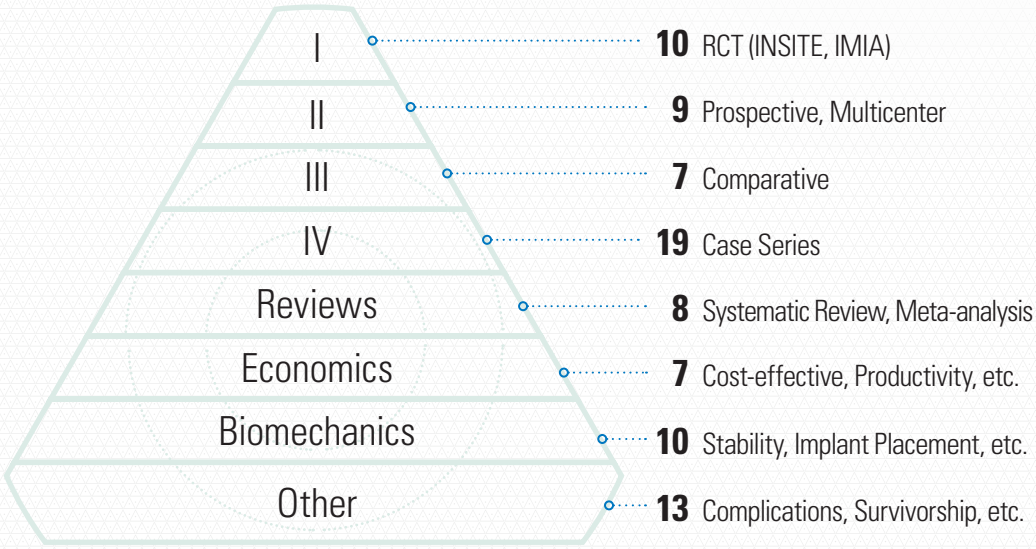
SI-BONE® | iFuse Implant System®
Minimally Invasive Sacroiliac Joint Surgery



iFuse Implant System™
Clinical Publications

February 2020

What's inside

This document lists **all** of the currently known peer-reviewed publications with results or data relating to the iFuse Implant System®. The publications are grouped by level of evidence (Level I, II, III, etc.). Each publication has the article title, number of patients involved in the study (if applicable), a brief description, along with a summary of the results.

Articles that are "open access" are designated by an orange open lock symbol (). The electronic (PDF) version of this listing of iFuse publications includes hyperlinks to the articles when available. Simiply click/tap on a row to be redirected to that article. Information about the prospective trials posted on ClinicalTrials.gov can be accessed through the respective trial identification number links below.

More information is available at SI-BONE.com/results

Prospective Clinical Trials on *ClinicalTrials.gov*

INSITE	NCT01681004
iMIA	NCT01741025
SIFI	NCT01640353
LOIS	NCT02270203
SALLY	NCT03122899

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	Article	Patients	Description	Results
LEVEL I - RANDOMIZED CONTROLLED TRIAL (10)	**Dengler – *JBJS Am* 2019** Randomized Trial of Sacroiliac Joint Fusion vs. Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint.	52 iFuse 51 CM	**iMIA Clinical Trial** Prospective, multicenter (9 sites, 4 European countries), randomized controlled trial 2-year results	**For chronic SI joint pain, iFuse provided safe and more effective improvement through 2 years in pain, disability, quality of life, and leg function than Conservative Management (CM).** iFuse provided clinically important improvements that were rapid (1 mo) and sustained (24 mo).
	Dengler – *Global Spine J* 2018 *[Epub 2017 Oct 5]* Risk Factors for Continued Opioid Use in Conservative Versus Surgical Management of Low Back Pain Originating From the Sacroiliac Joint	52 iFuse 49 CM	**iMIA Trial Data** Objective to identify risk factors for continued opioid use after conservative management (CM) or minimally invasive sacroiliac joint fusion (iFuse)	**Baseline** – opioid users had higher mean levels of disability (ODI) and depression scores (Zung) compared to non-opioid users. **6-mo Follow-up** – opioid users had higher pain, disability, and depression scores compared to non-opioid users. Risk Factors for continued opioid use: • CM – Patient age and increase in low back pain • iFuse – lack of improvement in depression scores
	Dengler – *Pain Physician* 2017 1-year Results of Randomized Controlled Trial of Conservative Management *vs.* Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain.	52 iFuse 51 CM	**iMIA Clinical Trial** Prospective, multicenter (9 sites, 4 European countries), randomized controlled trial 12-mo follow-up *(See 2-year results above)*	**iFuse provided superior improvements in pain, disability, function, and QOL** compared to the small improvements from Conservative Management (CM). iFuse improvements were rapid (1 mo), persisted to 12 mo, as well as clinically important and statistically significant.
	Dengler – *Spine* 2017 Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint – A Pooled Analysis	326 iFuse 97 NSM	Pooled, patient-level analysis of 2 RCTs (INSITE, iMIA) and 1 prospective, multicenter trial (SIFI) INSITE 2-year results iMIA 1-year results SIFI 2-year results	**iFuse produce significantly better results than NSM at 6 mo.** Predictors of outcome with iFuse: • Patients that are older and had longer pain duration had better improvement in pain and disability • Smokers and opioid users still derived significant benefit, but predicted poorer outcomes than non-users No predictors of outcome were found for NSM.
	Dengler – *Acta Neurochir* 2016 Referred Leg Pain Originating from the Sacroiliac Joint: 6-Month Outcomes from the Prospective Randomized Controlled iMIA Trial	52 iFuse 49 CM	**iMIA Clinical Trial** Prospective, multicenter (9 sites, 4 European countries), randomized controlled trial Effect on SIJ-associated referred leg pain (pain below the gluteal fold) 6-mo results	iFuse helped relieve referred leg pain (58.0 at baseline to 13.5 at 6 months) more effectively than Conservative Management (CM) which provided no significant improvement.
	Polly – *Int J Spine Surg* 2016 Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion *vs.* Nonsurgical Management for Sacroiliac Joint Dysfunction	102 iFuse 46 NSM	**INSITE Clinical Trial** Prospective, multicenter (19 sites), randomized controlled trial 2-year results	**iFuse provided superior results (pain, disability and QOL) compared to Non-Surgical Management (NSM), at 6 months.** Improvements after iFuse persisted to 24 months. • SI joint pain – mean decrease 55 points • Disability (ODI) – mean decrease 28 points No difference between groups for mean number of adverse events per subject in the first 180 days.

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	Article	Patients	Description	Results
LEVEL I - RANDOMIZED CONTROLLED TRIAL (10) *cont.*	**Sturesson – *Eur Spine J* 2016** Six-Month Outcomes from a Randomized Controlled Trial of Minimally Invasive SI Joint Fusion with Triangular Titanium Implants *vs.* Conservative Management	52 iFuse 51 CM	**iMIA Clinical Trial** Prospective, multicenter (9 sites, 4 European countries), randomized controlled trial 6-mo follow-up *(See 1- and 2-year results above)*	**At 6 months, iFuse provided superior outcomes over Conservative Management (CM) in:** • Pain relief (VAS LBP) • Disability reduction (ODI) • Functional improvement (ASLR) • Quality of life improvement (EQ-5D) 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).
	Polly – *Int J Spine Surg* 2016 Does Level of Response to SI Joint Block Predict Response to SI Joint Fusion?	320 (148 INSITE, 172 SIFI)	Correlation of SI joint block relief with SI joint fusion outcomes using data from prospective, multicenter trials (INSITE and SIFI). 6- and 12-mo results	Degree of pain improvement from SI joint block did not predict improvements in pain and ODI after SI joint fusion. 50% SI joint block threshold resulted in excellent SI joint fusion responses. Selection criteria of ≥75% SI joint block relief is overly stringent and would withhold a beneficial procedure from patients with SI joint dysfunction.
	Polly – *Neurosurgery* 2015* Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants *vs.* Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes **Received "Editor's Choice" distinction and was featured on the cover of the November 2015 issue*	102 iFuse 46 NSM	**INSITE Clinical Trial** Prospective, multicenter (19 sites), randomized controlled trial. 12-mo follow-up *(See 2-year results above)*	**iFuse is more effective than NSM at 12 months in relieving pain, improving function, and improving QOL in patients with SI joint dysfunction.** • iFuse group – clinical improvement at 6 mo was sustained to 12 mo • NSM group – small improvement at 6 mo. Nearly 80% crossed over to surgery after 6 mo and subsequently had clinical improvement in pain, function, and QOL similar to subjects originally randomized to iFuse. iFuse provided more clinically important improvement *vs.* NSM: • VAS SI joint pain (≥20 pt drop): 86.1% *vs.* 12.5% of subjects • ODI (≥15 pt drop): 72.4% *vs.* 10.0% of subjects Complications: similar adverse event rate per subject between groups at 12 mo (1.8 iFuse *vs.* 1.9 NSM, p=0.45).
	Whang – *Int J Spine Surg* 2015 Sacroiliac Joint Fusion Using Triangular Titanium Implants *vs.* Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial	102 iFuse 46 NSM	**INSITE Clinical Trial** Prospective, multicenter (19 sites), randomized controlled trial. 6-mo Primary Endpoint follow-up *(See 12-mo and 2-year results above)*	**iFuse provided superior clinical 6-month outcomes compared to NSM in patients with severe SI joint dysfunction:** • Better pain relief (VAS) • Better Improvement in back function (ODI) • Better quality of life (SF-36 and EQ-5D) • Better patient satisfaction Complications: adverse events were slightly more common (not statistically significantly) with surgical group *vs.* NSM (1.3 *vs.* 1.0 mean number of AEs per subject, p=0.1857).

See publications at
www.si-bone.com/results

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	Article	Patients	Description	Results
LEVEL II - PROSPECTIVE, MULTICENTER (9)	**Whang – *Med Devices Evid Res* 2019** Long-Term Prospective Clinical and Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants	93	**LOIS Clinical Trial** Prospective, multicenter (12 centers), long-term follow-up of patients enrolled in INSITE or SIFI 5-year Results	**Long-term sustained clinically important improvement in pain, disability and quality of life from baseline to 5 years:** • 54-point improvement (decrease) in SI joint pain • 26-point improvement (decrease) in back function [ODI] • 0.3-point improvement (increase) in QOL [EuroQol-5D] • 95% of subjects were very or somewhat satisfied **Opioid Reduction:** pre-surgery 77% of subjects used opioids compared to 41% at 5-year follow-up. **Safety:** 1 device-related adverse event, 1 procedure-related serious adverse event, and 3 revisions. **Radiographic Outcomes:** 88% of subjects had bridging bone with the SI joint.
	Patel – *Med Devices Evid Res* 2019 Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants	28	**SALLY Clinical Trial** Prospective, multicenter (8 centers), single-arm clinical trial treating patients with the iFuse-3D implant 6-month interim results (trial continues through 5 years)	**Early results confirm the clinical response to SI joint fusion with iFuse-3D implants is similar to prior trials (INSITE, iMIA, SIFI).** • 51-point improvement (decrease) in SI joint pain • 24-point improvement (decrease) in back function [ODI] • Physical function improved significantly • Opioid use decreased Safety: zero device-related and 4 procedure-related adverse events.
	Darr – *Med Devices Evid Res* 2018(b) Four-year Outcomes after Minimally Invasive Trans-Iliac Sacroiliac Joint Fusion with Triangular Titanium Implants	93	**LOIS Clinical Trial** Prospective, multicenter (12 sites), long-term follow-up of patients enrolled in INSITE and SIFI 4-year follow-up *(See 5-year results above)*	**Continued clinically important improvement in pain, disability and quality of life from baseline to 4 years:** • 54-point improvement (decrease) in SI joint pain • 26-point improvement (decrease) in back function [ODI] • 0.3-point improvement (increase) in QOL [EuroQol-5D] • 96% of subjects were very or somewhat satisfied Daily opioid use decreased from 77% of subjects pre-surgery to 43% at 4-year follow-up. No procedure or device-related adverse events between years 3 and 4.
	Darr – *Med Devices Evid Res* 2018(a) Long-term Prospective Outcomes After Minimally Invasive Trans-iliac Sacroiliac Joint Fusion Using Triangular Titanium Implants	96	**LOIS Clinical Trial** Prospective, multicenter (12 sites), long-term follow-up of patients enrolled in INSITE and SIFI 3-year follow-up *(See 5-year results above)*	**Sustained clinically important long-term improvements from baseline to 3 years:** • 55-point improvement (decrease) in SI joint pain • 28-point improvement (decrease) in back function [ODI] • 0.3-point improvement (increase) in QOL [EuroQol-5D] • 96% of subjects were very or somewhat satisfied After 3 years, one patient had revision surgery (at year 3.7) due to modest SI joint pain from index procedure. Five subjects underwent contralateral SI joint fusion.
	Duhon – *Int J Spine Surg* 2016 Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-year Follow-up from a Prospective Multicenter Trial	172	**SIFI Clinical Trial** Prospective, multicenter (26 sites), single-arm clinical trial 2-year results	**Clinically important and statistically significant long-term improvements in pain, disability and quality of life after iFuse** • Improvements at 6 and 12 months maintained to 2 years • Treated patients approaching normal values • No variation in response by diagnosis, history of prior lumbar fusion, smoking, or bi/unilateral procedure **Favorable safety profile** • 4.7% revision rate (8 subjects) • 7 device-related adverse events **28% reduction in opioid use from baseline to 2 years**
	Capobianco – *SpringerPlus* 2015 Safety and Effectiveness of Minimally Invasive Sacroiliac Joint Fusion in Women with Persistent Post-partum Posterior Pelvic Girdle Pain: 12-month Outcomes from a Prospective, Multi-center Trial	20 PPGP females (subset of SIFI 172)	Post-partum pelvic girdle pain (PPGP) females from a prospective, multicenter (26 sites), single-arm clinical trial (SIFI) 12-mo follow-up	PPGP subjects younger than no-PPGP females and males in the study Significant improvement in pain (VAS), back function (ODI), and QOL (SF-36 and EQ-5D) at 1 mo was sustained for 12 mo. Results reflect the overall study results.

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	Article	Patients	Description	Results
LEVEL II (9) *cont.*	**Duhon – *Global Spine J* 2016** *[Epub 2015 Aug 11]* Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study	172	**SIFI Clinical Trial** Prospective, multicenter (26 sites), single-arm clinical trial 12-mo follow-up *(See 2-year results above)*	Clinically important improvement in pain (VAS), back function (ODI), and QOL (SF-36 and EQ-5D) at 6 mo was sustained for 12 mo. High patient satisfaction at 6 mo (93.5%) and 12 mo (87.2%). High overall treatment success at 6 mo (80.5%) and 12 mo (79.6%). Acceptable safety profile: Adverse events device-related (2.9%), procedure-related (12.2%), revisions (2.3%).
	Cher – *Global Spine J* 2016 *[Epub 2015 Jun 25]* Improvement in Health State Utility after Sacroiliac Joint Fusion: Comparison to Normal Populations	172 iFuse	Health state utility before and after SI joint fusion (patients from SIFI), and comparison to normal cohort 6- and 12-mo follow-up	Baseline values indicate severe disability that is substantially depressed compared to age- and gender-matched normal individuals. MIS SI joint fusion using the iFuse Implant System: • Significantly improved the subjects overall QOL at 6 and 12 months post-surgery • Brought subjects back toward expected levels of overall health
	Duhon – *Med Devices Evid Res* 2013 Safety and 6-month Effectiveness of Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study	94 Safety 32 Effectiveness	**SIFI Clinical Trial** Prospective, multicenter (26 sites), single-arm clinical trial. 6-mo interim analysis. *(See 2-year results above)*	Clinically and statistically significant improvement in pain (VAS), back function (ODI), and QOL (SF-36 and EQ-5D). High patient satisfaction (85%). 6 severe adverse events, none device-related.

	Article	Patients	Description	Results
LEVEL III - CLINICAL COMPARISON (7)	**Claus – *World Neurosug* 2019** Minimally Invasive Sacroiliac Joint Fusion using Triangular Titanium vs. Cylindrical Threaded Implants: a comparison of patient-reported outcomes	82 iFuse 74 CTI	Retrospective review, comparing SI joint fusion with cylindrical threaded implants (CTI, Rialto) to iFuse Implants 12-month follow-up	**Outcomes at 6 and 12 months** • Both implants provided significant improvement in pain (VAS leg and back), function (ODI), or quality of life (SF-12) • No significant difference between implants **Procedure:** iFuse procedure was significantly shorter than procedure with CTI (41 min vs. 60 min, p<0.0005) **Revision Rate:** iFuse = 2.4%, CTI = 6.1%
	Vanaclocha – *Br J Neurosurg* 2018 High Frequency of Lumbar Fusion in Patients Denied Surgical Treatment of the Sacroiliac Joint	30 iFuse 56 RF 103 CM	Retrospective, single-center, study to determine whether under recognition of SI joint pain in LBP patients affects healthcare treatment	SI joint pain patients who were denied surgical treatment had a: • longer pain duration • higher likelihood of prior lumbar fusion • high rate (63%) of lumbar fusion within 2 years prior to SI joint pain Lack of SI joint pain education and its role in chronic LBP, results in diagnostic confusion and may lead to misdirected treatment.
	Vanaclocha – *Neurosurgery* 2017 Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation and Conservative Management for Sacroiliac Joint Pain: Six Year Comparative Study	27 iFuse 47 RF 63 CM	Retrospective, single-center, comparison of iFuse vs. radiofrequency ablation (RF) and Conservative Management (CM) Out to 6 years follow-up	**iFuse outcomes** • Markedly superior pain relief and ODI compared to RF and CM • Maintained clinically important improvement in pain and back function long-term • Decreased opioid users from baseline to last follow-up • Improved work status **RF and CM** • Provided only temporary pain relief and function improvement • Increased opioid user • Worsened work status
	Spain – *Int J Spine Surg* 2016 Surgical Revision after Sacroiliac Joint Fixation or Fusion	263 iFuse (fusion) 29 screws (fixation)	Retrospective, single-center, revision rate comparison iFuse vs. iFuse 4-yr cumulative revision rate	Lower 4-year revision rate after fusion with iFuse (5.7%) compared to fixation with screws (30.8%) (p<0.0001 for diff.). Subgroup analysis showed implant used was the only predictor of revision.
	Ledonio – *Med Devices Evid Res* 2014 Comparative Effectiveness of Open Versus Minimally Invasive Sacroiliac Joint Fusion	17 iFuse 22 Open	Retrospective, two-center, comparison Open *vs.* iFuse 12-mo follow-up	Both Open and iFuse provided significant ODI improvement. MIS SI joint fusion provided greater ODI improvement, shorter OR time and shorter hospital stay than Open.
	Ledonio – *Clin Orthop Relat Res* 2014 Minimally Invasive Versus Open Sacroiliac Joint Fusion: Are They Similarly Safe and Effective?	22 iFuse 22 Open	Retrospective, single-center, comparison Open *vs.* iFuse Minimum 12-mo follow-up	iFuse patients had significantly less estimated blood loss, shorter OR time, and spent fewer days in hospital compared to Open. Both Open and iFuse provided significant ODI improvement with no difference between the groups.
	Smith – *Ann Surg Innov Res* 2013 Open versus Minimally Invasive Sacroiliac Joint Fusion: A Multi-Center Comparison of Perioperative Measures and Clinical Outcomes	114 iFuse 149 Open	Retrospective, multicenter (7 surgeons), comparison Open *vs.* iFuse. 12- and 24-mo follow-up	MIS provided better operative measures (estimated blood loss, OR time, length of hospital stay) and greater pain relief than Open surgery at 12 and 24 months.

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LEVEL IV - CASE SERIES (19)	**Cleveland – *J Spine Surg* 2019** Mini-open sacroiliac joint fusion with direct bone grafting and minimally invasive fixation using intraoperative navigation	50	Retrospective, single-center 12-month follow-up	Mini-open SI joint fusion with iFuse, intraoperative navigation, and direct open bone grafting is safe and provides clinical benefit – improvement in pain, disability, and QOL. 3.5% complication rate and no revisions.
	Rainov – *Eur Spine J* 2018 Triangular Titanium Implants for Sacroiliac Joint Fusion	160	Retrospective, single-center 12-month follow-up	Fuse provided significant improvement in pain and disability in treating patients with SI joint dysfunction.
	Bornemann – *Technol Health Care* 2016 2-year Clinical Results of Patients with Sacroiliac Joint Syndrome Treated by Arthrodesis Using A Triangular Implant System	24	Retrospective, single-center 2-year results	Clinically significant improvement in VAS pain scores and ODI by 1 month that was maintained through 2 years. No adverse events, intraoperative complications, implant malpositioning or loosening.
	Sachs – *Med Devices Evid Res* 2016 Durable intermediate-to Long-Term Outcomes After Minimally Invasive Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants	107	Retrospective cohort study with a prospective evaluation (7 centers) Mean 3.7-year follow-up (range 3.0-4.7 years)	Highly debilitated subjects had durable and clinically important improvements in pain (VAS SI joint pain), disability (ODI), and activities of daily living. High patient satisfaction (87.9%). Procedure-related complications were uncommon (3 events). Low revision rate (4.7%).
	Bornemann – *Z Orthop Unfall* 2016 Clinical Trial to Test the iFuse Implant System in Patients with Sacroiliac Joint Syndrome: One Year Results	24	Retrospective, single-center 12-mo follow-up *(See 2-year results above)*	Clinically important VAS pain reduction (58 points). Clinically important ODI improvement (median 44 points). 63% (15 patients) were off pain killers at 12 months.
	Manfré – *Interv Neurorad* 2014 Percutaneous Sacroiliac Joint Fixation in Sacroiliac Instability: The First Case Report Using a Fully CT-Guided Technique	1	Case report 3-wk and 4-mo follow-up	3 weeks post-op: pain almost completely resolved, able to walk painlessly without crutches, no pain during SI joint provocative tests, CT demonstrated SI fixation. 4 months post-op: mild bone reaction was appreciated and increased on CT, patient remained painless.
	Rudolf – *Open Orthop J* 2014 Five-Year Clinical and Radiographic Outcomes After Minimally Invasive Sacroiliac Joint Fusion Using Triangular Implants	17	Retrospective, single-center 5-year follow-up	Clinically important pain relief at 12 mo, maintained for 5 years. 5-year mean ODI (21.5) indicates minimal/moderate disability. X-ray and CT imaging showed increased bone density along walls of all implants, no evidence of implant loosening, and 87% had intraarticular bony bridging.
	Vanaclocha – *J Spine* 2014 Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients	24	Retrospective, single-center Mean 23.3-mo follow-up (range 1-4.5 years)	Significant rapid and sustained improvement in VAS Pain and ODI. Marked reduction in analgesic usage (no patient taking opioids 1 year post-op). Return to work a mean 47.4 days post-op (range 30-67 days). Patient satisfaction 92% (22/24) at 1 year post-op. No intra-op or post-op major complications, no blood transfusions, no device failures.

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LEVEL IV - CASE SERIES (19) *cont.*	**Sachs – *Med Devices Evid Res* 2014** One-year Outcomes after Minimally Invasive Sacroiliac Joint Fusion with a Series of Triangular Implants: A Multicenter, Patient-Level Analysis	144	Retrospective, multicenter (6 sites). Mean 16-mo follow-up (range 12-26 mo)	Mean VAS pain improvement of 6.1 points from baseline to mean 16-mo follow-up. Over 90% of patients experienced clinically important improvement in pain with no differences for age or prior lumbar fusion.
	Scheyerer – *ISRN Min Invasive Surg* 2014 Implant-Bone Interface of Sacroiliac Joint Fusion Using iFuse Implant System	8 (10 SI joints)	Retrospective, single-center Assess stability and bone ingrowth using SPECT/CT Mean 5.8 mo follow-up	80% of SI joints had visually satisfying osseous integration as well as stability within the SI joint after iFuse.
	Schroeder – *HSS J* 2013 Early Results of Sacro-Iliac Joint Fixation Following Long Fusion to the Sacrum in Adult Spine Deformity	6	Retrospective, single-center, deformity patients with prior long-fusion to sacrum. Mean 10.25-mo follow-up (range 4-15 mo)	Prior long-fusion patients that developed SI joint pain and failed conservative treatment had reduced pain (VAS) and improved back function (ODI) after the iFuse procedure.
	Gaetani – *J Neurosurg Sci* 2013	10	Retrospective, single-center. Mean 10-mo follow-up (range 8-18 mo)	Clinically and statistically significant pain relief (VAS), and improvement in back function (ODI) and QOL (Roland-Morris Questionnaire).
	Cummings – *Ann Surg Innov Res* 2013	18	Retrospective, single-center. 12-mo follow-up	Clinically and statistically significant improvement in pain (VAS), back function (ODI), and QOL (SF-12).
	Sachs – *Adv Orthop* 2013	40	Retrospective, single-center. 12-mo follow-up	Rapid (6-wk) and sustained (12-mo) pain relief. High patient satisfaction.
	Rudolf – *Open Orthop J* 2013	40	Retrospective, single-center 24-mo follow-up	Significant pain relief regardless of prior lumbar fusion or prior treated lumbar pathology.
	Kim – *Open Orthop J* 2013	31	Retrospective, single-center	Good pain relief and high patient satisfaction. Radiographic evidence (CT scan) of bone ingrowth at 6 months.
	Sachs – *Ann Surg Innov Res* 2012	11	Retrospective, single-center 12-mo follow-up	Clinically significant pain relief. High patient satisfaction.
	Lokietek – *Le Rachis* 2012 *[In French]*	10	Retrospective, single-center	Decreased pain and improved function. Good or very good patient satisfaction.
	Rudolf – *Open Orthop J* 2012	50	Retrospective, single-center Mean 40-mo follow-up (range 24-56 mo)	Rapid (6-wk) and sustained (mean 40-mo) pain relief. High patient satisfaction.

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REVIEWS (8)	**Lodin – *Cesk Slov Neurol N* 2019** A Systematic Review of the Clinical Efficacy of Sacroiliac Joint Stabilization in the Treatment of Lower Back Pain	27 studies (14 iFuse)	Systematic Review	27 studies, including 14 with iFuse data. Reports mean improvement in pain (4.6 points) and ODI (25 points). Low overall morbidity. SI joint fusion is feasible and effective for properly selected patients.
	Yson – *PM R* 2019 Sacroiliac Joint Fusion: Approaches and Recent Outcomes	—	Review	In properly selected patients, SI joint fusion is a viable treatment option with minimally invasive procedure preferred over open
	Whelan – *Tech Orthop* 2019 The Evidence for Sacroiliac Joint Surgery	—	Review of diagnosis and treatments for SI joint dysfunction Reviews data from iFuse trials (SIFI, INSITE, iMIA), as well as SI-LOK and SImmetry.	Diagnosis of SI joint dysfunction should include use of composites of physical exam tests and SI joint injections. Firstline treatment should include 6-months of conservative treatment before considering surgery. After failed conservative management, surgery is being considered, minimally invasive techniques are preferred.
	Shamrock – *Global Spine J* 2019 The Safety Profile of Percutaneous Minimally Invasive Sacroiliac Joint Fusion	14 Studies (720 patients)	Systematic review to determine the safety of MIS SI joint fusion	MIS SI joint fusion is a relatively safe procedure but not without risks with the most common adverse event being surgical wound infection/drainage. Clinical outcomes include improvement in pain and disability.
	Tran – *Pain Physician* 2019 Sacroiliac Joint Fusion Methodology – Minimally Invasive Compared to Screw-Type Surgeries: A Systematic Review and Meta-Analysis	20 Studies	Systematic Review and Meta-analysis Compares iFuse to screw-type SI joint fusions	Study data pooled into 3 outcomes – Pain, Disability/Physical Function, and Global/QOL. iFuse treated patients had significantly better outcomes in all three categories.
	Lingutla – *Eur Spine J* 2016 Sacroiliac Joint Fusion For Low Back Pain: A Systematic Review and Meta-analysis	407 (92 Open 315 MIS)	Systematic review and meta-analysis Mean 17.6-mo follow-up	6 studies included in the meta-analysis (4 were iFuse studies: Duhon 2013, Ledonio – CORR 2014, Rudolf 2014, and Sachs 2014). Reports results on pain, ODI, SF-36, and Majeed Score. SI joint fusion appears to be a satisfactory procedure for alleviation of SI joint pain.
	Heiney – *Int J Spine Surg* 2015 A Systematic Review of Minimally Invasive Sacroiliac Joint Fusion Utilizing A Lateral Transarticular Technique	432 (368 iFuse) Lateral trans-articular technique only	Systematic review with random effects meta-analysis on select variables	MIS SI joint fusion provided consistent, rapid, sustained and clinically important improvement in SI joint pain (~5 point drop, VAS 0-10 scale) and disability (~30 point drop, ODI 0-100 scale). Confirmed MIS characteristics: minimal blood loss, short OR time, and short length of hospital stay. Typical, low rate of complications.
	Zaidi – *J Neurosurg Spine 2015* Surgical and Clinical Efficacy of Sacroiliac Joint Fusion: A Systematic Review of the Literature	430 (131 open 299 MIS)	Systematic review Mean follow-up: 60-mo open 21-mo MIS	16 articles included: 5 consecutive case series, 8 retrospective, 3 prospective (5 were iFuse studies: Rudolf 2012, Cummings 2013, Duhon 2013, Sachs 2013, Ledonio – CORR 2014) Surgical intervention for SI joint pain is beneficial in a subset of patients. However, with the difficulty in accurate diagnosis and evidence for the efficacy of SI joint fusion itself lacking, serious consideration of the cause of pain and alternative treatments should be given before performing the operation.

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ECONOMICS (7)	**Dale – *Appl Health Econ Health Policy* 2019** iFuse Implant System for Treating Chronic Sacroiliac Joint Pain: A NICE Medical Technology Guidance	—	Medical technology assessment of iFuse for minimally invasive SI joint fusion by the UK National Institute for Health and Care Excellence (NICE)	NICE published guidance in October 2018 recommending that the case for adoption of the iFuse Implant System in the UK National Health Service (NHS) was supported by clinical evidence.
	Cher – *Tech Orthop* 2019 Health Care Economics of SI Joint Fusion	—	Review: Evaluates published evidence with respect to clinical and economic value	Substantial, high-quality evidence supports SI joint fusion with iFuse for patients with chronic SI joint dysfunction. Other products have limited evidence. Treatment with iFuse shows sustained improvements in pain, disability, and quality of life with incremental cost-effectiveness ratios at least as good as high-volume orthopedic procedures and lower than other spine surgeries.
	Frank – *Clinicoecon Outcomes Res* 2016 Work Intensity in SI Joint Fusion and Lumbar Microdiscectomy	192 patient charts (4 sites) who underwent MIS SI joint fusion or lumbar micro-discectomy	Measures physician work for MIS SI joint fusion related to pre-op diagnosis and patient care, intra-op, and post-op care to assess RVUs (relative value units) and compare to lumbar microdiscectomy	MIS SI joint fusion, relative to lumbar microdiscectomy, had: • Shorter procedure and OR time • Longer pre- and post-service time • Higher number of post-op patient visits • Higher total service time (pre-op + OR time + post-op) • Higher intra-op intensity levels (mental, temporal, & physical demands, effort, frustration) The work RVU for MIS SI joint fusion is comparable to lumbar microdiscectomy and should be adjusted upwards commensurate to the relative amount of work required.
	Saavoss – *Clinicoecon Outcomes Res* 2016 Productivity Benefits of Minimally Invasive Surgery in Patients with Chronic Sacroiliac Joint Dysfunction	Data from National Health Interview Survey, and INSITE and SIFI	Assess changes in worker productivity after treatment with iFuse or non-surgical management	SI joint pain patients treated with iFuse may improve worker productivity compared to non-surgically treated patients Patients treated with iFuse had a • 16% increase in probability of working • $6,924 annual increase in productivity
	Polly – *Clinicoecon Outcomes Res* 2016 Ignoring the Sacroiliac Joint in Chronic Low Back Pain is Costly	Outcomes data from INSITE and SIFI, and LF studies	Model calculating 2-year direct health care costs in patients with chronic LBP considering lumbar fusion (LF) surgery	Including SI joint evaluation as part of diagnostic strategy in chronic LBP patients is likely to save money • Approximately $3100 savings/patient over 2 years • May avoid unnecessary lumbar fusions
	Cher – *Clinicoecon Outcomes Res* 2016 Cost-effectiveness of Minimally Invasive Sacroiliac Joint Fusion	Cost-utility model using SIFI and INSITE subjects	Markov model to evaluate 5-year health quality and US costs	Compared to non-surgical management for SI joint dysfunction, SI joint fusion with iFuse is a • cost-effective treatment • cost-savings treatment in the long-term Cost-effectiveness of MIS SI joint fusion is similar to hip and knee arthroplasty
	Garber – *Int J Spine Surg* 2015 How Much Work Effort is Involved in Minimally Invasive Sacroiliac Joint Fusion?	50 iFuse 89 PLD	Utilization for performing MIS SI joint fusion compared to primary lumbar discectomy (PLD) Retrospective review of prospectively collected data	Surgical time was comparable between MIS SI joint fusion (112 min) and PLD (119 min). Post-op work was greater for MIS SI joint fusion. Relative value units (RVUs) should be at a minimum equivalent to PLD.

Indicates open access article

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. Some research described herein was supported by SI-BONE.

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	Article	Patients	Description	Results
BIOMECHANICS (10)	**Casaroli – *Med Eng Phys* 2019** What do we know about the biomechanics of the sacroiliac joint and of sacropelvic fixation? A literature review.	Biomechanical Review (126 articles)	Summary of the biomechanics of the SI joint and sacropelvic fixation techniques. Defines experimental protocols as well as numerical modeling of the sacropelvic structures.	Complex anatomical features and variability of the SI joint make studying it very challenging. The kinematics and biomechanical behavior of SI joint have been extensively investigated according to in vivo, cadaveric, and numerical approaches. Summary: • Sacrum movement of is constrained by a strong ligament network and by its complex geometry • SI joint movement (rotation and displacement) can be larger with loss of ligament stiffness or structural changes • SI joint movement is multidimensional and within a small range, but with individual variability • Hard to validate and compare studies (in silico and FE mod-els) due to large anatomical variability and complex ligament structure
	Galbusera – *Eur Spine J* 2019 Biomechanics of Sacropelvic Fixation: A Comprehensive Finite Element Comparison of Three Techniques	FEA Model	Sacropelvic fixation in long posterior lumbar instrumentation and the effects of 3 techniques: • iliac screws (IL) • S2 alar-iliac screws (S2AI) • iFuse implants placed laterally (SI) *Boundary Condition: models for potential device loosening*	iFuse (SI) did not result in increased stress on the lumbosacral instrumentation, likely due to the lack of connection with the posterior rods. IL and S2AI had a mild protective effect on pedicle screws in terms of stresses and bone-implant loads. IL increased rod stresses.
	Joukar – *JOR Spine* 2019 Effects On Hip Stress Following Sacroiliac Joint Fixation: A Finite Element Study	FEA Model	Spine-sacroiliac-hip model was developed to study the effects SI joint fixation with iFuse (unilateral and bilateral) has on the hip	iFuse imparted little change in stress to the hip. • Average hip contact stress was ~2 MPa, with most change in motion being < 5% • Hip contact area changed < 10% for any motion
	Casaroli – *Eur Spine J* 2019 Evaluation of Iliac Screw, S2 Alar-Iliac Screw And Laterally Placed Triangular Titanium Implants For Sacropelvic Fixation In Combination With Posterior Lumbar Instrumentation: A Finite Element Study	FEA Model	Sacropelvic fixation in long posterior lumbar instrumentation and the effects of 3 techniques: • iliac screws (IL) • S2 alar-iliac screws (S2AI) • iFuse implants placed laterally (SI) *Boundary Condition: models full osteointegration with devices*	Implant stresses after S2AI and iFuse (SI) fixations were lower than those attributable to pedicle and iliac screws (IL). Long construct instrumentation may have lower risk of mechanical failure when coupled with S2AI screws or iFuse implants (SI).

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	Article	Patients	Description	Results
BIOMECHANICS (10) *cont.*	**Jeong – *World Neurosurg* 2018** Assessment of Biomechanical Changes After Sacroiliac Joint Fusion by Application of the 3-Dimensional Motion Analysis Technique	8 cadaveric specimens	New biomechanical method to assess SI joint range of motion (ROM) in 3 groups: intact, unilateral fusion, bilateral fusion	Statistically significant greater mobility in lateral mobility testing than in single motion testing. Comparisons among the intact, unilateral fusion, and bilateral fusion groups showed statistically significant differences in the lateral moment test.
	Lindsey – *World J Ortho* 2018 Sacroiliac joint stability: Finite element analysis of implant number, orientation, and superior implant length	FEA model	Analyze various implant placement variables on SI joint range of motion (ROM)	Best SI joint stabilization is achieved with: • 3 implants provided greatest reduction in ROM, better than 2 • Longer superior implant, reaching mid-sacrum • Implants furthest apart
	Lindsey – *J Neurosurg Spine* 2018 Biomechanics of unilateral and bilateral sacroiliac joint stabilization: laboratory investigation	8 cadaveric specimens	Biomechanical range of motion (ROM) effects of unilateral and bilateral implant placement for SI joint fusion	Unilateral SI joint fusion stabilizes treated side with little effect on contralateral side. Bi-lateral SI joint fusion needed to properly stabilize both joints.
	Lindsey – *Int J Spine Surg* 2015 Sacroiliac Joint Fusion Minimally Affects Adjacent Lumbar Segment Motion: A Finite Element Study	FEA model	Quantify change in range of motion (ROM) to SI joint and adjacent lumbar segments post-SI joint fusion	Substantial reduction of ROM of the SI joint. Minimal effect (< 5% ROM increase) to adjacent lumbar spinal segments. Increases in adjacent segment lumbar motion after SI joint fusion were substantially lower than the effect after lumbar fusion.
	Soriano-Barón – *Spine* 2015 Effect of Implant Placement on Sacroiliac Joint Range of Motion: Posterior *vs.* Trans-articular	7 cadaveric specimens	SI joint range of motion analysis: • Intact pelvis • Sectioned pubic symphysis • Post iFuse treated	Lateral placement of three 7.0mm implants using either a posterior or trans-articular technique significantly decreased SI joint range of motion (flexion-extension, lateral bending, axial rotation). Within the safe zones of the sacrum, there is surgical flexibility in the lateral placement of SI joint fusion implants to provide stabilization.
	Lindsey – *Med Devices Evid Res* 2014 Evaluation of a Minimally Invasive Procedure for Sacroiliac Joint Fusion – An in vitro Biomechanical Analysis of Initial and Cycled Properties	7 cadaveric specimens	Biomechanical analysis of SI joint: • Pre iFuse • Post iFuse • Post iFuse and cycles	Three 7.0mm iFuse implants significantly decreased flexion-extension of SI joint range of motion (ROM). Stability maintained after cyclical loading: ROM did not increase after 5000 flex-ex cycles.

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	Article	Patients	Description	Results
OTHER (13)	**Vanaclocha – *J Spine Surg* 2019** Sacroiliac joint pain: is the medical world aware enough of its existence? Why not considering sacroiliac joint fusion in the recalcitrant cases?	—	Editorial Commentary Invited by the journal to comment on Randomized Controlled Trial in Europe (iMIA) 2-year results.	• Findings are consistent with author's experience. • Surgeons do not recognize pain arising from the SI joint. • Many patients with SI joint pain get lumbar fusions and often derive no benefit. • To improve surgical outcomes in the care of patients with chronic LBP, practicing surgeons should learn more about SI joint pain and become familiar with its diagnosis and treatment.
	Polly – *J Spine Surg* 2019 Minimally Invasive Sacroiliac Joint Fusion vs. Conservative Management for Chronic Sacroiliac Joint Pain	—	Editorial Commentary Invited by the journal to comment on Randomized Controlled Trial in Europe (iMIA) 2-year results.	**Differences between iMIA and INSITE (RCT performed in the US):** • iMIA used a 1:1 Randomization vs. 2:1 in INSITE (iFuse:Non-surgical management) • iMIA incorporated 2 new patient function outcomes – straight leg raise test and walking distance results **Results** • Clinically significant improvement in pain and ODI • Improvements were sustained out to 2 years
	Janjau – *J Spine Surg* 2019 Is minimally invasive sacroiliac joint arthrodesis the treatment of choice for sacroiliac joint dysfunction?	—	Editorial Commentary Invited by the journal to comment on Randomized Controlled Trial in Europe (iMIA) 2-year results.	limitations prevent results from being generalizable to the larger population due to the lack of information regarding baseline degree of SI joint degenerative disease process and the patient comorbidities. Prior to widespread adoption, future studies with a bigger patient sample must further clarify the ideal target population of this surgical technique.
	Barros – *Fed Prac* 2019 Sacroiliac Joint Dysfunction in Patients with Low Back Pain	—	Reviews diagnosis and treatment, including SI joint fusion and an iFuse case, for SI joint dysfunction	Although difficult to distinguish from similarly presenting syndromes, a detailed history, appropriate physical maneuvers, imaging, and adequate response to intra-articular anesthetic SI joint injections can help health care providers treat this painful condition. MIS fusion of the SI joint has proven to be a safe, effective, and viable treatment option when non-surgical methods fail.
	Cher – *Med Devices Evid Res* 2018 Postmarket surveillance of 3D-printed implants for sacroiliac joint fusion	14,210	Complaints related to iFuse-3D compared to iFuse	Instrument-related Complaints – low and constant rate (1.3%). Pain-related Complaints – similar rate with iFuse-3D and iFuse (both < 0.5%). 1-year Probability of Revision – 1.0% for iFuse-3D, and 1.5% for iFuse Implants (P=0.0408 for difference). Implant Breakages or Migrations – none for either group.
	Mao – *Orthop Rev (Pavia)* 2018 A consideration for the utility of the post-operative Oswestry Disability Index for measuring outcomes after sacroiliac joint fusion	24	Utility of Oswestry Disability Index (ODI) as a measure of clinical outcomes in two groups: • Prior lumbar fusion • No prior lumbar fusion	Pain and Satisfaction – presence of lumbar fusion did not show any statistically significant differences in pain or satisfaction. ODI – patients with prior lumbar fusion reported lower ODI than those without lumbar fusion at 1-year post-op (P=0.015).
	MacBarb – *Int J Spine Surg* 2017 Fortifying the Bone-Implant Interface Part 2: An In Vivo Evaluation of 3D-Printed and TPS-Coated Triangular Implants	—	*In vivo* sheep study with 4 different implants: • TPS • 3D-printed • 3D-Printed-HA • 3D-Printed-Autograft 6- and 12-week post-implantation	Biomechanics – all implants had bony integration resulting in mechanically stable host bone interfaces; 3D implants had continuous ring of integrated bone. Histology – all implants had substantial bone ongrowth and ingrowth; 3D implants had through growth and greater area filled with bone. Augmentation – HA coating did not further promote osteointegration; autograft increased ingrowth and through growth 3D-Printed Fenestrations – allows for bony through growth; provides greater surface area than TPS; additive manufacturing process provides consistent and highly controlled porous surface.

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	Article	Patients	Description	Results
OTHER (13) *cont.*	**Vanaclocha – *Neurosurg Focus* 2016** Biplanar x-ray fluoroscopy for sacroiliac joint fusion	—	Technique video of an iFuse Procedure	Biplanar fluoroscopy allows excellent AP and lateral projections to be made quickly and particularly useful in same procedure bilateral cases. **Video**: https://youtu.be/TX5gz8c765M
	Cher – *Med Devices Evid Res* 2015 Implant Survivorship Analysis After Minimally Invasive Sacroiliac Joint Fusion Using the iFuse Implant System	11,388	4-year revision rate (or survivorship, free from revision) Retrospective analysis of complaints database	96.5% 4-year survivorship, free from revision (3.5% cumulative revision rate). Revision rate improved annually from 2009 to 2014. Revision rate compares favorably to other orthopedic procedures.
	Copay – *Qual Life Res* 2015 Is the Oswestry Disability Index a valid measure of response to sacroiliac joint treatment?	Used data from SIFI	Validate ODI as a disability measurement of SI joint pain and determine minimum clinically important difference (MCID) after SI joint treatment	ODI is a valid measure of change in SI joint health and can be used to measure disability caused by SI joint pain. MCID estimate for ODI is 13–15 points, which falls within the range of that previously reported for lumbar back pain.
	Woods – *Adv Orthop* 2014 Utility of Intraoperative Neuromonitoring during Minimally Invasive Fusion of the Sacroiliac Joint	37 patients (111 implants)	Retrospective case series, single-surgeon. Assess clinical utility of intraoperative neuromonitoring.	Stimulus threshold limits selected for pin and implant placement to more accurately determine distance from the nerve. Resulting EMG readings produced 80% sensitivity and 97% specificity.
	Geisler – *Neurosurg Focus* 2013 Stabilization of the Sacroiliac Joint with the SI-BONE Surgical Technique	—	Technique video of an iFuse Procedure	Part of *Neurosurgery Focus* supplement on Minimally Invasive Spine Surgery **Video:** http://youtu.be/2YtFddohZRk
	Miller – *Med Devices Evid Res* 2013 Analysis of Postmarket Complaints Database for the iFuse SI Joint Fusion System: A Minimally Invasive Treatment for Degenerative Sacroiliitis and Sacroiliac Joint Disruption	5,319	Retrospective analysis of complaints database. Apr 2009 – Jan 2013	3.8% overall complaint rate. 1.8% revision rate.

For information about the indications and intended use, visit *www.si-bone.com.* 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*

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