

Six-Month Outcomes from a Randomized Controlled Trial of Minimally Invasive SI Joint Fusion with Triangular Titanium Implants vs. Conservative Management

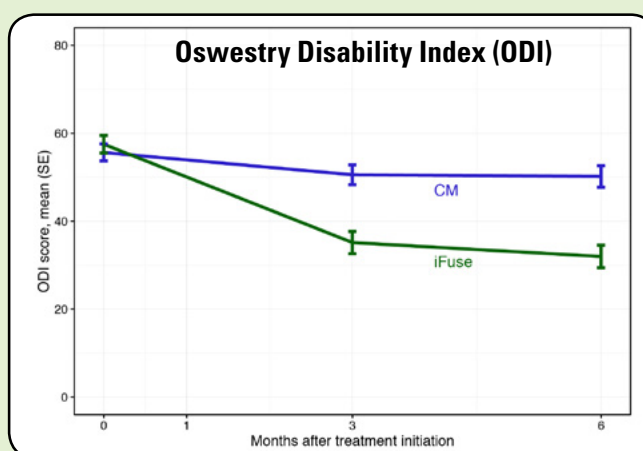
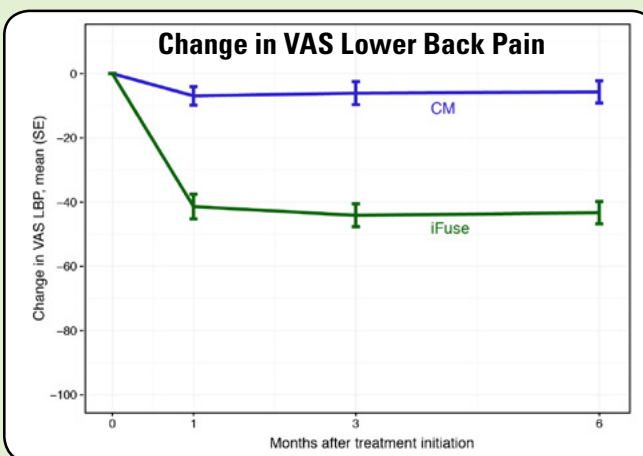
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Eur Spine J. 2016 May 14. Epub.



KEY POINTS

- Prospective, multicenter, randomized controlled trial (RCT) of minimally invasive surgical (MIS) fusion of the sacroiliac (SI) joint with the iFuse Implant System® (“iFuse”) vs. conservative management (CM) [iMIA, ClinicalTrials.gov ID [NCT01741025](#)]
 - 103 patients enrolled and treated (52 iFuse, 51 CM)
 - 9 sites, 4 European countries
- At 6 months, iFuse provided superior outcomes over conservative management in:
 - Pain relief (VAS LBP)
 - Disability reduction (ODI)
 - Functional improvement (ASLR)
 - Quality of life improvement (EQ-5D)
- Frequency of adverse events did not differ between groups (number of events per subject slightly smaller in the iFuse group compared to CM: 0.19 vs. 0.2, $p=0.0918$)
- 2nd RCT (Level I clinical evidence) demonstrating SI joint fusion with iFuse is a reasonable surgical option for patients with chronic SI joint pain not responsive to non-surgical management.



			iFuse	CM	Difference
Pain	Visual Analog Scale Lower Back Pain (VAS LBP)	Baseline	77.7	73.0	
		6 months	34.4	67.8	
		Change	-43.3	-5.7	37.6 ($p < 0.0001$)
		Subjects with ≥ 20 -point decrease	78.8%	22.4%	$p < 0.0001$
Disability	Oswestry Disability Index (ODI)	Baseline	56.6	56.6	
		Change at 6 months	-25.5	-5.8	19.8 ($p < 0.0001$)
		Subjects with ≥ 15 -point decrease	71.2%	24.5%	$p < 0.0001$
Functionality	Active Straight Leg Raise (ASLR)	Baseline	4.0	3.8	
		6 months	2.0	3.7	
		Change	-2.0	-0.2	
		No or minimal difficulty at 6 months	71.2%	32.0%	$p < 0.0002$
Quality of Life	EQ-5D Time Trade-off (TTO)	Change from Baseline to 6 months	+0.37	+0.11	0.21 ($p < 0.0001$)

Table generated from text in the article.

ABSTRACT

Purpose: To compare the safety and effectiveness of minimally invasive sacroiliac joint fusion (SIJF) using triangular titanium implants vs conservative management (CM) in patients with chronic sacroiliac joint (SIJ) pain.

Methods: 103 Adults with chronic SIJ pain at nine sites in four European countries were randomly assigned to and underwent either minimally invasive SIJF using triangular titanium implants (N=52) or CM (N=51). CM was performed according to the European guidelines for the diagnosis and management of pelvic girdle pain and consisted of optimization of medical therapy, individualized physical therapy (PT) and adequate information and reassurance as part of a multifactorial treatment. The primary outcome was the difference in change in self-rated low back pain (LBP) at 6 months. Additional endpoints included quality of life using EQ-5D-3L, disability using Oswestry Disability Index (ODI), SIJ function using active straight leg raise (ASLR) test and adverse events. NCT01741025.

Results: At 6 months, mean LBP improved by 43.3 points in the SIJF group and 5.7 points in the CM group (difference of 38.1 points, $p < 0.0001$). Mean ODI improved by 26 points in the SIJF group and 6 points in the CM group ($p < 0.0001$). ASLR, EQ-5D-3L, walking distance and satisfaction were statistically superior in the SIJF group. The frequency of adverse events did not differ between groups. One case of postoperative nerve impingement occurred in the surgical group.

Conclusions: In patients with chronic SIJ pain, minimally invasive SIJF using triangular titanium implants was safe and more effective than CM in relieving pain, reducing disability, improving patient function and quality of life.

Keywords: Sacroiliac joint dysfunction, Pelvic girdle pain, Sacroiliac joint fusion, Titanium sacroiliac implant, Randomized controlled trial, Conservative management, iFuse Implant System

One or more of the individuals named herein may be a past or present SI-BONE employee, paid consultant, investor, clinical trial investigator, or grant recipient. Research described herein was supported by SI-BONE.

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.