ISASS Policy 2016 Update – Minimally Invasive Sacroiliac Joint Fusion

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ISASS Policy 2016 Update – Minimally Invasive Sacroiliac Joint Fusion

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Rationale

The index 2014 ISASS Policy Statement - Minimally Invasive Sacroiliac Joint Fusion was generated out of necessity to provide an ICD9-based background and emphasize tools to ensure correct diagnosis. A timely ICD10-based 2016 Update provides a granular threshold selection with improved level of evidence and a more robust, relevant database.

KEYWORDS: ISASS, POLICY STATEMENT, MINIMALLY INVASIVE SURGERY, SACROILIAC JOINT, FUSION, COVERAGE
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Introduction

The sacroiliac joints (SIJ) are diarthrodial articulations of the sacrum and ilium. The SIJ 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]

Sacroiliac joint (SIJ) pain is likely responsible for chronic back pain in some patients; furthermore in some studies the prevalence is reported to be 15-30%.[2-6] Convergence of the sensory pathway from the hip, the SIJ and the lumbar spine may result in overlap of pain patterns from dysfunction of these structures. As such, proper SIJ pain diagnosis is key to appropriate patient management. Patients with SIJ pain typically report pain in the buttock(s), 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) are typically performed in the physician's office; in combination, these tests are thought to be predictive of SIJ pain.[7]

The spectrum of pain and disability from SIJ dysfunction is wide. Patients may be affected mildly or may have substantial functional impairment (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). Patients with chronic SIJ dysfunction seeking surgical treatment have marked impairment of quality of life,[8] similar to that observed in other conditions commonly treated surgically.[9] Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. In many cases, imaging can show non-specific findings in the SIJ.[10] 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) (Table 1).

The diagnosis of SIJ pain is confirmed by performing a fluoroscopy-guided percutaneous SIJ block with local anesthetic (e.g., lidocaine). An acute reduction in typical pain indicates a positive test, suggesting that the injected joint is a pain generator. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test.[11] Because other pathologic processes can coexist with SIJ pain, physicians should discuss with patients the degree to which treatment of the SIJ may relieve overall pain and disability without addressing other pain generators.

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SIJ pain should be made on the basis of typical history (bilateral symptoms), physical examination showing positive responses to SIJ-stressing maneuvers bilaterally, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SIJ block.

While a marked response to SIJ block might be pre-

dicted to reassure the physician that treatment will produce larger responses to anatomic-based treatment, published data suggest little, if any, relationship. In two large prospective clinical trials of SIJ fusion, patients with suspected SIJ pain were included only if intraarticular SIJ block resulted in a 50% or greater amount of acute pain relief within 60 minutes after the block. The degree of improvement at 6 and 12 months after SIJ fusion was unrelated to the degree of acute pain relief during the block.[12] In a retrospective analysis of predictors of outcome success after RF ablation of lateral branches of the sacral nerve roots in patients with SIJ pain, no relationship was observed between response to lateral branch block or SIJ anesthesia and response to RF ablation.[13] Randomized trials of RF ablation of lateral branches of the sacral nerve roots excluded patients with <75% pain reduction after lateral branch block (one block in Cohen et al.[14] and two blocks in Patel et al.[15]), leaving open the question of whether the selected threshold was appropriate.

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents), physical therapy, steroid injections into the SIJ, and radiofrequency ablation of the sacral nerves and SIJ fusion. While pain medications may relieve temporarily pain and/or disability, they have not been shown to impact the underlying disease process, and opioid addiction remains an important public health concern. Apart from a single clinical trial in post-partum pelvic pain (probably related to the SIJ),[16] the effectiveness of physical therapy for chronic SIJ dysfunction has not been demonstrated. Two randomized trials have shown that RF ablation of lateral branches of sacral nerve roots can temporarily reduce SIJ pain.[14,15] One-year follow-up from one RF ablation randomized trial showed modest pain reduction.[17] Responses in the non-surgical arms of two prospective randomized trials showed little, if any, improvement at 6 months.[18,19] Given the absence of published outcomes data supporting long-term pain relief from non-surgical 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, first reported in the early 1900s,[20] can provide pain relief but recovery times are long and complication rates are high,[21-25] intraoperative times, bleeding and hospital length of stay are more prominent compared to minimally invasive SIJ fusion,[26] and recovery times are long and may require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for minimally invasive SIJ fusion.

Minimally invasive fusion of the SIJ has been performed with several types of implants, including triangular, porous, titanium coated implants,[19,27-33] hollow modular screws,[34-36] titanium cages,[37,38] and allograft dowels[21] (Table 2). Minimally invasive fusion aims to permanently stabilize the SIJ but avoid the morbidity of the open procedure.

Two surgical approaches are commonly used for minimally invasive SIJ fusion:

- A **lateral transarticular approach**, in which devices are placed across the SI joint from lateral to medial. Multiple devices are FDA cleared for this approach for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. However, the vast majority of the published clinical literature for this approach reports use of triangular titanium implants (iFuse Implant System, SI-BONE, Inc.).
- A **posterior approach**, in which devices are placed into the ligamentous portion of the joint via dissection of the multifidus muscle and removal of ligaments covering the outer posterior surface of the joint. In the posterior approach, a portion of the interosseous SIJ ligament is sometimes removed.

Published Literature

Published outcomes data for minimally invasive SIJ fusion using a posterior approach are scarce. One cohort reported marginal response to use of cages placed into the SIJ through a posterior approach.[38] For the lateral approach, 3 retrospective case series (describing two cohorts) using hollow modular anchor (HMA) screws suggest reasonable 2- and 3-year outcomes.[35,36] HMA screws are not FDA-cleared for

SIJ fusion.and are not available for use in the U.S. The remaining published literature on SIJ fusion through a lateral approach used triangular titanium implants (iFuse Implant System, SI-BONE, Inc.). This literature includes:

- A US multicenter, randomized clinical trial (INSITE, n=148)[19] with an embedded cost-utility analysis[39]
- A European multicenter, randomized clinical trial (iMIA, n=103, in press[18])
- A US prospective multicenter single-arm clinical trial (n=172) with 24-month follow-up[31]
- Several single-center case series[26,27,40-44]
- A multicenter case series[32]
- 3 comparative studies comparing open and iFuse-based SI joint fusion[26,45,46]
- An analysis of implant survivorship[47]
- A systematic review and meta-analysis[48]
- A systematic review.[49] Both systematic reviews focused on laterally-based procedures and products. The majority of cohorts were triangular titanium implants.

Taken together, these studies provide substantial evidence that minimally invasive SIJ fusion with triangular titanium implants improves pain, function and quality of life. In both randomized trials, pain relief, disability reduction and improvement in quality of life were markedly higher in SIJ fusion subjects compared to non-surgically treated subjects. Specifically, in the SIJ fusion group of the US randomized trial,[19] mean SIJ pain improved from 82.3 at baseline to 30.4 at the 6-month follow-up (52.0-point improvement, p<.0001) and 28.3 at the 12-month follow-up (54.2-point improvement, p<.0001). Mean changes in the non-surgical group were not clinically significant (mean 12 points). Similarly, in the SIJ fusion group, mean ODI decreased from 57.2 at baseline to 29.9 at month 6 and 28.1 at month 12 (improvements of 27.4 and 29.3 points, respectively). In contrast, mean ODI decreased by only 4.6 points in the non-surgical group. In the European randomized trial,[18] Mean pain scores improved in the SIJ fusion group from 77.7 at baseline to 34.4 at 6 months (a 43.3 point improvement p<.0001) vs. 73.0 to 67.8 (an improvement of 5.7 points, p=.1105) in the non-surgical group. ODI improved by 20 points more in the surgical vs. non-surgical groups 9p<.0001). EQ-5D time trade-off index also improved more in the surgical vs. non-surgical group.

In a multicenter retrospective review of 263 patients undergoing either open or minimally invasive SIJ fusion with triangular titanium implants, minimally invasive SIJ fusion 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.).[26] Finally, two published studies report that favorable outcomes achieved at one year are sustained long term (up to 5 years).[30,33]

The complication rate for minimally invasive SIJ fusion with triangular titanium implants is low.[50] Revision rates over 4 years (3.5%[47]) are substantially lower than after lumbar fusion surgery, and revision rates in long-term retrospective[30,33] and prospective studies[19,31] have confirmed this low rate. 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. Revision rates with other products are unknown. Screw-based devices rely upon different fusion strategies (HA coating, fenestrations within the screws, etc.) with different biomechanics (threaded screws vs. triangular implants that are impacted across the SI joint). Regardless of implant, salvage revision remains challenging.

Bilateral Procedures

In cases of bilateral SIJ 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 that impacts quality of life or significantly limits activities of daily living;
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ (see list provided above) and reproduce the patient's typical pain.
- Confirmation of the SIJ as a pain generator with ≥50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic. Prospective trials have shown that patients with SIJ pain responses of 50-75% respond to MIS SIJ fusion as well as those with 75-100% acute responses.[12]
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and physical therapy. 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 considered. Physicians should take into account that patients can have multiple pain generators and addressing just one pain generator may not adequately relieve disability or all back pain.

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

- Less than 6 months of SIJ pain and/or functional impairment
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated);
- Pain not confirmed with a diagnostic SIJ block;
- Presence of other pathology that would substantially prevent the patient from deriving benefit from SIJ fusion

Bilateral SIJ pain is not uncommon. Diagnosis of bilateral SIJ 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 SIJ block with local anesthetic. Bilateral SIJ fusion is probably best performed serially as successful treatment of one side may improve pain/disability to a degree acceptable by the patient. SIJ fusion of the contralateral side may be necessary if contralateral SIJ pain continues and disability is significant for the patient. 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 SIJ fusion be coded using CPT code 27279. Revision and/or removal of the SIJ 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.

Documentation Requirements

- A complete history and physical documenting the likely existence of SIJ pain;

Table 1. ICD-10-CM Diagnosis.

ICD-10-CM Diagnosis Code	Code Descriptor
M46.1	Sacroiliitis, not elsewhere classified
M53.2x8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Disorders of sacrum
S33.2xxA	Dislocation of sacroiliac and sacrococcygeal joint
S33.6xxA	Sprain of sacroiliac joint
099.89	Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium
094	Sequelae of complication of pregnancy, childbirth and the puerperium

- Performance of a fluoroscopically-guided SIJ block on the affected side (or both sides, see discussion above) which shows at least a 50% acute reduction in pain;
- A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs 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
- SIJ pain has continued for a minimum of six months; and
- All other diagnoses that could be causing the patient's pain have been considered and the physician believes that SIJ fusion is clinically required.

Surgeon Qualifications

- Minimally invasive SIJ fusion is a surgical procedure performed 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.

Coverage/Conclusion

The utilization of minimally invasive surgical approach for SIJ fusion has become a recognized safe, predictable and preferred surgical method for the management of intractable, debilitating primary or secondary SIJ pain disorders.[57]

The ISASS policy does not endorse any specific MIS SIJ System. There are numerous devices available that have received FDA 510 (k) clearance for use in minimally invasive/percutaneous sacroiliac joint fusion stabilization. The instrumentation utilized in a MIS SIJ procedure is the purview of surgeon preference.[58]

Table 2. Published literature on minimally invasive SIJ fusion.

Inclusion criteria: indexed in PubMed, English language, fusion of the SIJ described as minimally invasive or percutaneous, and clinical outcomes available. Single patient case reports, imaging studies, and technique reports with no clinical outcomes are excluded. When multiple reports of the same cohort were published, only the most recent (longest follow-up) publication is summarized.

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)
Sturesson 2016[18]	Prospective, multicenter, randomized controlled trial (Only surgical arm reported herein) (iMIA, ClinicalTrials.gov NCT01741025)	52	iFuse Implant System	Lateral approach	Age: 49.4 (27-70) years Sex: 38F/14M Prior lumbar fusion: 34.6% Follow-up: 6mo	LBP VAS: 77.7 pre-op, 34.4 at 6mo for an improvement of 43.3 (25.0) ODI: 56.6 pre-op; improvement of 25.5 at 6mo 90% very or somewhat satisfied 80% would definitely have the surgery again Surgical time: 54 (19-107) min Fluoroscopy time: 2.1 (1.0-4.0) min Hospital stay: 3 (range 1-28) days	Within 180 days: 10 AEs in 9 subjects (0.19 events per subject), 8 severe AEs: device-related (0), procedure-related (2, both resolved). Device- and procedure-related events: postop radicular pain resulting from implant protrusion into foramen (1, resolved), postop hematomas (2, resolved). No subject has undergone late revision of implants.
Polly 2015[19] (prior pubs from same cohort/ trial: Whang 2015 - 6mo results[51])	Prospective, multicenter, randomized controlled trial (Only surgical arm reported herein) (INSITE, ClinicalTrials.gov NCT01681004)	102	iFuse Implant System	Lateral approach	Age: 50.2 (26-72) years Sex: 75F/27M Prior lumbar fusion: 39% Follow-up: 12mo	VAS: 82.3 (11.9) pre-op, 28.3 (29.3) at 12mo ODI: 57.2 (12.8) pre-op, 28.1 (20.8) at 12mo Surgical time: 44.9 (22.3) min Fluoroscopy time: 2.5 (3.6) min EBL: 32.7 (32.8) mL Hospital stay: 0.8 (range 0-7) days	Procedure-related adverse events within the first 6mo (180 days): neuropathic symptoms (2), postoperative medical problems (4: urinary retention, nausea/vomiting, atrial fibrillation), SIJ pain or trochanteric bursitis (4), surgical wound problems (4), iliac fracture (1), asymptomatic physical examination finding (1)
		35 of 44 (NSM patients that crossed over after 6mo visit)	iFuse Implant System	Lateral approach	Age: 53.0 (11.5) years Sex: 20F/15M Prior lumbar fusion: 39% Follow-up: 6mo post-fusion	VAS: 83.9 pre- op, 35.8 at 6mo post MIS SIJ fusion ODI: 58.3 pre- op, 30.2 at 6mo post MIS SIJ fusion	

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)
Duhon 2016[31] (Prior pubs from same cohort/ trial: Duhon 2015 - 12mo results[52], Duhon 2013 - 6mo interim results[53])	Prospective, multicenter (SIFI, ClinicalTrials.gov NCT01640353)	172	iFuse Implant System	Lateral approach	Age: 50.9 (24-72) years Sex: 120F/52M Prior lumbar fusion: 44% Follow-up: 24mo	VAS SI joint pain: 79.8 (12.8) pre-op, 30.4 (27.6) at 12mo, 26.0 (26.7) at 24mo ODI: 55.2 (11.5) pre-op, 31.5 (19.2) at 12mo, 30.9 (20.5) at 24mo SF-36 PCS: 31.7 (5.6) pre-op, 40.5 (9.6) at 12mo, 40.7 (10.3) at 24mo SF-36 MCS: 38.5 (11.3) pre-op, 48.2 (12.3) at 12mo, 49.0 (11.5) at 24mo EQ-5D TTO: 0.43 (0.18) pre-op, 0.71 (0.20) at 12mo, 0.71 (0.22) at 24mo Surgical time: 46.6 (16.1) min Fluoroscopy time: 2.7 (1.8) min EBL: 51.0 (75.8) mL Hospital stay: median 1 (range 0-7) day	Device-related: Neuropathic pain related to device malposition (3), SI joint or buttock pain (2), SI joint pain after fall associated with inadequate device placement (1), Hip pain related to periosteal bone growth around implant (1) Procedure-related: Wound drainage/irritation/infection (6), SI joint pain (5), SI joint pain (inadequate stabilization) (3), implant impingement (3), nausea/vomiting (3), buttock pain (2), foot weakness related to anesthesia (1), urinary retention (1), vascular injury (1), wound numbness (1)
Capobianco 2015[54]	Prospective, multicenter (SIFI, ClinicalTrials.gov NCT01640353) Subsets	20 (Females with PPGP)	iFuse Implant System	Lateral approach	Age: 43.3 (9.0) years Sex: 20F Prior lumbar fusion: 30% Follow-up: 12mo	VAS SI joint pain: 81.9 (10.0) pre-op, 21.3 (17.6) at 6mo, 31.4 (30.9) at 12mo ODI: 52.2 (12.7) pre-op, 30.4 (20.0) at 6mo, 32.8 (21.4) at 12mo SF-36 PCS: 32.0 (5.6) pre-op, 40.0 (11.1) at 6mo, 41.6 (10.8) at 12mo SF-36 MCS: 42.2 (12.4) pre-op, 49.7 (9.6) at 6mo, 49.0 (10.8) at 12mo EQ-5D TTO: 0.42 (0.14) pre-op, 0.72 (0.23) at 6mo, 0.72 (0.21) at 12mo 100% very or somewhat satisfied	37 total adverse events (1.8 event rate per subject) 4 device/procedure-related: wound infection (2), numbness around wound (1), fall causing SI joint pain (1)

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)
		100 (Females with No PPGP)	iFuse Implant System	Lateral approach	Age: 52.5 (11.1) years Sex: 100F Prior lumbar fusion: 42.2% Follow-up: 12mo	VAS SI joint pain: 79.9 (13.3) pre-op, 31.5 (27.0) at 6mo, 32.7 (28.5) at 12mo ODI: 55.0 (11.2) pre-op, 31.0 (18.7) at 6mo, 30.8 (19.1) at 12mo SF-36 PCS: 31.1 (5.6) pre-op, 40.5 (9.2) at 6mo, 40.0 (9.6) at 12mo SF-36 MCS: 37.7 (11.6) pre-op, 48.8 (10.8) at 6mo, 47.7 (12.9) at 12mo EQ-5D TTO: 0.43 (0.18) pre-op, 0.70 (0.19) at 6mo, 0.70 (0.20) at 12mo 84% very or somewhat satisfied	158 total adverse events (1.6 event rate per subject) 10 device/procedure-related: buttock pain (2), post-op neuropathy (1), post-op nausea/vomiting (3), intraop hemorrhage (1), neuropathy after contralateral SIJ fusion revision (1), urinary retention (1), would drainage (1)
		52 (Men)	iFuse Implant System	Lateral approach	Age: 50.7 (11.4) years Sex: 52M Prior lumbar fusion: 51.6% Follow-up: 12mo	VAS SI joint pain: 78.9 (12.9) pre-op, 30.2 (28.0) at 6mo, 25.0 (24.0) at 12mo ODI: 56.7 (11.5) pre-op, 36.4 (21.4) at 6mo, 31.9 (18.9) at 12mo SF-36 PCS: 32.7 (5.5) pre-op, 39.8 (10.1) at 6mo, 40.5 (8.9) at 12mo SF-36 MCS: 38.6 (10.3) pre-op, 45.1 (13.2) at 6mo, 48.0 (12.1) at 12mo EQ-5D TTO: 0.45 (0.19) pre-op, 0.64 (0.25) at 6mo, 0.72 (0.19) at 12mo 91.3% very or somewhat satisfied	88 total adverse events (1.7 event rate per subject) 7 device/procedure-related: wound infection (2), buttock pain (1), post-op neuropathy (1), SI joint pain (2), staple irritation (1)
Vanaclocha 2014[30]	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 (range 40-65) min EBL: 58 (range 40-70) mL	Immediate post-op pain (4-resolved), temporary post-op radicular pain (2)

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)
Rudolf 2014[33]	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)
Sachs 2014[32]	Multicenter, 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	No 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%),
Sachs 2013[55]	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[43]	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[29]	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 3 month CT scans show initial fusion	Local hematoma (2), low back pain (1)

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)
Schroeder 2013[44]	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[41]	Single center, sub-group analysis	40	iFuse Implant System	Lateral approach	Subgroup analysis from Rudolf 2012 to assess effect of prior lumbar fusion or lumbar treatment on outcomes. Follow up: 12 and 24 months		
		18 (no prior fusion)	iFuse Implant System	Lateral approach	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 fusion)	iFuse Implant System	Lateral approach	Age: 58 (11) Sex: 11F/4M	VAS decrease at 12mo: -3.50 (3.46) VAS decrease at 24mo: -5.81 (2.88) Surgical time: 64 (19) min	Superficial cellulitis (2), buttock hematoma (1), revision for implant malposition (1)
		7 (prior concomitant lumbar pathology treated non-surgically	iFuse Implant System	Lateral approach	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 2013[38]	Single center, Retrospective case series	19	DIANA cage [Product not approved for use in the US]	Posterior, longitudinally inserted into SI joint	Age: 60.9 (36-76) years Sex: 5F/14M Prior lumbar fusion: 100% Follow-up: 13.2 (6-24) mo	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 (3-10) days Fusion rate: 78.9% (15/19 joints), defined as lack of loosening and evidence of bone bridging around the implant	No neurovascular complications

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)
Mason 2013[36]	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[42]	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[21]	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%)
Khurana 2009[35]	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	SF-36 PF: 37.15 (14.28) pre- op, 79.33 (12.52) at follow-up Majeed's: 37 (18-54) pre- op, 79 (63-96) at follow-up Good to excellent results: 13/15 (87%) EBL: < 50 ml Hospital stay: 2.7 (1-7) days	No post-operative neurological or wound complications.

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)
Al-Khayer 2008[34]	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[37]	Single center Prospective cohort	13	Titanium cage packed with BMP	Posterior, Longitudinally inserted into SIJ	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							
Ledonio 2014[45]	Single center, retrospective, comparative cohort study	22	iFuse Implant System	Lateral approach	<u>MIS Cohort</u> Age: 47.9 (13.1) years Sex: 17F/5M Prior lumbar fusion: 64% Follow-up: median 15 (12-26) mo	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 Hospital Stay: 2.0 (1.5) days	Pulmonary embolism that resolved with treatment (1), revisions due to halo formation on the sacral side with recurring sacroiliac joint pain (2)
		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	<u>Open Cohort</u> 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)

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)
Ledonio 2014[46]	Multicenter, retrospective, comparative cohort study	17	iFuse Implant System	Lateral approach	<u>MIS Cohort</u> 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	<u>Open Cohort</u> 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[26]	Multicenter, retrospective comparative cohort study	114	iFuse Implant System	Lateral approach	<u>MIS Cohort</u> 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	<u>Open Cohort</u> 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).

NOTE: The table excludes 3 systematic reviews:
Zaidi - *J Neurosurg Spine* 2015[49]: systematic review of studies on SIJ fusion, includes open and MIS.
Heiney - *Int J Spine Surg* 2015[48]: systematic review and meta-analysis of MIS SIJ fusion utilizing a lateral transarticular technique.
Lingutla - *Eur Spine J* 2016[56]: Systematic review and meta-analysis of observational studies describing outcome of SIJ fusion in patients with LBP.
Abbreviations: SIJ: sacroiliac joint; MIS: minimally invasive surgery/surgical; 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.

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