse events.¹⁴ A cumulative meta-analysis reporting results from a wide variety of metallic implants for SIJ fusion showed high rates of efficacy and safety.⁸

In our case series, we used a more recently available (2021) 3D-printed PTI. While early evidence of safety and effectiveness for SIJ fusion using this implant is available,¹⁰ to our knowledge, ours is the first report of long-term results with PTI. Our favorable two-year results show that lateral SI joint fusion using an osseointegrating implant with self-harvesting flutes continues to be a safe and effective long term treatment option. Our results compare favorably with those of TTI trials.

Lateral transiliac placement of pelvic fixation screws for fracture fixation was first popularized in the mid-1990s.¹⁵ Reported complications from this procedure typically relate to implant misplacement. While rare, such malposition can result in injury to branches of the superior gluteal artery (SGA). SGA injuries can result in pseudoaneurysm or major bleeding but have not caused reported deaths.^{16,17} Cadaveric studies suggest lateral SGA injury rates up to 18%, though the true incidence in patients is much lower and possibly overstated.¹⁸ Risk factors like sacral dysmorphism remain debated, and actual lateral vascular injury rates are low (0.6–1.2%).^{19–22} Proper imaging, including preoperative advanced imaging and high quality intraoperative imaging, as well as knowledge of the specific anatomy are essential to minimize risks. In our experience, adherence to meticulous surgical technique and the utilization of soft tissue protection instruments are essential for the safe execution of SIJ fusion procedures.^{10,23,24}

Directions for future research include prospective studies (for example, STACI)²⁵ that include patient-reported outcomes, opioid use, return to function, late imaging and cost or utilization endpoints.

Advantages of our case series include the use of two centers with physicians of different practice types and the availability of long-term (two-year) data. Limitations of this case series include its retrospective nature and the use of only 2 centers. Further, while 61 patients were treated, 2-year outcomes were available in 49 (80%), which may result in bias as not all patients return for follow up or may limit generalizability. Additionally, pain scores were unavailable at baseline in 7 cases and in follow-up in 6 cases. Patients with chronic SIJ pain often have multifactorial pain with many having undergone spinal fusion surgery either prior to or after their SIJ fusion. This can complicate their ability to discern discrete pain scores for low back and SIJ pain.

Conclusions

Two-year outcomes after lateral SIJ fusion using an osseointegrative porous threaded implant are favorable. Nearly all patients experienced clinical improvement, independent of a history of prior lumbar fusion. There was no evidence of implant breakage or migration.

Disclosure

Dr Michael Jung reports consultancy from SI-BONE and Genesys during the conduct of the study.

Dr Craig Kuhns reports royalties, stock, consulting, none for SI joint implants from ATEC, Royalties, none for SI joint implants from Globus, Consulting, but none for SI joint from Medtronic, outside the submitted work.

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