iFuse Implant System®
Clinical Evidence Summary

January 2014

PUBLICATIONS

Article	Description	Results/Summary
Duhon*† 2013 **Safety and 6-month Effectiveness of Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study** ► *Med Dev (Auckl).* 2013;6:219-29	**Prospective, multicenter clinical study (SIFI)** **6-month outcomes** *Cohorts:* *32 patients (Efficacy)* *94 patients (Safety)*	Mid-term results of first prospective study of MIS SI joint fusion with iFuse Implant System. ***Efficacy Cohort (n=32, 6 mo data from 26 patients)*** • Clinically significant reductions in pain (VAS) and improvement in function (ODI) and quality of life (SF-36 and EQ-5D) sustained through 6-months • 88.5% (23/26) of patients deemed successful (i.e., met all primary endpoint criteria: >20mm pain relief, no device-related SAEs, no neurological worsening, no surgical re-intervention) • 85% (22/26) patients were satisfied and might or definitely would have procedure again ***Safety Cohort (n=94)*** • 48.2 min mean procedure time (range 20-225 min, 77% < 60 min) • 59 cc mean EBL (range 5-800 cc, 75% < 50 cc) • Low perioperative morbidity and AEs: No post-op neuropathy or implant revisions • 6 severe AEs: none device-related, 2 probably/definitely procedure-related
Ackerman† 2013 **Comparison of the Costs of Nonoperative Care to Minimally Invasive Surgery for Sacroiliac Joint Disruption and Degenerative Sacroiliitis in a United States Medicare Population: Potential Economic Implications of a New Minimally-Invasive Technology** ► *Clinicoecon Outcomes Res.* 2013;5:575-87.	**Economic model comparing SI joint treatment costs (non-op vs. MIS SI joint fusion)** *196,452 Medicare beneficiaries with degenerative sacroiliitis or SI joint disruption annually*	Model extrapolated lifetime costs for hospital inpatient setting using 2005-2010 Medicare 5% Standard Analytic Files using primary ICD-9-CM and DRG codes. • Economic burden of treating LBP in the U.S. is significant • Lifetime costs for MIS SI joint fusion was $48,185/patient compared to $51,543/patient for non-operative care • $660 million potential lifetime savings to Medicare with MIS SI joint fusion (196,452 beneficiaries at $3,358 in savings/patient)
Graham Smith† 2013 **Open versus Minimally Invasive Sacroiliac Joint Fusion: A Multi-center Comparison of Perioperative Measures and Clinical Outcomes** ► *Ann Surg Innov Res* 2013;7:14.	**Retrospective, multicenter comparative review** **24-month outcomes** *263 patients* *(149 Open, 114 MIS)* *7 sites* *(3 Open, 4 MIS)*	MIS SI joint fusion had significantly better operative measures and outcomes than Open fusion. • No intraoperative complications with either Open or MIS procedure • MIS slightly lower complication rate (18%) compared to the open group (21%)

Mean (±SD)	Open	MIS	p-value
OR Time, min	163 (25)	70 (24)	< 0.0001
EBL, mL	288 (182)	33 (27)	< 0.0001
LOS, days	5.1 (1.9)	1.3 (0.5)	< 0.0001
VAS Pain			
Mean Chg 12mo	-2.7 (3.2)	-6.2 (3.1)	< 0.0001
Mean Chg 24mo	-2.0 (3.3)	-5.6 (3.5)	< 0.0001

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Gaetani*† *2013 **Percutaneous Arthrodesis of Sacro-iliac Joint: A Pilot Study** ▶ J Neurosurg Sci. 2013 Dec;57(4):297-301.	**Retrospective** **8-18 month follow-up** *10 consecutive patients (12 cases)*	• Operative Measures: Mean OR Time = 65±16 SD; Mean EBL was < 45 cc • Clinically & statistically significant mean improvement from baseline to last follow-up (all p=0.01) NRS pain (-4 points) ODI (-19.4 points) Roland-Morris Disability (-14.6 points) • High patient satisfaction • Low complication rate
Cummings**† *2013 **Minimally Invasive Sacroiliac Joint Fusion: One-Year Outcomes in 18 Patients** ▶ Ann Surg Innov Res. 2013;7:12	**Retrospective** **12-month follow-up** *18 patients*	• Clinically & statistically significant improvement in pain, back function & QOL from baseline to 12-month follow-up: VAS pain -6.56 points ($p < 0.001$); 90% patients ≥ 2 point change ODI -37.5 points ($p < 0.001$); 89% patients achieved Substantial Clinical Benefit (SCB defined as ≥ 18.8 point change or < 31.3 final score) SF-12 PCS +11.2 points mean improvement (32.3 to 44.6, $p < 0.005$) SF-12 MCS +20.4 points mean improvement (37.8 to 53.8, $p < 0.001$) • Low 5% major complication rate
Sachs**† *2013 **Minimally Invasive Sacroiliac Joint Fusion: One-Year Outcomes in 40 Patients** ▶ Adv Orthop. 2013;2013:536128.	**Retrospective** **12-month follow-up** *40 consecutive patients*	• Early (6 weeks) and sustained (12 months) clinically and statistically significant pain relief VAS pain improvement (-7.8 decrease from baseline to 12 mo, $p < 0.001$) No difference in clinical outcomes for patients with and without prior lumbar fusion • High patient satisfaction • Low complication rate
Miller*† *2013 **Analysis of the Postmarket Complaints Database for the iFuse SI Joint Fusion System®: A Minimally Invasive Treatment for Degenerative Sacroiliitis and Sacroiliac Joint Disruption** ▶ Med Device (Auckl). 2013;6:77-84.	**Prospective complaints database characterization** *5,319 patients (~16,000 implants) in the US and Europe from Apr 2009-Jan 2013, performed by 487 different surgeons.*	iFuse Implant System is a safe minimally invasive alternative to open SI joint fusion for patients refractory to conservative care • 3.8% overall complaint rate • 1.8% revision rate • Complaint rates compare favorably with open surgical and other MIS SIJ fusion systems • Decreasing complaint trend from 2009-2012
Sachs**† *2012 **One Year Successful Outcomes for Novel Sacroiliac Joint Arthrodesis System** *Ann Surg Innov Res.* 2012;6:13.	**Retrospective** **12-month follow-up** *11 consecutive patients*	• Statistically and clinically significant pain relief at 12 months: VAS pain improvement (-6.2 mean decrease from baseline, 7.9 to 2.3; $p < 0.000$) 80% of patients had clinically significant improvement (≥ 2 point drop from baseline) • Intra-operative blood loss < 50 mL in all cases • No intra-operative complications and no surgical revisions at 12 months
Rudolf**§‡ *2012 **Sacroiliac Joint Arthrodesis-MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes** *Open Orthop J.* 2012;6:495-502.	**Retrospective** **Min 24-month follow-up** *50 consecutive patients*	• Early and sustained statistically significant improvement in 7 of 9 QOL domains at all post-op time points • Clinically significant pain improvement (≥ 2 point drop) experienced by 78%, 85%, 71%, and 82% of the patients at 3, 6, 12, and mean 40 months respectively. • VAS pain: -5.6 mean improvement from baseline to minimum 24-mo follow-up (mean 40 mo, range 24-56 mo) • Patient satisfaction: 91% at 3 months and 82% at 6, 12, and mean 40 months. • Mean intra-op blood loss < 50 ml

* Paid SI-BONE consultant

† Compensated for providing clinical research services to SI-BONE

§ Ownership interest in SI-BONE

‡ Recipient of an SI-BONE research grant

PUBLICATIONS IN PROGRESS

Topic	Author(s)	Description	Status
SI Fusion: Open *vs.* MIS iFuse	*Ledonio, Polly*	**Retrospective, single-center comparison of 2 case series from University of Minnesota (2 surgeons within the same institution), perioperative measures.** 53 patients (26 Open vs. 27 MIS iFuse)	Submitted
	Ledonio	**Retrospective, single-center comparison of 2 case series from University of Minnesota (2 surgeons within the same institution), perioperative measures and ODI. 12-month follow-up.** 44 patients (22 Open vs. 22 MIS iFuse)	Accepted (publication pending)
	*Ledonio, Cummings**†*	**Retrospective, comparative analysis of 2 surgeons' case series, perioperative measures and ODI. 12-month follow-up.** 39 patients (22 Open vs. 17 MIS iFuse)	Submitted
iFuse Outcomes	*Rudolf**†§‡*	**Retrospective case series, minimum 5-year follow-up, radiographic analysis and clinical outcomes.** 15 patients	In progress
	(multiple)	**Retrospective case series. Multi-center outcomes.**	In progress
Prevalence	*Lorio*	MIS SI joint fusion prevalence, survey results of ISASS and SMISS members.	Accepted (publication pending)
Healthcare Economics	*Ackerman, Polly, et al.*	Medicare – Cost of non-operative care in SI joint treatment	Accepted (publication pending)
		Commercial – Cost of non-operative care in SI joint treatment	Accepted (publication pending)
		Commercial – Cost comparison: Non-op vs. MIS SI joint fusion	In progress

CLINICAL TRIALS IN PROGRESS

Evidence	Study	Description
Level I	**INSITE** Investigation of Sacroiliac Fusion Treatment *ClinicalTrials.gov ID:* ▶ NCT01681004	**iFuse vs. Non-surgical Management (USA)** • Multicenter, Prospective, Randomized Controlled Trial (RCT) • 200 patients, up to 30 sites • Follow-up: 1, 3, 6, 12, 18, and 24 months • Endpoints: VAS SI joint pain, back pain, ODI, QOL (SF-36 and EQ-5D), ambulatory status, return to work, AEs
	iMIA iFuse Implant System® Minimally Invasive Arthrodesis *ClinicalTrials.gov ID:* ▶ NCT01741025	**iFuse vs. Non-surgical Management (EU)** • Multicenter, Prospective, Randomized Controlled Trial (RCT) • 100 patients • Follow-up: 1, 3, 6, 12, and 24 months • Endpoints: Low back pain, leg pain, ODI, EQ-5D, work status, Zung depression scale, ASLR (functional test), walking distance, patient satisfaction, AEs, device complications
	VaReFi Validity and Reliability of Diagnostic Findings of SI Joint Blocking *ClinicalTrials.gov ID:* ▶ NCT01874236	**Diagnosis Injections Evidence Trial (USA)** • Multicenter, Prospective, Double Blinded, Randomized Controlled Trial (RCT) • 80 patients • Purpose: confirm the validity and reliability of diagnostic SI joint blocks • Subjects with suspected SI joint pain will undergo 3 SI joint blocks each separated by a week: 2 local anesthetic, 1 saline placebo (randomly assigned)
Level II/III	**SIFI** Sacroiliac Joint Fusion with iFuse Implant System *[Enrollment complete; Follow-up ongoing]* *ClinicalTrials.gov ID:* ▶ NCT01640353	**Prospective iFuse Outcomes Trial (USA)** • Multicenter, Prospective, Single-arm • 250 patients, up to 30 sites • Follow-up: 1, 3, 6, 12, 18, and 24 months • Endpoints: VAS SI joint pain, back pain, ODI, QOL (via SF-36 and EQ-5D), ambulatory status, return to work, AEs

The iFuse Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant. Please review the iFuse Instructions For Use for a complete discussion of contraindications, warnings, precautions, and risks.

SI-BONE® | **iFuse** Implant System®
Minimally Invasive Sacroiliac Joint Surgery

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