Randomized Trial of Sacroiliac Joint Arthrodesis Compared with Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint

Dengler J, Kools D, Pflugmacher R, Gasbarrini A, Prestamburgo D, Gaetani P, Cher D, Van Eeckhoven E, Annertz M, Sturesson B.

OPEN ACCESS

J Bone Joint Surg Am. 2019;101(5):400-411.

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

iFuse provides SUPERIOR results compared to conservative management throughout 2 years in:

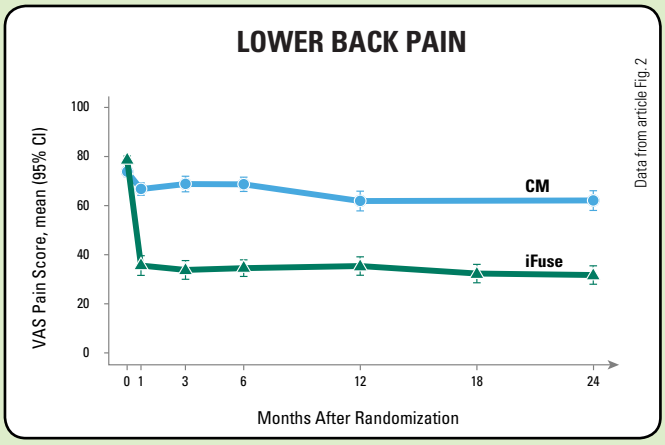
- Low Back Pain – Visual Analog Scale (VAS) *[see graph below]*
- Back Function – Oswestry Disability Index (ODI) *[see graph below]*
- Quality of Life – EQ-5D Time Trade-off (EQ-5D TTO)
- Depression – Zung Depression Scale
- Opioid Use – percentage of patients taking opioid medication
- Overall Patient Satisfaction
- Walking Distance

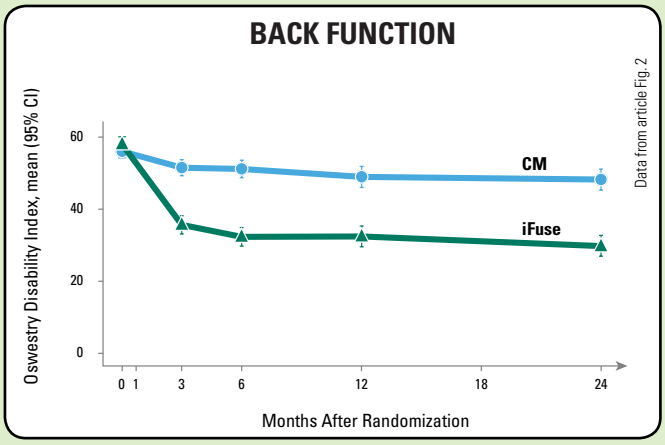
Adverse Events and Revisions

- During the first 6 months (200 days) there was no difference in the rate of adverse events between iFuse and CM
- At 2 years events rated as severe:
  - iFuse: 39 events (only 4 were probably or definitely device or procedure related)
  - CM: 27 events (only 1 was related to the study procedure)

		LBP	ODI	EQ-5D TTO	Depression	Opioid Use
iFuse	Mean Improvement Baseline to 2 years	45 points	26 points	0.39	5.3 points	Decreased 56% → 33%
	% patients with clinical improvement*	79% (37 of 47)	64% (30 of 47)			
CM	Improvement Baseline to 2 years	11 points	8 points	0.15	No improvement	No improvement 47% → 46%
	% patients with clinical improvement*	24% (11 of 46)	24% (11 of 46)			
Difference between iFuse and CM		34 points	18 points			
P-value (difference between iFuse and CM)		< 0.0001	< 0.0001	< 0.001	< 0.001	

** Clinical Improvement: VAS Low Back Pain ≥ 20-point improvement from baseline to 2 years; Oswestry Disability Index (ODI) ≥ 15-point improvement from baseline to 2 years*





See Article Abstract, Indications and Risk Statement on back

ABSTRACT

Background: Sacroiliac joint pain is increasingly recognized as a cause of low back pain. We compared the safety and effectiveness of minimally invasive sacroiliac joint arthrodesis using triangular titanium implants and conservative management in patients with chronic sacroiliac joint pain.

Methods: This study was a prospective, multicenter randomized controlled trial of adults with chronic sacroiliac joint pain assigned to either conservative management or sacroiliac joint arthrodesis with triangular titanium implants. The study end points included self-rated low back pain, back dysfunction (Oswestry Disability Index [ODI]), and quality of life. Ninety percent of subjects in both groups completed the study.

Results: Between June 6, 2013, and May 15, 2015, 103 subjects were randomly assigned to conservative management (n = 51) or sacroiliac joint arthrodesis (n = 52). At 2 years, the mean low back pain improved by 45 points (95% confidence interval [CI], 37 to 54 points) after sacroiliac joint arthrodesis and 11 points (95% CI, 2 to 20 points) after conservative management, with a mean difference between groups of 34 points ($p < 0.0001$). The mean ODI improved by 26 points (95% CI, 21 to 32 points) after sacroiliac joint arthrodesis and 8 points (95% CI, 2 to 14 points) after conservative management, with a mean difference between groups of 18 points ($p < 0.0001$). Parallel improvements were seen in quality of life. In the sacroiliac joint arthrodesis group, the prevalence of opioid use decreased from 56% at baseline to 33% at 2 years ($p = 0.009$), and no significant change was observed in the conservative management group (47.1% at baseline and 45.7% at 2 years). Subjects in the conservative management group, after crossover to the surgical procedure, showed improvements in all measures similar to those originally assigned to sacroiliac joint arthrodesis. In the first 6 months, the frequency of adverse events did not differ between groups ($p = 0.664$). By month 24, we observed 39 severe adverse events after sacroiliac joint arthrodesis, including 2 cases of sacroiliac joint pain, 1 case of a postoperative gluteal hematoma, and 1 case of postoperative nerve impingement. The analysis of computed tomographic (CT) imaging at 12 months after sacroiliac joint arthrodesis showed radiolucencies adjacent to 8 implants (4.0% of all implants).

Conclusions: For patients with chronic sacroiliac joint pain due to joint degeneration or disruption, minimally invasive sacroiliac joint arthrodesis with triangular titanium implants was safe and more effective throughout 2 years in improving pain, disability, and quality of life compared with conservative management.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Disclosure: The study was funded by SI-BONE (Santa Clara, California), the manufacturer of the iFuse Implant System used in the study. One author of this study (D.C.) is an employee at SI-BONE. Four authors (D.K., R.P., E.V.E., and B.S.) are consultants to SI-BONE. The study sponsors participated in study design, data collection, data analysis, data interpretation, and writing of the report. One author of this study (J.D.) had full access to all study data and had final responsibility for the decision to submit for publication. Study data are available through the Yale University Open Data Access (YODA) data-sharing program. **The Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article. *(http://links.lww.com/JBJS/F143).*

SI-BONE, Inc.
471 El Camino Real,
Suite 101
Santa Clara, CA 95050
U.S.A.

t. 408-207-0700
f. 408-557-8312
info@si-bone.com
www.si-bone.com