Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-year Follow-up from a Prospective Multicenter Trial

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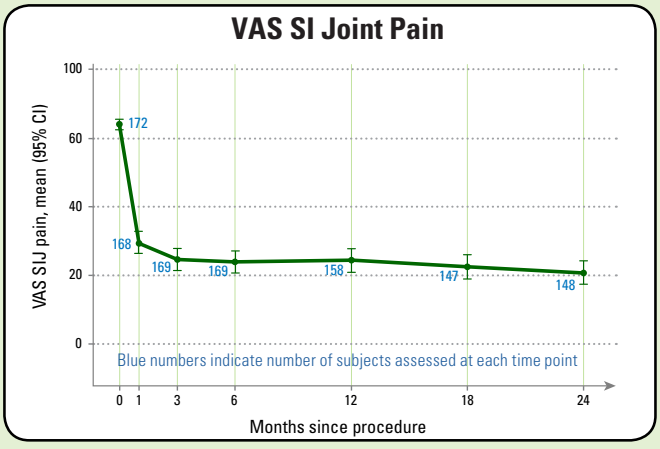
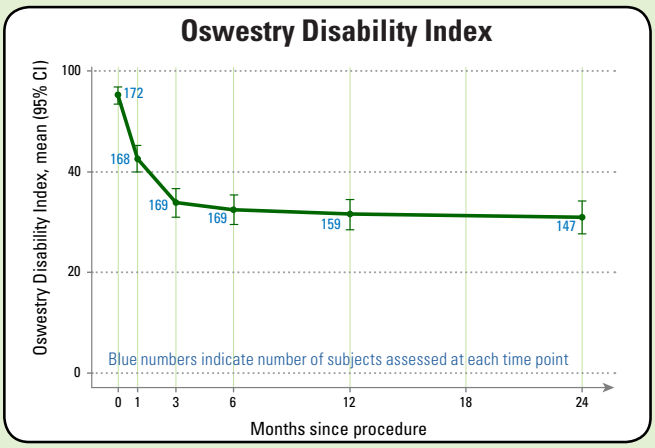
KEY POINTS

- Prospective, multicenter study of minimally invasive surgical (MIS) fusion of the sacroiliac (SI) joint with the iFuse Implant System®
  [SIFI, ClinicalTrials.gov ID NCT01640353]
  - 172 patients enrolled and treated
  - 26 clinical sites in US
- Clinically important and statistically significant long-term improvements in pain, disability and quality of life (see table and figures)
  - Improvements at 6 and 12 months were maintained to 24 months
  - Treated patients approaching normal values
  - No variation in response by diagnosis, history of prior lumbar fusion, smoking, or bi/unilateral
- 28.2% reduction in opioid medication use from baseline to 24 months (37 patients completely stopped)
- Radiographs show high rate (97%) of bony apposition to at least two implants on both the iliac and sacral sides
- Favorable safety profile
  - 4.7% revision rate (8 subjects)
  - 7 device-related adverse events

		Mean	Improvement from Baseline, Mean	P-value*
VAS SI Joint Pain	Baseline	79.8	—	<0.0001
	Month 1	37.0	42.7	
	Month 3	30.7	49.2	
	Month 6	30.0	49.9	
	Month 12	30.4	49.3	
	Month 18	28.1	51.5	
	Month 24	26.0	53.3	
Oswestry Disability Index	Baseline	55.2	—	<0.0001
	Month 1	42.6	12.5	
	Month 3	33.8	21.3	
	Month 6	32.5	22.7	
	Month 12	31.5	23.8	
	Month 24	30.9	24.5	
SF-36 PCS	Baseline	31.7	—	<0.0001
	Month 6	40.1	8.3	
	Month 12	40.5	8.8	
	Month 24	40.7	8.9	
SF-36 MCS	Baseline	38.5	—	<0.0001
	Month 6	47.8	9.3	
	Month 12	48.2	9.5	
	Month 24	49.0	10.1	
EQ-5D TTO	Baseline	0.43	—	<0.0001
	Month 6	0.69	0.25	
	Month 12	0.71	0.27	
	Month 24	0.71	0.27	

*Repeated measures analysis of variance compared to baseline





See Article Abstract, Indications and Risk Statement on back

ABSTRACT

Background: Sacroiliac joint (SIJ) dysfunction is an underdiagnosed condition. Several published cohorts have reported favorable mid-term outcomes after SIJ fusion using titanium implants placed across the SIJ. Herein we report long-term (24-month) results from a prospective multicenter clinical trial.

Methods: One hundred and seventy-two subjects at 26 US sites with SI joint dysfunction were enrolled and underwent minimally invasive SI joint fusion with triangular titanium implants. Subjects underwent structured assessments preoperatively and at 1, 3, 6, 12, 18 and 24 months postoperatively, including SIJ pain ratings (0-100 visual analog scale), Oswestry Disability Index (ODI), Short Form-36 (SF-36), EuroQOL-5D (EQ-5D), and patient satisfaction. Adverse events were collected throughout follow-up. All participating patients underwent a high-resolution pelvic CT scan at 1 year.

Results: Mean subject age was 50.9 years and 69.8% were women. SIJ pain was present for an average of 5.1 years prior to surgical treatment. SIJ pain decreased from 79.8 at baseline to 30.4 at 12 months and remained low at 26.0 at 24 months ($p<.0001$ for change from baseline). ODI decreased from 55.2 at baseline to 31.5 at 12 months and remained low at 30.9 at 24 months ($p<.0001$ for change from baseline). Quality of life (SF-36 and EQ-5D) improvements seen at 12 months were sustained at 24 months. The proportion of subjects taking opioids for SIJ or low back pain decreased from 76.2% at baseline to 55.0% at 24 months ($p <.0001$). To date, 8 subjects (4.7%) have undergone one or more revision SIJ surgeries. 7 device-related adverse events occurred. CT scan at one year showed a high rate (97%) of bone adherence to at least 2 implants on both the iliac and sacral sides with modest rates of bone growth across the SIJ.

Conclusions: In this study of patients with SIJ dysfunction, minimally invasive SI joint fusion using triangular titanium implants showed marked improvements in pain, disability and quality of life at 2 years. Imaging showed that bone apposition to implants was common but radiographic evidence of intraarticular fusion within the joint may take more than 1 year in many patients.

This prospective multicenter clinical trial was approved by local or regional IRBs at each center prior to first patient enrollment. Informed consent with IRB-approved study-specific consent forms was obtained from all patients prior to participation.

Keywords: sacroiliac joint dysfunction, sacroiliac joint fusion, degenerative sacroiliitis, sacroiliac joint disruptions, multicenter clinical trial

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The iFuse Implant System® is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life at 12-months post-implantation. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: *www.si-bone.com/risks*

Patent Nos. 8,202,305; 8,840,623; 8,986,348 and 9,039,743; pending U.S. and foreign patent applications.

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