Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion *vs.* Non-Surgical Management for Sacroiliac Joint Dysfunction

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KEY POINTS

- **Level I Clinical Evidence**
  Prospective, Multicenter (19 clinical sites), Randomized Controlled Trial (RCT);
  iFuse Implant System® (iFuse, n=102) vs. Non-surgical Management (NSM, n=46)

- **24-month Outcomes**

iFuse – rapid (6 mo) and sustained (24 mo) improvement

At 6 months:

– Superior results compared to NSM
– 82% of subjects met primary success endpoint

At 24 months (n=89):

– SI joint pain (VAS) – mean decrease 55.4 points
– Disability (ODI) – mean decrease 28.4 points
– Quality of life (EQ-5D and SF-36) – clinically significant improvement
– Clinically significant improvement in pain and disability (see table below)

NSM – small improvement

At 6 months:

– Minimal decrease in pain and disability
– 26% of subjects met primary success endpoint

Post 6 months (39 crossed over, 5 stayed with NSM):

– 89% (39 of 44) crossed over to iFuse after 6 months indicating high rate of NSM failure
– Crossover subjects experienced significant improvement similar to those originally assigned to iFuse (see graphs below)
– Few (≤ 10% at 12 and 24 mo) had clinically significant improvement in pain and disability due to NSM alone (see table below)

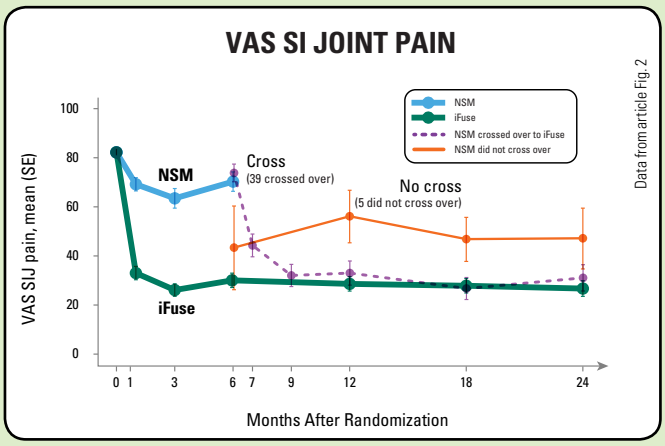
- **Opioid Use (% subjects taking opioids)**
  – iFuse group incidence decreased by 30% over 24 months
  – NSM group incidence slightly increased from baseline to 6 months

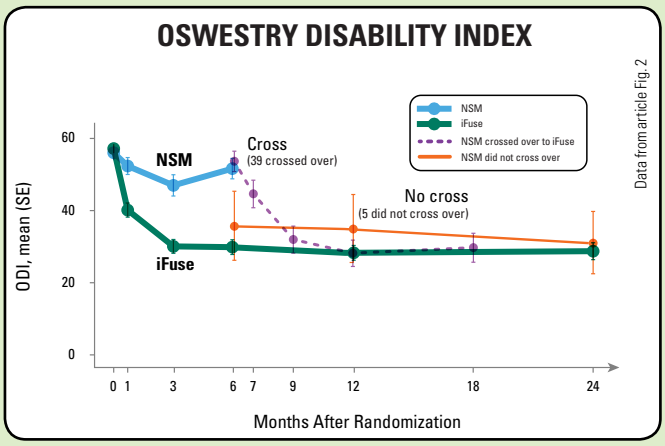
- **Adverse Events (AEs)**
  – No statistical difference between groups for mean number of AEs per subject in the first 180 days (1.5 iFuse vs. 1.3 NSM, p=0.2253)
  – Device-related AEs were low
  – 3% iFuse revision rate at 24 months (3 subjects originally assigned to iFuse)

Clinically Significant Improvement

(or minimum clinically important difference, MCID)

	VAS SI Joint Pain ≥ 20 point Improvement from Baseline		ODI ≥ 15 point Improvement from Baseline	
	iFuse	**NSM**	**iFuse**	**NSM**
1 month	84.0%	28.9%	49.0%	13.3%
3 months	87.0%	39.5%	72.0%	30.2%
6 months	83.2%	27.9%	73.3%	13.6%
12 months	81.0%	10%	72.0%	7.5%
24 months	83.1%	10%	68.2%	7.5%





See Article Abstract, Indications and Risk Statement on back

ABSTRACT

Background: Sacroiliac joint (SIJ) dysfunction is an important and underappreciated cause of chronic low back pain.

Objective: To prospectively and concurrently compare outcomes after surgical and non-surgical treatment for chronic SIJ dysfunction.

Methods: One hundred and forty-eight subjects with SIJ dysfunction were randomly assigned to minimally invasive SIJ fusion with triangular titanium implants (SIJF, n=102) or non-surgical management (NSM, n=46). SIJ pain (measured with a 100-point visual analog scale, VAS), disability (measured with Oswestry Disability Index, ODI) and quality of life scores were collected at baseline and at scheduled visits to 24 months. Crossover from non-surgical to surgical care was allowed after the 6-month study visit was complete. Improvements in continuous measures were compared using repeated measures analysis of variance. The proportions of subjects with clinical improvement (SIJ pain improvement ≥20 points, ODI ≥15 points) and substantial clinical benefit (SIJ pain improvement ≥25 points or SIJ pain rating ≤35, ODI ≥18.8 points) were compared.

Results: In the SIJF group, mean SIJ pain improved rapidly and was sustained (mean improvement of 55.4 points) at month 24. The 6-month mean change in the NSM group (12.2 points) was substantially smaller than that in the SIJF group (by 38.3 points, p<.0001 for superiority). By month 24, 83.1% and 82.0% received either clinical improvement or substantial clinical benefit in VAS SIJ pain score. Similarly, 68.2% and 65.9% had received clinical improvement or substantial clinical benefit in ODI score at month 24. In the NSM group, these proportions were <10% with non-surgical treatment only. Parallel changes were seen for EQ-5D and SF-36, with larger changes in the surgery group at 6 months compared to NSM. The rate of adverse events related to SIJF was low and only 3 subjects assigned to SIJF underwent revision surgery within the 24-month follow-up period.

Conclusions: In this Level 1 multicenter prospective randomized controlled trial, minimally invasive SIJF with triangular titanium implants provided larger improvements in pain, disability and quality of life compared to NSM. Improvements after SIJF persisted to 24 months.

Keywords: sacroiliac joint dysfunction, sacroiliac joint fusion, minimally invasive surgery, randomized clinical trial

* Paid consultant of SI-BONE participating primarily in educational events.

† Consultant of SI-BONE participating primarily in educational events, but receives only reasonable expense reimbursement as compensation.

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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. 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.

SI-BONE® | **iFuse** Implant System®
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