Advocacy: ISASS Proposed Recommendations / Coverage Criteria for Minimally Invasive Sacroiliac Joint Fusion 2015

Coverage Indications, Limitations, and/or Medical Necessity

Updated March 15, 2015 (This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion in IJSS)

Author: *ISASS Task Force (Coding & Reimbursement) Chair; Morgan P. Lorio, MD, FACS*

Introduction

The sacroiliac joint (SIJ) is a cause of chronic lower back pain. SI joints are paired diarthrodial articulations of the sacrum and ilium. The SI joint serves as the biomechanical mediator between the spine and pelvis. The subchondral bone, capsule, and surrounding ligaments of the SIJ are innervated by spinal nerves.(1)

Because SIJ pain can be confused with lumbar and hip pain, proper diagnosis of SIJ pain is key to appropriate patient management. Patients with SIJ pain typically report pain in the buttocks, with possible radiation into the groin or upper legs. Specific physical examination tests that stress the SIJ (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver, sacral sulcus tenderness) are typically performed in the physician's office; in combination, these tests are thought to be predictive of SI joint pain.(2) Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration). The diagnosis of SIJ pain is confirmed by performing a fluoroscopy guided percutaneous SI joint block with local anesthetic (e.g., lidocaine). An acute reduction in pain of 75%(3,4) (using visual analog scale) or more compared to immediately prior to the block is diagnostic as a positive test and indicates that the injected joint is the pain generator based on published studies. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test.(5) Because other pathologic processes can coexist with SIJ pain, in order to assure that SI joint pain is the primary (or only) diagnosis, the physician should ensure that non-SIJ causes of pelvic or lower back pain are ruled out on the basis of history, physical exam and/or imaging; examples of alternative diagnoses include pelvic fracture, tumor, infection, skeletal deformity, hip arthritis, and degeneration of the L5/S1 disc or other base-of-spine pathologies.

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of typical history, physical examination showing bilateral SIJ pain with maneuvers (listed above) that stress the SIJ, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SI joint block.

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents, opioids), physical therapy, steroid injections into the SIJ and radiofrequency ablation of the SIJ. Most patients respond adequately to conservative treatment. However, a small number of patients do not have satisfactory pain relief and may be functionally disabled (e.g., cannot sit or stand for more than five minutes, cannot perform normal activities of daily living (ADLs) cannot walk up or down stairs, may require a wheelchair, may require chronic opioid treatment). Patients with a diagnosis of SIJ pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SIJ fusion.

Coverage Rationale for Open and Minimally Invasive SIJ Fusion

Open fusion of the SIJ can provide pain relief but recovery times are long and the complication rate is high.(6-10) Patients can experience significant intraoperative bleeding and require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for minimally invasive SIJ fusion.(11)

Minimally invasive fusion of the SIJ has been performed with several types of implants, including triangular, porous, titanium coated implants,(8–16) hollow modular screws,(17–19) titanium cages,(18) and allograft dowels(6) (Table 1). These devices

are placed either inside or across the SIJ using a minimally invasive surgical approach. Minimally invasive SIJ fusion provides pain relief by acutely stabilizing the painful SI joint with subsequent fusion. In addition to outcomes published of multiple retrospective case series,(8–10,15,21,22) published results from a prospective multicenter randomized controlled trial (RCT) of minimally invasive SIJ fusion vs. non-surgical management (NSM)(14) and a multi-center prospective single arm trial(13) have substantiated high rates of pain relief, improvement in functional measures (SF-36, ODI and EQ-5D) and a low rate of both revisions (<5%) and serious adverse events. Furthermore, these improvements are significantly greater in patients treated with MIS SIJ fusion compared to NSM; VAS scores improved by 53-points in the fusion group compared to 12-points for NSM. ODI improved 30 points in the surgery group vs. 4.9 points in NSM patients, EQ-5D scores improved by 0.29 in the fusion group (p<.0001) vs. 0.05 points in the NSM group. Mean scores for all SF-36 domains improved significantly in the surgery group while no improvement was seen for any domain in the NSM group. Mean SF-36 Physical Component Summary (PCS) improved by 12.7 points in the surgery group vs. 1.2 points in the NSM group. All values were highly statistically significant (p<.0001). In a multicenter retrospective review of 263 patients undergoing either open or minimally invasive SIJ fusion, the latter was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 (-2.7 points on 0-10 scale vs. -6.2 points) and 2-year (-2.0 vs. -5.6 points) follow-up (all differences are statistically significant.).(11) Two published studies report that favorable outcomes achieved at one year are sustained long term (up to 5-years).(12,16)

The complication rate for minimally invasive SI joint fusion is low. Importantly, the rate of removal or revision is less than 2%. (13,14,23) Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection.

In cases of bilateral SI joint pain, bilateral SIJ fusion may occasionally be indicated and is usually performed serially to minimize the impact on rehabilitation (i.e., patients who undergo simultaneous bilateral fusion procedures may be wheelchair or bedbound for several weeks, possible slowing overall recovery).

Indications/Limitations of Coverage

Patients who have all of the following criteria may be eligible for minimally invasive SIJ fusion:

- Significant SIJ pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (see list provided above) and cause the patient's typical pain.(2)
- Confirmation of the SIJ as a pain generator with ≥ 75%(3,4) acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic.
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SIJ steroid injection. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability;
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been ruled out (e.g., L5/S1 compression, hip osteoarthritis).

Minimally invasive SIJ fusion is NOT indicated for patients with the following:

- Less than 6 months of back pain;
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- Pain not confirmed with a diagnostic SIJ block;
- Existence of other pathology that could explain the patient's pain.

In rare instances, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon fluoroscopically-guided intra-articular SI joint block with local anesthetic.

Bilateral SIJ fusion is probably best performed serially to ensure that fusion of both joints is necessary (i.e., pain/disability continues after the first fusion in spite of conservative treatment and a nerve block of the unfused joint results in more than

75% reduction in pain). If bilateral fusion is performed at the same operative session, the surgeon must document both medical necessity and why serial fusion is not indicated in the patient.

It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed.

Coding

The American Medical Association recommends minimally invasive SI joint fusion be coded using CPT code 27279. Revision and/or removal of the SI joint implant would typically be coded using 22899 (unlisted procedure, spine) or 27299 (unlisted procedure, pelvis or hip joint) depending on the type of approach and procedure performed, whether within the global period of the fusion, or not.

ICD-9 codes that support medical necessity are shown below.

Table 1: ICD-9 Codes That Support Medical Necessity

ICD-9 Code	Description
720.2	Sacroiliitis not elsewhere classified; inflammation of sacroiliac joint NOS
721.3	Lumbosacral spondylosis without myelopathy
724.6	Disorders of sacrum
739.4	Nonallopathic lesions, not elsewhere classified in the sacral region; sacrococcygeal region or sacroiliac region
846.9	Sprains and strains of the sacroiliac region, unspecified site of sacroiliac region
847.3	Sprains and strains of sacrum

Documentation Requirements

For patients undergoing minimally invasive SI joint fusion, the following must be documented in the medical record and available upon request:

- A complete history and physical documenting the likely existence of SI joint pain;
- Performance of a fluoroscopically- guided SI joint block on the affected side (or both sides, see discussion above) which shows at least a 75% acute reduction in pain;
- A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs and/or opioids (unless contraindicated) and one of the following: (1) an adequate period of rest, (2) an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment, (3) SI joint steroid injections into the affected joint with inadequate response or return of pain after weeks to months, or (4) radiofrequency ablation of the affected SI joint with either inadequate response or return of pain after weeks to months;
- SI joint pain has continued for a minimum of six months;
- All other diagnoses that could be causing the patient’s pain have been ruled out;
- Within one month after surgery, that the level of pain and/or functional disability is continuing and that in the surgeon’s opinion the only treatment option that will provide long term relief is SI joint fusion

Surgeon Qualifications

- Minimally invasive SIJ fusion is a surgical procedure performed only by orthopedic or neurologic surgeons who have successfully completed a residency in that specialty as well as at least one specialized training course in the procedure. Training should include device placement in cadavers under supervision of a surgeon experienced in the procedure.
- Surgeons performing minimally invasive SIJ fusion should be specifically credentialed and/or privileged by at least one hospital to perform the procedure.

Table 2: MIS SIJ Fusion Surgery Published Literature

Inclusion criteria**:** indexed in PubMed, English language, fixation of the SI joint described as *minimally invasive* or *percutaneous*, clinical outcomes available. Single patient case reports, imaging studies, and technique reports with no clinical outcomes are excluded

Cohort studies including prospective, retrospective, single and multi-center

Author, Year	**Study design**	**N**	**Implant**	**Technique**	**Demographics** *Mean (±SD) or (range), unless otherwise specified*	**Results** *Mean (±SD) or (range) unless otherwise specified*	**Complications (n)**
Whang 2015 (14)	Prospective, multi-center, randomized \ trial of fusion vs. NSM	102	iFuse Implant System	Lateral approach	Age: 50.2 (26-72) years Sex: 75F/27M Prior lumbar fusion: 38.2% Follow-up: 6mo	VAS: 8.2 (1.2) pre-op, 2.9 (2.9) at 6mo ODI: 62.2 (14.5) pre-op, 31.9 (22.7) at 6mo EQ5D: 0.44 (0.18) pre-op, 0.72(0.21) Surgical time: 44.9 (22.3) min EBL: 32.7 (32.8) mL Hospital stay: 0.8 (range 0-7) days Success rate: 81.4%	Trochanteric bursitis (4), surgical wound problems (4), iliac fracture (1), hairline ilium fracture (1), nerve root impingement (1)
		46	N/A (NSM)	N/A	Age: 54.0 (29.5-76.0)) years Sex: 28 F/18M Prior lumbar fusion: 37% Follow-up: 6mo	VAS: 8.2(1) baseline, 7.0 (2.6) at 6 mo ODI: 61.1(15.3) baseline, 56.4 (20.8) at 6mo EQ5D: 0.47(0.19) baseline, 0.52(0.22) at 6mo Success rate: 23.9%	N/A
Vanaclocha 2014 (12)	Single center case series	24	iFuse Implant System	Lateral approach	Age: 47.4 (32-71) years Sex: 15F/9M Prior lumbar fusion: 2 Follow-up: 23 mo (1-4.5 years)	VAS: 8.7 pre-op, 1.7 at 1yr, 2.1 at 4.5yrs ODI: 54.1 pre-op, 14.3 at 1yr, 16.3 at 4.5yrs Surgical time: 48 (40-65) min, unilateral cases EBL: 58 (40-70)mL	Immediate post-op pain (4-resolved), temporary post-op radiculopathic pain (2)
Rudolf, 2014 (16)	Single center case series	17	iFuse Implant System	Lateral approach	Age: 58 (36-85) years Sex: 13F/4M Prior lumbar fusion: 8 (47%) Follow-up: 60 mo Bridging bone: 87% (13/15)	VAS: 8.3 (1.4) pre-op, 3.4 (2.4) at 1yr, 1.4 (2.6) at 2yrs, 2.4 (2.2) at 5yrs ODI: 21.5 (22.7) at 5yrs Surgical time: 65 (18) min	No intraoperative complications, hematoma (1), cellulitis (2), deep wound infection secondary to diverticulitis (1)
							No

Sachs, 2014 (15)	Multi-center, Retrospective	144	iFuse Implant System	Lateral approach	Age: 58 (30-89)years Sex: 30F/10M Prior lumbar fusion: 62% Follow-up: 16 (12-26) mo	VAS: 8.6 pre-op, 2.7 at follow-up 91% Very or somewhat satisfied 91.7% would have surgery again Surgical time: 73min EBL: 31mL Hospital stay: 0.8 days	intraoperative complications. 28 post-op complications, most common: fall (5), trochanteric bursitis (4), piriformis syndrome (3), facet pain (3). 1 implant revision (1-year revision rate 0.7%),
Duhon, 2013 (24)	Multi-center, Prospective, single arm. Safety (S) and efficacy (E) cohorts reported	32 (E) 94 (S)	iFuse Implant System	Lateral approach	Age: 50.2 (12.6) years Sex: 21F/11M Prior lumbar fusion: 69% Follow-up: 6 mo	VAS: 76.2 (16.2) pre-op, 29.3 (23.3) at 6mo ODI: 55.3 (10.7) pre-op, 38.9 (18.5) at 6mo SF-36 PCS: 30.7 (4.3) pre-op, 37 (10.7) at 6mo 88.5% (23/26) success rate Surgical time: 48 (16.1) min EBL: 59 (95) mL Hospital stay: 0.8 days	No implant revision or removal, 6 AEs probably or definitely procedure-related (2 nausea, 2 wound infections, 1 cellulitis, 1 buttock pain)
Sachs, 2013 (8)	Single center, Retrospective case series	40	iFuse Implant System	Lateral approach	Age: 58 (30-81) years Sex: 30F/10M Prior lumbar fusion: 30% Follow-up: 12 mo	VAS: 8.7 (1.5) pre-op, 0.9 (1.6) at 12mo 98% reached MCID 100% patient satisfaction	Piriformis syndrome (1), new LBP (1), facet joint pain (8), trochanteric bursitis (2)
Cummings, 2013 (25)	Single center, Retrospective case series	18	iFuse Implant System	Lateral approach	Age: 64 (39-81) years Sex: 12F/6M Prior lumbar fusion: 61% Follow-up: 12 mo	VAS: 8.9 (1.9) pre-op, 2.3 (2.1) at 12mo 90% reached MCID ODI: 52.6 (18.8) pre-op, 13.2 (12.6) at 12mo SF-12 PCS: 37.8 (10.4) pre-op, 44.6 (10.5) at 12mo	Trochanteric bursitis (3), hematoma (1), fluid retention (1), toe numbness (1), implant malposition (1)
Gaetani, 2013 (10)	Single center, Retrospective case series	10	iFuse Implant System	Lateral approach	Age: 53.2 (36-71) years Sex: 12F Prior lumbar fusion: 8.3% Follow-up: 10 (8-18) mo	VAS: 7.7 (1.3) pre-op, 3 (1.2) at follow-up ODI: 31.4 (6.3) pre-op, 12 (3.5) at follow-up RDQ: 17.6 (1 pre-op, 3 (4.1) at follow-up Surgical time: 65 (16) min EBL: <45 mL	Local hematoma (2), low back pain (1)

						3 month CT scans show initial fusion	
Schroeder, 2013 (26)	Single center, Retrospective case series	6	iFuse Implant System	Lateral approach	Age: 50 (25-60) years Sex: 6F/0M Prior lumbar fusion: 100% (deformity correction) Follow-up: 10.25 (4-15)mo	VAS: 7.83 pre-op, 2.67 at follow-up ODI: 22.1 pre-op, 10.5 at follow-up Hospital stay: 2 days (range 1-4) Bony bridging seen in 4 patients	No intraoperative or post-operative complications.
Rudolf, 2013 (22)	Single center, Sub-group analysis	40	iFuse Implant System	Lateral approach	*Subgroup analysis from Rudolf 2012 to assess effect of prior lumbar fusion on outcomes. Follow up: 12 and 24 months		
		18	*No prior fusion Age: 49(12) Sex: 12F/6M			VAS decrease at 12mo: -5.94 (3.3) VAS decrease at 24mo: -5.47 (2.88) Surgical time: 60(19) min	Superficial cellulitis (2), wound infection (1), revision for implant malposition (1)
		15	*Prior lumbar spinal fusion Age: 58(11) Sex: 11F/4M			VAS decrease at 12mo: -3.5 (3.46) VAS decrease at 24mo: -5.81 (3.5) Surgical time: 64(19) min	Superficial cellulitis (2), buttock hematoma (1), revision for implant malposition (1)
		7	*Concomitant lumbar pathology treated non-surgically Age: 58(17) Sex: 3F/4M			VAS decrease at 12mo: -3.71 (3.11) VAS decrease at 24mo: -4.79 (4.28) Surgical time: 64(19) min	None
Endres,	Single center, Retrospective	19	DIANA cage *[Product*	Posterior, Longitudinally	Age: 60.9 (36-76) years Sex: 5F/14M Prior lumbar fusion:	VAS: 8.5 (7.5-9) pre-op to 6.0 (2.2-9) at follow-up ODI: 64.1 (40-82) pre-op to 56.97 (8-82) at follow-up EBL: <150mL Hospital stay: 7.3 (3-	No neurovascular

2013 (27)	case series		*not approved for use in the US]*	inserted into SI joint	100% Follow-up: 13.2 (6-24) mo	10) days Fusion rate: 78.9% (15/19 joints), defined as lack of loosening and evidence of bone bridging around the implant	complications
Mason, 2013 (19)	Retrospective case series	55	HMA screw packed with DBM	Lateral approach	Age: 57 years Sex: 46F/9M Prior lumbar fusion: 40% Follow-up: 36 (12-84) mo	VAS: 8.05 (1.9) pre-op, 4.48 (2.81) at follow-up SF-36PCS: 26.6 (15.2) pre-op, 43 (22.68) follow-up Majeed scoring: 36.18 (15.08) pre-op, 64.78 (20.18) follow-up	Post-op nerve pain requiring reoperation (2)
Rudolf, 2012 (28)	Single center, Retrospective case series	50	iFuse Implant System	Lateral approach	Age: 54 (24-85) years Sex: 34F/16M Prior lumbar fusion: 44% Follow-up: 40 (24-56) mo	VAS: 7.6 pre-op, 2.0 at follow-up 82% reached MCID 82% patient satisfaction Surgical time: 65 (26) min	Superficial cellulitis (3), deep wound infection (1), hematoma (2), reoperation (3)
Sachs, 2012 (21)	Single center, Retrospective case series	11	iFuse Implant System	Lateral approach	Age: 65 (45-82) years Sex: 10F/1M Prior lumbar fusion: 18% Follow-up: 12 mo	VAS: 7.9 (2.2) pre-op, 2.3 (3.1) at 12mo Surgical time: 77.5 (31.8) min EBL: 21.8 (18.9) mL	Piriformis syndrome (1), low back pain (1)
McGuire, 2012 (3)	Retrospective case series	37	Fibular allograft dowels	Posterior, Longitudinally inserted into SI joint	Age: 42.5 (23-63) years Sex: 34F/3M Follow-up: 39.6 (8-62) mo	Baseline VAS: 9.1 Final VAS: 3.4 Fusion rate: 89.5%	Nonunion requiring revision (4) (10.5%)
						SF-36 PF: 37.15 (14.28) pre-op, 79.33 (12.52) at	

Khurana, 2009 (18)	Retrospective case series	15	HMA screw packed with DBM	Lateral approach	Age: 48.7 (37.3-62.6) years Sex: 11F/4M Prior lumbar fusion: 40% Follow-up: 17 (9-39) mo	follow-up Majeed's: 37 (18-54) pre-op, 79 (63-96) at follow-up Good to excellent results: 13/15 EBL: < 50 ml Hospital stay: 2.7 (1-7) days	No post-operative neurological or wound complications.
Al-Khayer, 2008 (17)	Retrospective case series	9	HMA screw packed with DBM	Lateral approach	Age: 42 (35-56) years Sex: 9F Follow-up: 40 (24-70) mo	VAS decreased: 8.1 (7-9) to 4.6 (3-7) ODI decreased: 59 (34-70) to 45 (28-60) EBL: <50 ml Hospital stay: 6.9 (2-11) days Return to work: 44.44%	Deep wound infection requiring debridement and IV antibiotics (1)
Wise, 2008 (20)	Single center Prospective cohort	13	Titanium cage packed with BMP	Posterior, Longitudinally inserted into SI joint	Age: 53.1 (45-62) years Sex: 12F/1M Prior lumbar fusion: 61.5% Follow-up: 29.5 (24-35) mo	Back VAS improved by 4.9 pts Leg VAS improved by 2.4 pts EBL: < 100 ml Hospital stay: 1.7 days Fusion rate: 89% (17/19 joints) on CT at 6mo	Reoperation via open arthrodesis secondary to nonunion and persistent pain (1)

Comparative Cohort Studies of Open Surgery vs MIS

Author, year	**Study design**	**N**	**Implant**	**Technique**	**Demographics** *Mean (±SD) or (range), unless otherwise specified*	**Results** *Mean (±SD) or (range), unless otherwise specified*	**Complications**
		22	iFuse Implant System	Lateral approach	**MIS Cohort** Age: 47.9 (13.1) years Sex: 17F/5M Prior lumbar fusion: 64% Follow-up: median	ODI: 61.5 (12.5) pre-op, 52 (16.9) at follow-up Surgical time: 68.3(26.8) min EBL: 40.5 (31.4) mL	(1) pulmonary embolism that resolved with treatment, (2) revisions due to halo formation on the sacral side with

Ledonio, 2014 (29)	Single center Retrospective, comparative cohort study				15 (12-26) mo	Hospital Stay: 2.0 (1.5) days	recurring sacroiliac joint pain
		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	**Open Cohort** Age: 51 (9.4) years Sex:13F/9M Prior lumbar fusion: 50% Follow-up: median 13 (11-33) mo	ODI: 61.8 (10.8) pre-op, 47.4 (21.7) at follow-up Surgical time: 128 (27.9) min EBL: 168.8 (479.0) mL Hospital Stay: 3.3 (1.1) days	Pulmonary embolism (1), revision due to failed implant and nerve root irritation (2)
Ledonio 2014 (30)	Multi-center Retrospective, comparative cohort study	17	iFuse Implant System	Lateral approach	**MIS Cohort** Age: median 66 (39-82) years Sex: 11F/6M Prior lumbar fusion: 82% Follow-up: 12 mo	*Values reported as median (range)* ODI: 53 (14-84) pre-op, 13 (0-38) at 12 mo Surgical time: 27 (18-72) min Hospital Stay: 1 (1-2) days	Transient trochanteric bursitis (3), hematoma (1), transient toe numbness (1), revision due to malpositioned implant (1)
		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	**Open Cohort** Age: median 51 (34-74) years Sex: 82F/32M Prior lumbar fusion: 47% Follow-up: 24 mo	*Values reported as median (range)* ODI: 64 (44-78) pre-op, 46 (10-80) at 12 mo Surgical time: 128 (73-180) min Hospital Stay: 3 (2-6) days	Pulmonary embolism (1), revision due to failed implant and nerve root irritation (2)
Graham-Smith, 2013 (31)	Multi-center Retrospective comparative cohort study	114	iFuse Implant System	Lateral approach	**MIS Cohort** Age: 57.4 (14.0) years Sex: 82F/32M Prior lumbar fusion: 47.4% Follow-up: 24 mo	VAS: 8.3 (1.6) pre-op, 2.3 (2.6) at 12mo, 1.7 (2.9) at 24mo MCID: 86% reached at 12mo, 82% at 24mo Surgical time: 70 (24) min EBL: 33 (27) mL Hospital stay: 1.3 (0.5) days	No intraoperative. Postop repositioning of implants (4), 3.5% (4/114).
		149	Screws, plates	Open posterior approach	**Open Cohort** Age: 45.8 (11.3) years Sex: 103F/46M Prior lumbar fusion: 23.5% Follow-up: 24 mo	VAS: 7.1 (1.9) pre-op, 4.6 (3.0) at 12mo, 5.6 (2.9) at 24mo MCID: 61% reached at 12mo, 50% at 24mo Surgical time: 163 (25) min EBL: 288 (182) mL Hospital stay: 5.1 (1.9) days	No intraoperative. Postop removal of implants (66), 44% (66/149).

Abbreviations: F: female; M: male; EBL: estimated blood loss; mo: month; ODI: Oswestry Disability Index; VAS: Visual Analog Scale; NSM: Non-surgical management; DBM: demineralized bone matrix; HMA: hollow modular anchorage; BMP: bone morphogenic protein.

References

1. Szadek, K. M., Hoogland, P. V., Zuurmond, W. W., de Lange, J. J. & Perez, R. S. Nociceptive nerve fibers in the sacroiliac joint in humans. *Reg. Anesth. Pain Med.* **33,** 36–43 (2008).
2. Szadek, K. M., van der Wurff, P., van Tulder, M. W., Zuurmond, W. W. & Perez, R. S. G. M. Diagnostic validity of criteria for sacroiliac joint pain: a systematic review. *J. Pain* **10,** 354–368 (2009).
3. McGuire, R. A., Chen, Z. & Donahoe, K. Dual fibular allograft dowel technique for sacroiliac joint arthrodesis. *Evid.-Based Spine-Care J.* **3,** 21–28 (2012).
4. Buchowski, J. M. *et al.* Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. *Spine J. Off. J. North Am. Spine Soc.* **5,** 520–528; discussion 529 (2005).
5. Belanger, T. A. & Dall, B. E. Sacroiliac arthrodesis using a posterior midline fascial splitting approach and pedicle screw instrumentation: a new technique. *J. Spinal Disord.* **14,** 118–124 (2001).
6. Waisbrod, H., Krainick, J. U. & Gerbershagen, H. U. Sacroiliac joint arthrodesis for chronic lower back pain. *Arch. Orthop. Trauma. Surg. Arch. Für Orthop. Unf.-Chir.* **106,** 238–240 (1987).
7. Moore, M. R. in *Movement, stability, and low back pain: the essential role of the pelvis* 563–572 (Churchill Livingstone, 1997).
8. Sachs, D. & Capobianco, R. Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv. Orthop.* **2013,** 536128 (2013).
9. Rudolf, L. MIS Sacroiliac (SI) Joint Fusion in the Context of Previous Lumbar Spine Fusion: 50 Patients with 24 Month Follow up. in *International Society for the Advancement of Spine Surgery* 107 (2013).
10. Gaetani, P. *et al.* Percutaneous arthrodesis of sacro-iliac joint: a pilot study. *J. Neurosurg. Sci.* **57,** 297–301 (2013).
11. Graham-Smith, A., Capobianco, R. A. & Cher, D. J. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. *Ann. Surg. Innov. Res.* **7,** 1–12
12. Vanaclocha, V. V. *et al.* Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients. *J. Spine* **03,** (2014).
13. Duhon, B. S. *et al.* Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med. Devices Auckl. NZ* **6,** 219–229 (2013).
14. Whang, P. G. *et al.* Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. *Int J Spine Surg* **9,** (2015).
15. Sachs, D. *et al.* One-year outcomes after minimally invasive sacroiliac joint fusion with a series of triangular implants: a multicenter, patient-level analysis. *Med. Devices Evid. Res.* **7,** 299–304 (2014).
16. Rudolf, L. & Capobianco, R. Five-Year Clinical and Radiographic Outcomes After Minimally Invasive Sacroiliac Joint Fusion Using Triangular Implants. *Open Orthop. J.* **8,** 375–383 (2014).
17. Al-Khayer, A., Hegarty, J., Hahn, D. & Grevitt, M. P. Percutaneous sacroiliac joint arthrodesis: a novel technique. *J. Spinal Disord. Tech.* **21,** 359–363 (2008).
18. Khurana, A., Guha, A. R., Mohanty, K. & Ahuja, S. Percutaneous fusion of the sacroiliac joint with hollow modular anchorage screws: clinical and radiological outcome. *J. Bone Joint Surg. Br.* **91,** 627–631 (2009).
19. Mason, L. W., Chopra, I. & Mohanty, K. The percutaneous stabilisation of the sacroiliac joint with hollow modular anchorage screws: a prospective outcome study. *Eur. Spine J.* **22,** 2325–2331 (2013).
20. Wise, C. L. & Dall, B. E. Minimally invasive sacroiliac arthrodesis: outcomes of a new technique. *J. Spinal Disord. Tech.* **21,** 579–584 (2008).
21. Sachs, D. & Capobianco, R. One year successful outcomes for novel sacroiliac joint arthrodesis system. *Ann. Surg. Innov. Res.* **6,** 13 (2012).
22. Rudolf, L. MIS Fusion of the SI Joint: Does Prior Lumbar Spinal Fusion Affect Patient Outcomes? *Open Orthop. J.* **7,** 163–168 (2013).
23. Miller, L., Reckling, W. C. & Block, J. E. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. *Med. Devices Evid. Res.* **6,** 77–84 (2013).
24. Duhon, B. *et al.* Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. *Med. Devices Evid. Res.* **6,** 219–229 (2013).
25. Cummings, J., Jr & Capobianco, R. A. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Ann. Surg. Innov. Res.* **7,** 12 (2013).
26. Schroeder, J. E., Cunningham, M. E., Ross, T. & Boachie-Adjei, O. Early Results of Sacro–Iliac Joint Fixation Following Long Fusion to the Sacrum in Adult Spine Deformity. *Hosp. Spec. Surg. J.* **10,** 30–35 (2013).
27. Endres, S. & Ludwig, E. Outcome of distraction interference arthrodesis of the sacroiliac joint for sacroiliac arthritis. *Indian J. Orthop.* **47,** 437–442 (2013).
28. Rudolf, L. Sacroiliac Joint Arthrodesis-MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes. *Open Orthop. J.* **6,** 495–502 (2012).
29. Ledonio, C. G. T., Polly, D. W. & Swiontkowski, M. F. Minimally invasive versus open sacroiliac joint fusion: are they similarly safe and effective? *Clin. Orthop.* **472,** 1831–1838 (2014).
30. Ledonio, C., Polly, D., Swiontkowski, M. F. & Cummings, J. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. *Med. Devices Evid. Res.* **2014,** 187–193 (2014).
31. Graham Smith, A. *et al.* Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison of perioperative measures and clinical outcomes. *Ann. Surg. Innov. Res.* **7,** 14 (2013).