Washington State Health Care Authority

Sacroiliac Joint Fusion Update

Final Evidence Report

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Health Technology Assessment Program (HTA)

Washington State Health Care Authority

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This evidence report is based on research conducted by the RTI-University of North Carolina Evidence-based Practice Center through a contract between RTI International and the State of Washington Health Care Authority (HCA). The findings and conclusions in this document are those of the authors, who are responsible for its contents. The findings and conclusions do not represent the views of the Washington HCA and no statement in this report should be construed as an official position of Washington HCA.

The information in this report is intended to help the State of Washington's independent Health Technology Clinical Committee make well-informed coverage determinations. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

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List of Abbreviations

ADL	Activity of daily living
AMD	Absolute mean difference
ARD	Absolute risk difference
CBA	Cost-benefit analysis
CCA	Comparative cost analysis
CCS	Controlled cohort study
CCT	Controlled clinical trial
CEA	Cost-effectiveness analysis
CI	Confidence interval
CM	Conservative management
CPG	Clinical practice guideline
CPT	Current Procedural Terminology
CQ	Cost question
CT	Computed tomography
CUA	Cost-utility analysis
DALY	Disability-adjusted life-year
EQ	Efficacy question
EQ-5D	EuroQol 5 Dimensions
ES	Executive summary
FDA	Food and Drug Administration
GBP	British pound sterling
HTA	Health technology assessment
ICER	Incremental cost-effectiveness ratio
IQR	Interquartile range
ISASS	International Society for the Advancement of Spine Surgery
LOCF	Last observation carried forward
MAC	Medicare Administrative Contractors
MCS	Mental health component score of SF-36
MID	Minimally important difference
MRI	Magnetic resonance imaging
NASS	North American Spine Society
NHS	National Health Service

NICE	National Institute for Health and Care Excellence
NR	Not reported
NRS	Numeric Rating Scale
NS	Not significant
NSAID	Nonsteroidal anti-inflammatory
ODI	Oswestry Disability Index
OIS	Optimal information size
OR	Odds ratio
PCS	Physical health component score of SF-36
PT	Physical therapy
QALY	Quality-adjusted life year
QoL	Quality of life
RCT	Randomized controlled trial
RFA	Radiofrequency ablation
RM	Repeated measures
RR	Risk ratio
SD	Standard deviation
SF-12	Short Form Survey 12 item
SQ	Safety question
SR	Systematic review
U.K.	United Kingdom
UN	United Nations
U.S.	United States
VAS	Visual analog scale

Executive Summary

Structured Abstract

Purpose: To conduct a health technology assessment (HTA) update on the efficacy, safety, and cost of sacroiliac (SI) joint fusion.

Data Sources: PubMed Embase, and Cochrane from January 1, 2018 through January 31, 2021; clinical trial registry; government, payor, and clinical specialty organization websites; hand searches of bibliographies, relevant clinical practice guidelines (CPG), and systematic reviews to identify relevant studies.

Study Selection: Using a priori criteria, we selected English-language primary research studies that were conducted in very highly developed countries that enrolled adults with SI joint pain or dysfunction and compared SI joint fusion to nonsurgical interventions, or that compared alternative surgical procedures. We selected randomized controlled trials (RCTs) or controlled cohort studies (CCSs) that reported efficacy outcomes (e.g., pain, physical function), safety outcomes (e.g., adverse events, revision surgery), or cost analyses. We also selected uncontrolled studies that reported safety outcomes.

Data Extraction: One research team member extracted data and a second checked for accuracy. Two investigators independently assessed risk of bias of included studies. We rated the certainty of the body of evidence for each comparison and outcome using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach.

Data Synthesis: We included 57 studies in total; 9 were controlled studies (2 RCTs and 7 CCSs), 43 were uncontrolled studies, and 5 were cost studies.

Two RCTs and 1 CCS compared minimally invasive SI joint fusion surgery using the iFuse Implant System with conservative management and observed larger improvements in a visual analog scale (VAS) for pain (calculated between-group differences at 6 months based on the RCTs: -40.5 mm [95% CI, -50.1 to -30.9], -38.1 mm [95% CI not reported; $P<0.0001$] and at 6 months to 3.5 years based on the CCS: -60 mm [95% CI, not reported; $P<0.001$]) with minimally invasive fusion. These studies also observed larger improvements with minimally invasive fusion in physical function measured using the Oswestry Disability Index (ODI) (between-group differences at 6 months based on the RCTs: -25.4 points (calculated) [95% CI, -32.5 to -18.3] and -19.8 points [95% CI, not reported, $P<0.0001$] and at 6 months to 3.5 years based on the CCS: -24 points [95% CI, not reported; $P<0.001$]). Improvements in pain and physical function for the RCTs appeared durable at 1- and 2-year follow-up. We graded the outcomes from RCTs at 6 months as moderate certainty and at 1 to 2 years as low or very low certainty. Adverse events appeared higher in the minimally invasive fusion group at 6 months though we could not determine the direction of the effect at 2 years; we graded the adverse events outcomes as very low certainty. The incidence of revision surgery varied by study; the highest incidence reported was 3.8% at 2 years. Cost-effectiveness studies reported the cost per

quality-adjusted life-year gained to be between $2,697 and $13,313; we graded this outcome as very low certainty. One CCS compared open fusion to no surgery at 11 to 32 years and observed no difference in pain, physical function, and quality of life; we graded these outcomes as very low certainty. The incidence of adverse events was 10% among open surgery patients and revision surgery was performed on 8.4% of the joints among open surgery patients.

Three CCSs compared minimally invasive fusion with iFuse to open fusion. We graded all outcomes for this comparison as very low certainty. One CCS reported larger improvements in pain with iFuse measured with a VAS (between-group difference over 2 years: -30 mm [95% CI, -40 to -21]; the other 2 studies did not report pain outcomes but found mixed findings for physical function measured by the ODI. All 3 studies observed significantly shorter hospital length of stay among iFuse recipients compared to open fusion; the range of difference was 1.3 to 3.8 days. All 3 studies reported a similar incidence of adverse events between groups but reported mixed findings for the incidence of revision surgery. One of the 3 studies reported significantly fewer revisions among participants that received iFuse (absolute risk difference [ARD] -40.8% [95% CI, -49.5% to -32.1%]); the other 2 studies reported infrequent revisions (1-2 per group) in both the iFuse and the open fusion groups.

Two CCS comparing the effectiveness of alternative minimally invasive fusion procedures. One CCS compared minimally invasive fusion with iFuse to minimally invasive fusion with the Rialto Implant System and reported no differences in pain, function, quality of life, length of stay, and revision surgeries from 6 months to 1 year. We graded all of these outcomes as very low certainty. One CCS compared minimally invasive fusion with iFuse to minimally invasive fusion with screw fixation; significantly fewer revisions were required among participants who received iFuse (ARD -61.0% [95% CI, -78.4% to -43.5%]). We graded this outcome as very low certainty.

Forty-three uncontrolled studies reported safety outcomes for a variety of open and minimally invasive fusion procedures. We evaluated many as having a high risk of bias; further outcome definition and ascertainment methods varied widely. One study, which used an insurance claims database to identify 469 minimally invasive fusion procedures between 2007 and 2014 reported a 90-day incidence of complications of 13.2%. Another study, which used a post market surveillance database of 14,210 iFuse procedures, reported an incidence of revision surgery of 3.1% over the years 2015 to 2018.

Limitations: Most included studies were uncontrolled, which limits a comparative assessment. We did not consider efficacy outcomes from uncontrolled studies. CCSs and uncontrolled studies had critical methodological flaws. Extensive crossovers occurred in the 2 RCTs after 6 months lowering our certainty of findings at longer follow-up time points. The only comparative studies of minimally invasive procedures were nearly all industry-sponsored evaluations of the iFuse system, which limits the generalizability of findings to other minimally invasive procedures. We did not evaluate unpublished data or data from passive surveillance systems.

Conclusions: Among patients meeting diagnostic criteria for SI joint pain or dysfunction and who have not responded adequately to conservative management, minimally invasive SI joint

fusion surgery is probably more effective than conservative management for reducing pain, improving function, improving quality of life at 6 months follow-up and at 1 to 2 years of follow-up, and is likely cost-effective though the certainty of this evidence varies from very low to moderate and varies by different follow-up timepoints. This evidence also suggests that adverse events up to 6 months are higher from minimally invasive SI joint surgery than conservative management, though the certainty of this evidence is very low. Minimally invasive SI joint fusion surgery may be more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay, but the certainty of this evidence is very low. Based on evidence from uncontrolled studies, serious adverse events from minimally invasive SI joint surgery may be higher in usual practice compared to what is reported in RCTs. The incidence of revision surgery is likely no higher than 3.8% at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or across different minimally invasive devices and procedures.

ES 1. Background

We updated this health technology assessment (HTA) to assist the State of Washington's independent Health Technology Clinical Committee with determining coverage for sacroiliac (SI) joint fusion.

ES 1.1 Condition Description

SI joint fusion is a surgical treatment used to address chronic pain that is believed to originate from the joint between bones in the spine and hip (sacrum and ilium). The clinical presentation of chronic SI joint pain varies from patient to patient, but buttock pain extending into the posterolateral thigh is the most common pattern.[1] Aside from major trauma events resulting in serious pelvic injury, several predisposing factors for SI joint pain and dysfunction exist, including leg length discrepancies, gait abnormalities, persistent strain/low-grade trauma (i.e., running), scoliosis, pregnancy, and prior spine surgery, particularly spinal fusion.[1]

ES 1.2 Disease Burden

SI joint pain is thought to be the primary source of pain for approximately 10% to 38% of cases of mechanical low back pain and its frequency may be higher among persons with new or ongoing pain after lumbar fusion because of stress transfer from the lumbar spine to the SI joint after such surgery.[2-12] However, estimating an accurate prevalence of SI joint pain is challenging; the current reference standard for diagnosis is relief of pain after anesthetic SI joint injection.[2] Imaging is generally not helpful in establishing a diagnosis of SI joint pain or dysfunction but may be helpful in ruling out other etiologies of low back pain.[2] Although diagnosis can be challenging, the impact of SI joint pain on quality of life is significant.[12]

ES 1.3 Technology Description

SI joint fusion procedures are typically reserved for persons who fail less invasive treatments. Fusion of the SI joint can be performed as an open procedure, or since the late 1990s, as a minimally invasive procedure, which is what is predominantly used in the current era. Numerous

proprietary surgical systems for SI joint fusion exist. These systems typically consist of 2 to 3 specialized implants or screws inserted to span the SI joint and create immediate fixation. The implants or screws used in some systems have specialized designs or coatings to promote bone growth onto and into the implant or screw to achieve fusion. Other systems combine decortication and insertion of a bone graft with immediate fixation to promote solid bone growth across the joint space for what some consider to be a 'true' fusion of the joint space.[13] According to a survey of members of the International Society for the Advancement of Spine Surgery and the Society for Minimally Invasive Spine Surgery, the percent of SI joint fusion procedures that were performed using minimally invasive techniques increased from 39% in 2009 to 88% in 2012.[14]

ES 1.4 Regulatory Status

The U.S. Food and Drug Administration (FDA) has cleared (through the 510k process for medical devices) or approved (under Title 21 CFR Part 1271 for structural allografts and demineralized bone allografts) 34 products for SI joint fusion made by various manufacturers and that are currently being marketed. Detailed information is provided in ***Table 1*** of the Full Technical Report.

ES 1.5 Policy Context

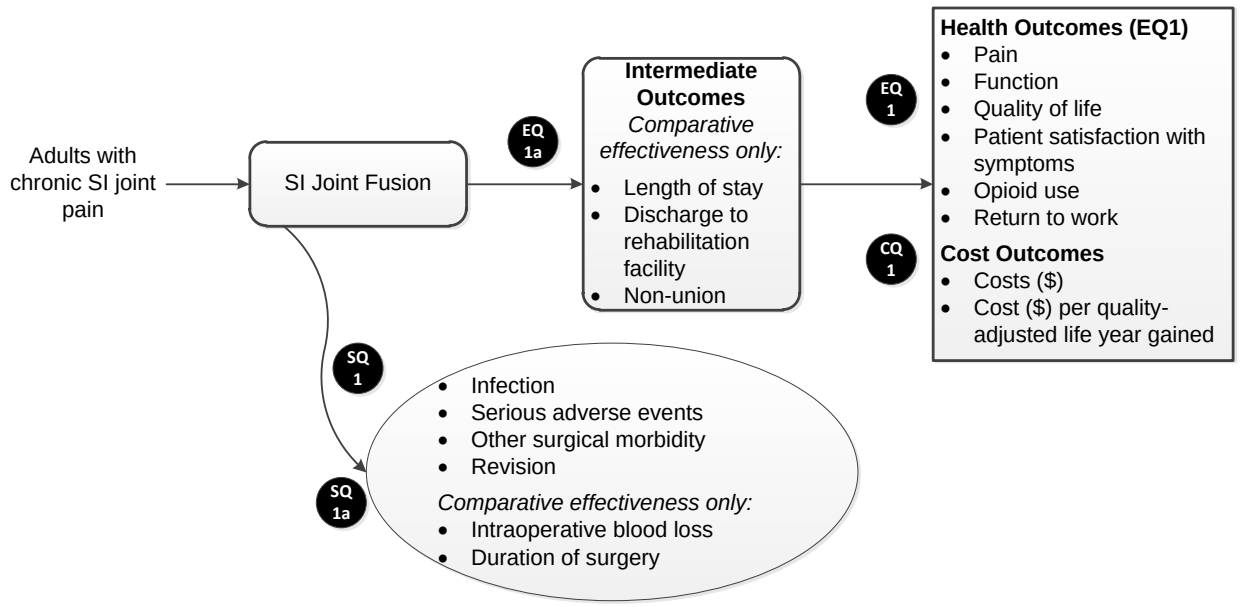
The State of Washington Health Care Authority selected SI joint fusion as a topic for an HTA in 2018 based on high concerns for efficacy, safety, and cost. SI joint fusion was selected for a re-review based on a signal search report conducted in 2020, petition, and public comments received on the topic. This HTA update was conducted to assist the State of Washington's independent Health Technology Clinical Committee in determining coverage for SI joint fusion procedures to treat SI joint pain related to degenerative sacroiliitis or SI joint disruption. Utilization data for this procedure was provided by the state and is located in ***Appendix A***.

ES 2. Methods

This section describes the methods we used to conduct this HTA update.

ES 2.1 Research Questions and Analytic Framework

Figure ES-1. Analytic framework for HTA on sacroiliac joint fusion



Efficacy Question 1 (EQ1). What is the effectiveness and comparative effectiveness of sacroiliac joint fusion surgery on health outcomes?

> **Effectiveness Question (EQ1a):** What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

Safety Question 1 (SQ1). What is the safety of sacroiliac joint fusion surgery?

> **Safety Question 1a (SQ1a):** What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

Cost Question 1 (CQ1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery?

In addition to the key research questions, we addressed the following contextual question related to the diagnosis of SI joint pain. This question was not systematically reviewed and is not shown in the analytic framework.

1. What are the recommended ways to diagnose SI joint pain or disruption and what is the accuracy of various diagnostic tests?

ES 2.2 Data Sources and Search

We searched MEDLINE, Embase, Cochrane, and a clinical trials registry for relevant English-language studies from January 1, 2018 through January 31, 2021. We searched the Centers for Medicare & Medicaid Services and FDA websites, selected payer and health care professional society websites, and websites of other organizations. We used medical subject headings (MeSH

terms) and text words associated with SI joint and fusion. The detailed search strategy is in ***Appendix B.***

ES 2.3 Study Selection

Two reviewers independently screened titles and abstracts and full-text articles based on the following study selection criteria (complete details are in ***Table 2*** of the Full Technical Report).

- Population: adults with chronic SI joint pain and positive diagnostic tests.
- Intervention(s): open SI joint fusion, minimally invasive SI joint fusion.
- Comparator(s): fusion surgery (head-to-head comparison), active conservative treatment, placebo or sham surgery, no treatment.
- Outcomes: pain, physical function, quality of life, patient satisfaction, opioid use, return to work, infection, surgical morbidity, adverse events, revision surgery, costs, and cost-effectiveness We also considered the following outcomes from head-to-head studies—length of stay, non-union, discharge to rehabilitation facility, intraoperative blood loss, and duration of surgery.
- Study design(s): randomized controlled trials (RCTs), controlled trials, controlled cohort studies (CCSs), and systematic reviews of similar scope; we also considered uncontrolled studies for the safety question, and cost analyses for the cost question.
- Setting: inpatient or outpatient settings from countries as assessed as 'very high' on the United Nations Human Development Index.[15]
- Other: English-language, no restrictions on time period included.

ES 2.4 What is Excluded from This HTA

This review did not include studies published in languages other than English or conducted in countries that are not very highly developed based on the United Nations Human Development Index.[15] This review did not include studies conducted among children or adolescents. It was designed to focus on SI joint fusion surgery to treat chronic SI joint pain related to degenerative sacroiliitis or SI joint disruption, or both, and we excluded studies evaluating surgical interventions focused on addressing other etiologies of low back pain or SI joint surgery related to acute trauma, infection, or cancer. This study also did not use data from the Manufacturer and User Facility Device Experience (MAUDE) database because of limitations with this passive surveillance system including incomplete, inaccurate, untimely, and unverified data.[16]

ES 2.5 Data Abstraction and Risk of Bias Assessment

Two team members extracted relevant study data from new studies into a structured abstraction form, and a senior investigator checked those data for accuracy. We rechecked data previously abstracted for completeness and accuracy. We contacted some study authors to clarify

discrepancies within or across articles. Two team members conducted independent risk of bias assessments on all newly included studies. We used the Cochrane Risk of Bias (RoB 2.0) tool[17] to assess the risk of bias for RCTs, the ROBINS-I tool[18] to assess the risk of bias for nonrandomized comparative studies (e.g., CCSs) and the Quality of Health Economic Studies Instrument[19] to assess cost analyses. We used a checklist for critical appraisal of uncontrolled studies based on several existing instruments designed for case series.[20,21] For all study designs, risk of bias was assessed as low, some concerns, or high.

ES 2.6 Data Synthesis and Certainty of Evidence Assessment

We synthesized studies comparing the surgical interventions to nonsurgical interventions separately from studies comparing alternative surgical interventions. We qualitatively synthesized study characteristics and results in tabular and narrative formats. We used OpenEpi (version 3.01) to calculate effect estimates and associated 95% confidence intervals (CI) when not provided by study authors. These calculations are specified as "calculated" in the report and tables. Using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach, we updated the GRADE ratings from the previous HTA to reflect the incorporation of new studies and additional data from previously included studies. Two team members independently applied the GRADE approach to grade the certainty of each body of evidence. With GRADE, the certainty of evidence can be graded as "very low," "low," "moderate," or "high". ***Table 3*** in the Full Technical Report defines these levels.

ES 3. Results

ES 3.1 Literature Yield

We included a total of 57 studies published between 1987 and January 2021; 43 of these studies were included in the previous 2018 HTA report. Nine studies (2 RCTs, 7 CCSs) provided evidence on efficacy or comparative effectiveness (EQ1) and safety (SQ1), 43 uncontrolled studies (8 uncontrolled trials, 34 uncontrolled cohort studies, and 1 unclear study) provided evidence on safety (SQ1), and 5 studies provided evidence on costs or cost-effectiveness (CQ1).

ES 3.2 Sacroiliac Joint Fusion Compared with Conservative Management

We identified 2 RCTs[22,23] and 1 CCS[24] that compared minimally invasive SI joint fusion with the iFuse Implant System to conservative management and 1 CCS[25] that compared open fusion to no treatment. Conservative management in the 2 trials included components such as optimization of medical therapy, physical therapy; 1 of the trials also allowed therapeutic SI joint injections and radiofrequency nerve ablation if other measures failed.[23] The certainty of evidence (GRADE rating) for efficacy and safety outcomes comparing iFuse to conservative management is provided in ***Table ES-1*** and comparing open fusion to no surgery is provided in ***Table ES-2***. Both RCTs comparing iFuse to conservative management reported pain outcomes among subgroups defined by history of prior lumbar fusion; no differences in efficacy were observed between those with or without prior lumbar fusion. Both RCTs reported visual analog scale (VAS) pain and Oswestry Disability Index (ODI) physician function measures beyond 6 months; because extensive unplanned crossovers occurred, these findings have a high risk of bias because

of deviation from the randomized assignment in the intent-to-treat analyses and because of confounding introduced by analyzing based on treatment received rather than the randomized allocation. In both trials, participants who crossed over had higher 6-month mean VAS and ODI scores compared to participants who did not cross over. Despite these limitations, improvements in pain and physical function appeared to be durable at 1- and 2-year follow-up and differences between the surgery and conservative management groups persisted.

Table ES-1. Summary of findings and certainty of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) with conservative management

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in pain at 6 months (Visual Analog Scale; MID = 7 to 11 mm)						
2 RCTs[22,23]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with MI SIJF compared to conservative management; calculated between-group difference -40.5 mm (95% CI, -50.1 to -30.9) in 1 study[23] and -38.1 mm (95% CI NR, *P*<0.0001) in other study.[22]	⊕⊕⊕◯ MODERATE Favors MI SIJF
Change in pain at 6 months to 3.5 years (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[24]	Very serious[b]	Not serious[c]	Not serious	Not serious[d]	Total N = 137. Significantly larger improvement with MI SIJF compared to SI denervation (between-group difference: -45 mm, *P*<0.001) and to conservative management (between-group difference: -60 mm, *P*<0.001).	⊕◯◯◯ VERY LOW Favors MI SIJF
Change in pain at 1 year (Visual Analog Scale; MID = 7 to 11 mm)						
2 RCTs[26,27]	Very serious[k]	Not serious	Not serious	Not serious	Total N = 234. Compared with conservative management, significantly larger improvements for MI SIJFin 1 study[22] (between-group difference -27.6 mm, *P*<0.0001). In other study;[23] significantly larger improvements for MI SIJF compared to conservative management participants who did not cross over (between-group difference -32.6 mm, 95% CI, -58.7 to -6.6, *P*=0.01) and no difference when compared to conservative management participants who crossed over (-5.7 mm, 95% CI, -17.1 to 5.7, *P*=0.32).	⊕⊕◯◯ LOW Favors MI SIJF
Threshold improvement in pain at 2 years (at least 20 mm improvement on Visual Analog Scale)						
2 RCTs[28,29]	Very serious[k]	Not serious	Not serious	Not serious	Total N =218. Compared with conservative management, a significantly higher proportion of participants achieve a threshold improvement with MI SIJF compared to conservative management. In 1 study,[29] 79% vs. 24% (calculated RR 3.3, 95% CI, 1.92 to 5.6); in other study,[28] 83% vs. 10% (calculated RR 8.3, 95% CI, 3.3 to 21.2).	⊕⊕◯◯ LOW Favors MI SIJF
Change in physical function at 6 months (Oswestry Disability Index; MID = 8 to 11 points)						

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
2 RCTs[22,23]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with MI SIJF compared to conservative management, between-group difference -25.4 points (calculated) (95% CI, -32.5 to -18.3, *P*<0.0001) in 1 study[23] and -19.8 (95% CI NR, *P*<0.0001) in other study.[22]	⊕⊕⊕◯ MODERATE Favors MI SIJF
Change in physical function at 1 year (Oswestry Disability Index; MID = 8 to 11 points)						
2 RCTs[26,27]	Very serious[k]	Serious[l]	Not serious	Not serious	Total N = 234. Compared with conservative management, significantly larger improvements for MI SIJF in 1 study[22] (calculated between-group difference -20.1 points, *P*<0.0001); no difference in other study[23] for MI SIJF compared to conservative management participants who crossed over (calculated between-group difference -1.1, 95% CI, -8.9 to 6.7, *P*=0.78) and conservative management participants who did not cross over (calculated between-group difference -0.4, 95% CI, -18.5 to 17.7, *P*=0.97)	⊕◯◯◯ VERY LOW Mixed findings
Threshold improvement in physical function at 2 years (at least 15-point improvement on Oswestry Disability Index)						
2 RCTs[28,29]	Very serious[k]	Not serious	Not serious	Not serious	Total N =218. Compared with conservative management, a significantly higher proportion of participants achieve a threshold improvement with MI SIJF compared to conservative management. In 1 study,[29] 64% vs. 24% (calculated RR 2.7, 95% CI, 1.5 to 4.7); in other study,[28] 68% vs. 8% (calculated RR 9.1, 95% CI, 3.0 to 27.2).	⊕⊕◯◯ LOW Favors MI SIJF
Change in physical function at 6 months to 3.5 years (Oswestry Disability Index; MID = 8 to 11 points)						
1 CCS[24]	Very serious[b]	Not serious[c]	Not serious	Not serious[e]	Total N = 137. Significantly larger improvement with MI SIJF compared to SI denervation (between-group difference -17 points [*P*<0.001]) and to conservative management (between-group difference -24 points [*P*<0.001]).	⊕◯◯◯ VERY LOW Favors MI SIJF
Change in quality of life at 6 months (EQ-5D [MID = 0.18] and SF-36 [MID = 2 to 3 points])						
2 RCTs[22,23]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with MI SIJF compared to conservative management; EQ-5D between-group difference 0.24 (calculated) (95% CI, 0.16 to 0.32) in 1 study[23] and 0.21 (95% CI NR, *P*<0.0001) in other study.[22] Calculated between-group difference on SF-36 PCS 11.5 (95% CI, 8.1 to 14.9) and MCS 5.6 (95% CI, 1.8 to 9.4) in 1 study.[23]	⊕⊕⊕◯ MODERATE Favors MI SIJF
Change in quality of life at 1 to 2 years (EQ-5D [MID = 0.18] and SF-36 PCS [MID = 2 points])						

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
2 RCTs[22,23,26-29]	Very serious[k]	Not serious	Not serious	Not serious	Total N = 234. Significantly larger improvements persisted with MI SIJF compared to conservative management; EQ-5D calculated between-group difference 0.22 (*P*=0.0009) at 1 yr. and 0.24 (*P*<0.001) at 2 yrs. in 1 study.[26,29] In other study[27,28] Calculated EQ-5D change from baseline (SD) at 1 yr. for MI SIJF participants compared to conservative management participants that crossed over to surgery was 0.01, and for those that did not cross over was 0.11; these values persisted at 2 yrs. A similar pattern was observed for SF-36 PCS.	⊕⊕◯◯ Low Favors MI SIJF
Opioid use at 6 months						
1 RCT[23]	Serious[a]	Not serious[f]	Not serious	Very Serious[g]	Total N = 148. No significant difference in percentage of participants using opioids; calculated within group difference -9% among MI SIJF participants and 8% among conservative management participants (reported *P*=0.08).	⊕◯◯◯ VERY LOW Favors MI SIJF
Opioid use at 1 to 2 years						
2 RCTs[27-29]	Very serious[k]	Serious[m]	Not serious	Not serious	Total N = 233. In one study,[29] calculated change in percentage of participants using opioids -23% among MI SIJF participants and -1.4% among conservative management participants at 2 yrs. (calculated RR 0.75, 95% CI, 0.45 to 1.24). In other study,[27,28] calculated change in percentage of participants using opioids -16.6% among MI SIJF participants at 1 yr. and 20.3% at 2 yrs. and -8.0% among conservative management participants (unclear which group included the crossovers; *P* NR).[27]	⊕◯◯◯ VERY LOW Favors MI SIJF
Opioid use at 6 months to 3.5 years						
1 CCS[24]	Very serious[b]	Not serious[f]	Not serious	Not serious	Total N = 137. Significant difference (*P*<0.001) between groups in oral morphine equivalents used at the time of last follow-up: MI SIJF (3.1 mg/day), SI denervation (32.2 mg/day), conservative management (38.5 mg/day).	⊕◯◯◯ VERY LOW Favors MI SIJF
Adverse events at 6 months						

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
2 RCTs[22,23]	Serious[a]	Serious[n]	Not serious	Serious[h]	Total n = 249. In one study, 129 events among 102 MI SIJF participants and 49 events among 46 conservative management participants; # severe events related to the device or procedure 6 vs. 1.[23,28] In other study, 20 events among 52 MI SIJF participants and 17 events among 51 conservative management participants; # severe events related to device or procedure 4 vs. 0.[22,29] Unable to determine direction of effect beyond 6 months because data for CM participants not reported by crossover status.[22,23]	⊕◯◯◯ VERY LOW Favors CM
1 CCS[24]	Very serious[b]	Not serious[f]	Not serious	Very serious[i]	Total N = 137. No serious adverse events reported in either group.	⊕◯◯◯ VERY LOW No difference
Revision surgery						
2 RCTs[22,23,26-29]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. In one study, incidence 3.4% at 2 yrs. among 89 MI SIJF participants with follow-up data and 2.6% among 39 conservative management participants who crossed over to surgery.[23] In other study, incidence 3.8% at 2 yrs. among 52 MI SIJF participants and 4.8% among 21 conservative management participants who crossed over to surgery.[22]	⊕⊕⊕◯ MODERATE Favors CM
1 CCS[24]	Very serious[b]	Not serious[f]	Not serious	Very serious[j]	Total N = 137. No revision surgery reported among participants who received MI SIJF at 6 months to 3.5 years.	⊕◯◯◯ VERY LOW Favors CM

Notes: a. Some concerns for bias because of no masking of treatment allocation.
b. High concerns for bias because of large amounts of missing data at timepoints greater than 1 year and use of repeated measures analysis through all timepoints; some concerns for selection bias, confounding, and measurement of outcome.
c. Not applicable as is a single study body of evidence but findings are consistent with the 2 RCTs.
d. Data not provided to estimate 95% CI, but based on Figure 3 in original publication, the treatment effect confidence intervals for iFuse do not overlap with the confidence intervals for the 2 control groups.
e. Data not provided to estimate 95% CI, but based on Figure 4 in original publication, the treatment effect confidence intervals for iFuse do not overlap with the confidence intervals for the 2 control groups.
f. Not applicable, single study body of evidence.
g. Requires a sample size of 386 to meet OIS criteria (RR = 0.8, power = 0.8, alpha = .05); CI spans a range from moderate benefit to no effect.
h. Somewhat infrequent events, requires a sample size of 4,168 to meet OIS criteria (RR = 1.2, power = 0.8, alpha = 0.05); unable to calculate confidence intervals because number of participants with events was not reported.
i. Zero events reported in both groups, OIS criteria not met.
j. Zero revisions reported in intervention group, OIS criteria not met.
k. High concern for bias because of no masking of treatment allocation and extensive crossover from conservative management to surgery after 6 mos. One study[23,27,28] did not clearly state which participants were included in 1 year outcomes and did not report 2 year outcomes for the CM group; and the other study[22,26,29] used the last observation carried forward method to estimate outcomes after 6 mos. for those assigned to conservative management.
l. One study[26] reported a significant improvement, and the other study[27] observed no difference between the groups.
m. One study[29] did not calculate the significance of the difference between the groups and the other study[27] observed no difference between the groups.
n. Similar direction of effect, but absolute number of events higher in INSITE compared to iMIA, partially but not entirely explained by differences in treatments used in control groups.

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; CM=conservative management; EQ-5D = EuroQOL measure of generic health status; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mm = millimeters; mo(s). = months; N=number of participants; NA = not applicable; NR = not reported; OIS = optimal information size; RCT = randomized controlled trial; RR = relative risk; SF-36 = Short Form 36-item Survey Physical Health Component Score (PCS) and Mental Health Component Score (MCS); yr(s). = year(s).

Table ES-2. Summary of findings and certainty of evidence comparing open sacroiliac joint fusion with no surgery

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY / Direction of Effect
Pain at 11 to 23 years (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[c]	Total N = 78. No significant between-group difference (calculated): -6 mm (95% CI, -10.2 to 22.2).	⊕◯◯◯ VERY LOW No difference
Physical function at 11 to 23 years (Oswestry Disability Index; MID = 8 to 11 points)						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[d]	Total N = 78. No significant between-group difference (calculated): -4 points (95% CI, -9.1 to 17.1).	⊕◯◯◯ VERY LOW No difference
Quality of life at 11 to 23 years (SF-36)						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[e]	Total N = 78. No significant between-group differences in any of the 8 subscale scores.	⊕◯◯◯ VERY LOW No difference
Adverse events						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[f]	Total N = 78. Incidence 10% among 58 open surgery participants; adverse events not reported in the no surgery group.	⊕◯◯◯ VERY LOW NA
Revision surgery						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[g]	Total N = 78. Incidence 8.4% of joints among 50 open surgery participants. No revision surgery reported among participants who received no surgery.	⊕◯◯◯ VERY LOW NA

Notes: a. High or some concerns in multiple domains including confounding, selection bias (both enrollment methods and high attrition) and outcome measurement.
b. Not applicable, single study body of evidence.
c. Requires a sample size of 344 (mean difference 10 mm, power = 0.8, alpha = .05, SD estimate from study) to meet OIS criteria; confidence intervals around mean difference are wide and include a clinically meaningful increase and decrease.
d. Requires a sample size of 202 (mean difference 10 points, power = 0.8, alpha = 0.05, SD estimate from study) to meet OIS criteria; confidence interval spans a clinically meaningful decrease and increase.
e. CIs around subscale estimates were wide and overlapping between groups.
f. Somewhat infrequent events; events were not reported for the no surgery group.
g. Somewhat infrequent events; unable to calculate confidence intervals because number of participants with events was not reported; revisions were not reported for the no surgery group.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MID = minimally important difference; mm = millimeters; OIS = optimal information size; SD = standard deviation; SF-36 = Short Form 36-item survey.

ES 3.3 Minimally Invasive Fusion Compared With Open Fusion

We identified 3 CCSs that compared minimally invasive fusion with open fusion. The certainty of evidence for efficacy and safety outcomes is provided in ***Table ES-3***.

Table ES-3. Summary of findings and certainty of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) to open fusion

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in pain over 2 years (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[30]	Very serious[a]	Not serious[b]	Not serious	Not serious	Total N = 263. Significantly larger improvement for MI SIJF compared to open fusion (between-group repeated measures difference -30 mm [95% CI, -40 to -21]).	⊕◯◯◯ VERY LOW Favors MI SIJF
Change in physical function at 13 to 15 months (Oswestry Disability Index; MID = 8 to 11 points)						
2 CCS[31,32]	Very serious[a]	Serious[c]	Not serious	Serious[d]	Total N = 83; mixed findings. Compared with open fusion, significantly larger improvements for MI SIJF in 1 study[31] (calculated between-group difference -33 points, *P*<0.0008); no difference in other study[32] (calculated between-group difference 4.9 points, *P*=0.272).	⊕◯◯◯ VERY LOW Mixed findings
Length of hospital stay						
3 CCS[30-32]	Very serious[a]	Not serious	Serious[e]	Not serious	Total N = 346. Significantly shorter length of stay for MI SIJF participants compared to open fusion participants; range of differences were 1.3 to 3.8 days across studies.	⊕◯◯◯ VERY LOW Favors MI SIJF
Adverse events						
3 CCS[30-32]	Very serious[a]	Serious[f]	Not serious	Very serious[g]	Total N = 346. No intraoperative complications reported in any study; frequency of postoperative complications similar between groups and ranged from 14% to 35% across groups.	⊕◯◯◯ VERY LOW No difference
Revision surgery						
3 CCS[30-32]	Very serious[a]	Very serious[h]	Not serious	Very serious[g]	Total N = 346. Infrequent revision in both groups in 2 studies (1 to 2 per group)[31,32]; significantly fewer revisions in MI SIJF in third study (calculated ARD -40.8% [95% CI, -49.5% to -32.1%]; calculated RR 0.08 [95% CI, 0.03 to 0.21]).[30]	⊕◯◯◯ VERY LOW Mixed findings

Notes: a. High risk or some concerns for bias in multiple domains, including confounding, selection bias (both because of methods of enrollment and attrition), and outcome measurement.
b. Not applicable, single study body of evidence.
c. One study[32] observed similar improvements and the other study[31] shows significantly larger improvements.
d. Based on SDs observed for measure at follow-up in Ledonio et al.[32]; a sample size of 1,040 participants would be required to meet OIS criteria for a difference of 3.38 points, which represents a small effect size (0.2 SDs).
e. Unclear whether length of stay has a direct correlation to clinical status versus reflecting surgeon or hospital preferences.
f. The incidence of adverse events was highly varied suggesting differences in monitoring or reporting of events or heterogeneity in underlying population.
g. Infrequent events in 2 of the 3 studies.
h. Similar frequency of revision surgery among groups in 2 studies[31,32]; large difference between iFuse and open surgery in third study.[30]

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; N = number of participants; MI SIJF = minimally invasive sacroiliac fusion; mm = millimeters; OIS = optimal information size criteria; RR = risk ratio; SD = standard deviation.

ES 3.4 Comparative Effectiveness of Alternative Minimally Invasive Fusion Procedures

We identified 2 CCSs comparing the effectiveness of alternative minimally invasive fusion procedures. One CCS, new to this update, compared the minimally invasive posterior oblique approach with Rialto (a cylindrical threaded implant) to the minimally invasive lateral transiliac approach with the iFuse Implant System (a triangular dowel implant).[33] The other CCS compared minimally invasive fusion with implants (iFuse) to percutaneous screw fixation; this study did not report any eligible efficacy outcomes. The certainty of evidence (GRADE rating) for efficacy and safety outcomes comparing iFuse to Rialto is provided in ***Table ES-4***, and the certainty of evidence for safety outcomes comparing iFuse to percutaneously screw fixation is provided in ***Table ES-5***.

Table ES-4. Summary of findings and certainty of evidence ratings comparing minimally invasive sacroiliac joint fusion using the iFuse Implant System to the Rialto Implant System

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in pain at 6 months to 1 year (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[33]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N = 156; no significant differences between Rialto and iFuse (between-group difference 4.3 mm [95% CI, -8.7 to 17], *P*=0.53 at 6 mos.; -3.7 mm [95% CI, -23 to 15], *P*=0.70 at 1 yr.)	⊕◯◯◯ VERY LOW No difference
Change in physical function at 6 months to 1 year (Oswestry Disability Index; MID = 8 to 11 points)						
1 CCS[33]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N = 156; no significant differences between Rialto and iFuse (between-group difference 3.0 (95% CI, -2.1 to 8.1), *P*=0.25 at 6 mos.; -2.1 (95% CI, -9.2 to 4.9), *P*=0.55 at 1 yr.)	⊕◯◯◯ VERY LOW No difference
Change in quality of life at 6 months to 1 year (SF-12)						
1 CCS[33]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N = 156; no significant differences between Rialto and iFuse (between-group difference 1.7 (95% CI, -1.5 to 4.9), *P*=0.28 at 6 mos.; 3.0 (95% CI, -0.48 to 6.5), *P*=0.09 at 1 yr.)	⊕◯◯◯ VERY LOW No difference
Length of stay						
1 CCS[33]	Serious[a]	Not serious[b]	Serious[c]	Not serious	Total N = 156; no significant differences between Rialto (1.7 days) and iFuse (1.8 days) (*P*=0.42)	⊕◯◯◯ VERY LOW No difference
Revision surgery						
1 CCS[33]	Serious[d]	Not serious[b]	Not serious	Serious[e]	Total N = 156; no significant differences between Rialto (6.1%) and iFuse (2.4%); calculated ARD -5.7% (95% CI, -12.7% to 1.4%), calculated RR 0.30 (95% CI, 0.06 to 1.44).	⊕◯◯◯ VERY LOW No difference

Notes: a. Serious or moderate concerns for bias because of confounding, selection, and outcome measurement.
b. Not applicable, single study body of evidence.
c. Unclear whether length of stay has a direct correlation to clinical status versus reflecting surgeon, hospital, or insurer preferences.
d. High or some concerns for bias in multiple domains, including confounding, selection bias (both because of methods of enrollment and attrition), and outcome measurement.

e. Somewhat infrequent events.

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; ml = milliliters; mo(s). = month(s); N=number of participants; RR = risk ratio; yr(s). = year(s).

Table ES-5 Summary of findings and certainty of evidence comparing minimally invasive sacroiliac joint fusion (iFuse) to screw fixation

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Revision surgery at 2.8 to 4.6 years						
1 CCS[34]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N = 292; significantly fewer revisions with MI SIJF (4.6%) compared to screws (65.5%); calculated ARD -61.0% (95% CI, -78.4% to -43.5%); calculated RR 0.07 (95% CI, 0.04 to 0.13).	⊕◯◯◯ VERY LOW Favors MI SIJF

Notes: a. Some concerns for bias because of confounding and differential attrition.
b. Not applicable, single study body of evidence.

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; MI SIJF = minimally invasive sacroiliac fusion; N = number of participants; RR = risk ratio.

ES 3.5 Safety Outcomes From Uncontrolled Studies

In addition to the 2 RCTs and 7 CCSs evaluating SI joint fusion, we identified 43 uncontrolled studies that reported safety outcomes from various SI joint fusion procedures; 11 uncontrolled studies are new to this update.[35-46] Nine studies[37,47-54] evaluated open fusion procedures, and the rest evaluated various minimally invasive fusion procedures. We rated 27 studies as having a high risk of bias, 14 as having some concerns of bias, and 2 as having a low risk of bias. The way in which study authors defined and monitored adverse events, including timeframe over which participants were followed, varied greatly. Prospective uncontrolled trials were more likely to actively monitor participants and report all adverse events participants experienced during the study time frame, regardless of whether the event was device- or procedure-related.[55-57] Some studies reported only whether major complications of surgery occurred.

Among the 8 studies evaluating open fusion, the frequency of adverse events ranged from 5.3% to 75% experiencing complications. The frequency of revision surgery, which was reported only among 7 of the 9 studies, ranged from 4.0% to 64.7%.

Among the 20 studies evaluating the iFuse Implant System, the frequency of adverse events that were definitely or probably related to the device or procedure ranged from 0% to 102%.[35,39,40,42-45,55-66] The frequency of severe or serious adverse events ranged from 0% to 46%. One study reported that 33% of serious events were device related at 6 months[55]; the frequency of severe adverse events that were device or procedure related decreased to less than 10% of severe adverse events after one or more years of follow-up.[35,55,56] One study retrospectively evaluated the frequency of adverse events after minimally invasive SI joint fusion using a large insurance claims database from 2007 to 2014.[67] Study authors could not report the specific procedures or systems used based on available data. The overall incidence of complications was 13.2% at 90 days and 16.4% at 6 months among 469 claimants that had received surgery.

Among the 20 studies evaluating the iFuse Implant System, the frequency of revision surgery ranged from 0% to 8%. One of the largest of these studies reported the incidence of revision based on the manufacturer's postmarket surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320 (2.8%) underwent a revision and 63% of the revisions occurred within the first year postoperatively.[68] Similarly, another study using the same postmarket surveillance database over the years 2015 to 2018 observed that 3.1% of the 14,210 participants who underwent the initial procedure with iFuse had a revision.[42]

ES 3.6 Cost and Cost-effectiveness

Three studies reported on cost outcomes; all compared minimally invasive SI joint fusion surgery with iFuse to conservative management.[69-71] ***Table ES-6*** summarizes these outcomes.

Table ES-6 Summary of findings and certainty of evidence comparing costs and cost-effectiveness of minimally invasive sacroiliac joint fusion (iFuse Implant System) to conservative management

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY
Costs over 3 to 5 years in a commercially insured population						
1 CCA[69]	Not serious	Not serious[a]	Not serious	Serious[b]	Minimally invasive SI joint fusion with iFuse costs $14,545 more over 3 years and $6,137 more over 5 years.	⊕◯◯◯ VERY LOW
Lifetime costs in a Medicare population						
1 CCA[70]	Not serious	Not serious[a]	Not serious	Serious[b]	Minimally invasive SI joint fusion with iFuse costs $3,358 less than nonoperative care.	⊕◯◯◯ VERY LOW
Cost-effectiveness over 5 years						
2 CEA[71,72]	Not serious	Not serious[b]	Not serious	Serious[c]	Minimally invasive SI joint fusion with iFuse costs range from $2,697 to $13,313 per QALY gained.	⊕◯◯◯ VERY LOW

Notes: a. Not applicable, single study body of evidence.
b. Although the magnitude of the incremental cost-effectiveness ratios were not entirely consistent, they were in the same direction and the inconsistency is likely explained by differences in cost between the United States and the United Kingdom and in differences in costing methods used in the studies.
c. No information provided (e.g., standard error, standard deviations, confidence intervals) in the studies to be able to judge precision of estimates.

Abbreviations: CCA = comparative cost analysis; CEA = cost-effectiveness analysis; QALY = quality-adjusted life-year; SI = sacroiliac.

ES 3.7 Contextual Questions on Diagnostic Accuracy

The diagnosis of SI joint pain or disruption is challenging since symptoms may be similar to those of other causes of low back and hip pain due to overlapping pain referral zones.[4,73] Experts recommend a diagnostic approach that includes history, physical exam, diagnostic joint block, and additional diagnostic tests (e.g., radiography) to rule out other pain contributors.[4,74] Pain in the buttock with radiation to the groin or upper legs is a typical history, and specific physical exam tests that stress the SI joint (listed in *Section 1.2* in the Full Report) can be performed in office settings.[4,73,74] These physical exam tests in combination are predictive of a positive

response to intra-articular SI joint block and can indicate the SI joint as a source the low back pain.[4] No specific imaging findings are pathognomonic for the diagnosis of non-inflammatory, nontraumatic SI joint pain; thus, imaging is primarily used to rule out alternative diagnoses for the low back pain.[4,74]

Confirmation of suspected SI joint etiology for low back pain is achieved through temporary pain relief from an intra-articular SI joint block with no more than 2.5 mL of a local anesthetic under imaging guidance to assure intra-articular placement.[4,75,76] However, there is not agreement on the level of pain improvement that constitutes a positive diagnostic injection. Some experts recommend 75% temporary pain relief or more after SI joint injection,[73,75] and others recommend a lower range, such as 50% or greater as some studies have suggested no correlation between degree of improvement after diagnostic block and response to fusion surgery (see *Section 3.7* in the Full Report) arguing against the use of overly stringent pain relief criteria.[4,74,75,77] Several known limitations associated with SI joint injection as a reference standard for diagnosis is the potential for insufficient anesthesia of the entire joint (which reduces positive target specificity) or extravasation of the injectate outside of the joint (which may serve to anesthetize other structures in close proximity to the SI joint and increase negative target specificity).[77]

We identified 1 systematic review[78] published in 2009 of diagnostic test accuracy of history and physical exam maneuvers for the diagnosis of SI joint dysfunction. Authors of this review included 18 studies that evaluated 1 or more history or physical exam tests (or combination of tests). Most studies were set in university or hospital spine centers, and many tests were assessed in only 1 study. All compared the index test with contrast-enhanced intraarticular injection with local anesthetics as a reference test. In the studies in this review, reference test administration varied in terms of the volume of injected medications and cut-off used for a positive test (e.g., 5 studies required 80% reduction in pain, some required 50% or 70%, and some did not specify a level).[78] Presence of pain in the SI joint region alone had relatively poor accuracy based on 1 study but asking patients to point to the pain with the finger had improved accuracy.[78]. Pooled analyses of studies comparing 3 or more positive provocation tests had improved accuracy (sensitivity of 85% and specificity of 76%) compared to most single provocation tests alone.

ES 4. Discussion

ES 4.1 Summary of the Evidence

Compared to conservative management, minimally invasive SI joint fusion surgery with the iFuse Implant System appears to improve pain, physical function, and quality of life. The certainty of evidence from 2 RCTs for pain was moderate at 6 months, low at 1 and 2 years, and from 1 CCS was very low for pain between 6 months and 3.5 years. For physical function, findings from RCTs probably favor minimally invasive SI joint fusion surgery at 6 months (moderate certainty of evidence) and 2 years (low certainty of evidence) but were mixed at 1 year. Physical function findings from the 1 CCS also appear to favor minimally invasive SI joint fusion surgery over outcomes between 6 months and 3.5 years (very low certainty of evidence). Quality of life was also probably improved compared to conservative management at 6 months

and 1 year in 2 RCTs (moderate to low certainty of evidence). Similarly, opioid use may be improved at 6 months and 1 to 2 years (very low certainty of evidence). For adverse events, findings from RCTs suggest that minimally invasive SI joint fusion surgery increased the number of adverse events compared to conservative management at 6 months (very low certainty of evidence). The directionality of overall adverse events could not be determined from the evidence in 2 RCTs (very low certainty of evidence) while no difference in serious adverse events were observed (very low certainty of evidence [1 CCS]). The incidence of revision surgery based on the RCT evidence was likely no higher than 3.8% at 2 years (moderate certainty of evidence). Minimally invasive surgery with iFuse costs between $2,697 and $13,313 per quality of life-adjusted year gained compared to conservative management (very low certainty of evidence); an amount that most would consider cost-effective. This evidence is applicable to persons who do not adequately respond to an initial period of nonsurgical management, such as medication, physical therapy, and therapeutic joint injections. No differences were observed between open fusion and conservative management with respect to pain, function, and quality of life based on very low certainty of evidence from 1 CCS that only measured very long-term outcomes (11 to 32 years). The incidence of adverse events was 10% among open surgery participants and not reported for the no surgery group (not graded). Revision surgery was performed on 8.4% of the joints in open surgery participants (very low certainty of evidence).

Minimally invasive SI joint fusion with the iFuse Implant System appears to improve pain over 2 years and was associated with a shorter length of hospital stay compared to open fusion, but findings were inconsistent for the impact on physical function. The incidence of adverse events appears similar for open fusion and iFuse, but findings were mixed for the incidence of revision surgery. All findings related to this comparison are based on very low certainty of evidence.

No differences were observed between minimally invasive SI joint fusion surgery with the iFuse implant system and the Rialto implant system with respect to pain, function, quality of life, length of stay, and revision surgeries from 6 months to 1 year (very low certainty of evidence) based on from 1 CCS. Lastly, compared to minimally invasive fusion with screw fixation, minimally invasive fusion with iFuse appears to result in fewer revisions (very low certainty of evidence) based on 1 CCS.

We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events and revision surgery across the 9 uncontrolled studies evaluating open fusion limits our ability to draw definitive conclusions from this body of evidence. Similarly, the incidence of adverse events and revision surgery reported in the 34 uncontrolled studies of minimally invasive surgery (iFuse and other devices) is also very heterogenous, likely reflecting differences in outcome definitions and ascertainment or heterogeneity in study populations and follow-up times. The incidence of complications from minimally invasive fusion reported from an analysis of insurance claims is higher than the incidence reported in controlled studies and likely reflects the incidence in usual practice. The incidence of revision surgery after fusion with iFuse observed in trials is similar to the incidence reported in postmarket surveillance.

ES 4.2 Limitations of the Evidence Base

Most studies we identified were uncontrolled studies, which prevents a comparative assessment. Twelve studies (3 CCSs and 9 uncontrolled studies) evaluated an open approach to fusion; however, the outcomes reported from these studies were limited. Of the 8 controlled studies evaluating minimally invasive fusion, all evaluated the iFuse Implant System, which limits the generalizability of findings to other minimally invasive procedures; only 2 controlled studies compared iFuse with other minimally invasive procedures. Additionally, almost all of the included controlled studies and all the cost-effectiveness studies report some financial ties to industry, through study sponsorship, author consultancies, or author employment; studies where authors report financial competing interests have been associated with favorable results for the experimental intervention.[79] Many studies included a significant proportion of participants with prior lumbar fusion; however, most studies either did not prespecify subgroup analyses or sample sizes among subgroups were too small to conduct meaningful analyses.

All of the controlled observational studies we included had critical methodological flaws leading us to assess them as high risk of bias; specifically confounding and selection bias because of high attrition or because of only allowing participants with complete follow-up data into the analysis. The 2 included RCTs had some concerns for bias since they were not blinded. Comparative outcomes reported after 6 months from these trials should be considered high risk of bias because of the extensive degree of crossovers from conservative management to surgery that occurred, despite analytic methods used by study authors to mitigate the impact.

Lastly, small sample sizes and heterogeneity in the reporting of adverse events and incidence of revision surgery limit the comparability of these outcomes across this body of evidence.

ES 4.3 Clinical Practice Guideline Summary

In addition to the systematic evidence review of primary research studies, we synthesized clinical practice guidelines (CPGs) to review how different organizations have provided guidance on the provision of minimally invasive SI joint fusions (***Table 22*** in the Full Report). We appraised each guideline using the Appraisal of Guidelines for Research & Evaluation II (AGREE) instrument.[80,81] We identified 6 publicly accessible CPGs, including 2 guidelines (1 general guideline for minimally invasive SI joint fusion and 1 iFuse specific guideline) from the National Institute for Health and Care Excellence (United Kingdom), 1 from the North American Spine Society (NASS), 1 from AIM Specialty Health, 1 from eviCore, and 1 from the International Society for the Advancement of Spine Surgery (ISASS). Our appraisals of these guidelines ranged between 3 and 4 on the AGREE-II scale from 1 (lowest quality) to 7 (highest quality).

Two guidelines were from the National Institute for Health and Care Excellence (both appraised as a "4" on the AGREE-II scale). The general guideline on minimally invasive SI joint fusion surgery for chronic SI pain[82] concluded that that the current evidence on safety and efficacy is adequate to support use of minimally invasive SI joint fusion but also qualified that the procedure should only be done by surgeons who regularly use image-guided surgery and who have had specific training. The iFuse specific guideline[83] concluded that the current evidence supported the use of the iFuse implant system to treat chronic sacroiliac joint pain. The guideline

further recommended that iFuse be considered for use in people with a confirmed diagnosis of SI joint pain (through clinical assessment and a diagnostic injection of an anesthetic) and whose pain is inadequately controlled by non-surgical management.

Similar to the iFuse-specific guidelines by the National Institute for Health and Care Excellence, guidelines by AIM Specialty Health[84] and eviCore[85] (both appraised as a "3" on the AGREE-II scale) stated that minimally invasive SI joint fusion using iFuse may be considered if selected criteria were met, including 1) persistent pain that interferes with function and that has not responded to conservative management, 2) diagnostic confirmation through provocative physical exam testing and pain reduction after SI joint injection, and 3) imaging that excludes non-SI joint sources of pain. The eviCore guidelines also required additional criteria, including that the procedure should be done by a trained orthopedic surgeon or neurosurgeon, documentation of nicotine-free status, and absence of unmanaged significant behavioral health disorders.

A fifth guideline by the International Society for the Advancement of Spine Surgery (ISASS)[4] (appraised as a "4" on the AGREE-II scale) stated that lateral transiliac minimally invasive SI joint fusion may be considered if the same 3 criteria specified by AIM Specialty Health and eviCore were met. However, this guideline did not recommend minimally invasive surgical posterior (dorsal) SI joint fusion because there was limited clinical evidence supporting the safety and effectiveness of this procedure. This guideline did not endorse any specific minimally invasive SI joint system.

Finally, the North American Spine Society (NASS) guideline[86] (appraised as a "4" on the AGREE-II scale) performed a systematic review that yielded no studies with patients with SI joint dysfunction and no prior lumbar surgery or lower limb pain. This guideline could not make any definitive statements regarding SI joint fusion for patients with low back pain.

ES 4.4 Payer Coverage

An overview of selected payer coverage policies for SI joint fusion related to degenerative sacroiliitis and SI joint disruption is provided in ***Table ES-7***. Details for these coverage policies are provided in ***Table 24*** of the Full Technical Report. The Center for Medicare & Medicaid Services does not have a national coverage determination for SI joint fusion procedures though all 8 Medicare Administrative Contractors (MACs) do cover this procedure, including the 1 that operates in the State of Washington (Noridian Healthcare Solutions).[87] All commercial payers reviewed in this HTA update, except Kaiser Permanente of Washington, cover minimally invasive fusion when certain clinical criteria are met.

Table ES-7 Overview of payer coverage policies for sacroiliac joint fusion for degenerative sacroiliitis, sacroiliac joint dysfunction, or sacroiliac joint pain

Medicare NCD	Medicaid	Aetna	Cigna	Humana	Kaiser Permanente	Noridian Healthcare Solutions (MAC)	Premera Blue Cross	Regence Blue Shield	Tri-care	UnitedHealth Care (Medicare Advantage)	UnitedHealth Care (Commercial)
—[a]	Covered in 44 states	✓[b]	✓[b]	✓[b]	✗	✓	✓[c]	✓[c]	✓	✓[b]	✓[d]

Notes: ✓ = covered; ✕ = not covered; — = no policy identified.
a. No national coverage determination identified but all 8 MACs consider coverage, at least on a case-by-case basis.
b. Covered when clinical criteria are met.
c. Covered when clinical criteria are met and only covered for minimally invasive fusion with triangular, titanium coated implants (i.e., iFuse).
d. Does not manage a UnitedHealth policy specific to this procedure but has adopted MCG clinical coverage criteria for this procedure.

Abbreviations: MAC = Medicare Administrative Contractor; MCG = Medicare Milliman Clinical Guidelines; NCD = national coverage determination.

ES 4.5 Limitations of this HTA

We limited the scope to English-language publications and we only searched 3 databases. We did not search for unpublished data and did not use data presented only in conference abstracts. We did not consider efficacy outcomes from uncontrolled studies and did not use GRADE to evaluate the body of evidence consisting of uncontrolled studies. We also did not use data from the FDA Manufacturer and User Facility Device Experience (MAUDE) database to assess safety because passive surveillance systems include incomplete, inaccurate, untimely, and unverified data.[16] Lastly, the AGREE guideline appraisal instrument largely focuses on evaluating the processes through which a guideline is developed; it does not assess how well the evidence included in the guideline was evaluated and if it was interpreted correctly, or whether the conclusions of the guideline are consistent with the evidence. Thus, some guidelines may score artificially high and this explains why conclusions may differ between guidelines despite having similar quality scores.

ES 4.6 Ongoing Research and Future Research Needs

Four studies of SI joint fusion are ongoing; two are sponsored by device manufacturers and two are sponsored by a practice or hospital. One is an uncontrolled trial of the SI-LOK joint fixation system (NCT01861899), one is an uncontrolled, postmarket study of the SImmetry device (NCT02074761), one is an uncontrolled multi-site study of the LinQ fusion procedure sponsored by a group practice (NCT04423120), and the fourth is a double-blind, multi-center RCT comparing iFuse with sham operation sponsored by an academic hospital (NCT03507049).

Future comparative effectiveness research that assesses long-term (greater than 1 year) efficacy and safety outcomes is needed to confirm the durability of outcomes from shorter-term studies. As an emerging field, high quality clinical trials are needed to assess the efficacy and safety of the many SI joint fusion procedures currently marketed in the United States. Further, comparative effectiveness research is needed to assess the relative efficacy and safety of alternative minimally invasive SI joint fusion procedures. Continued standardization of diagnostic criteria in future studies will also help to ensure comparability of findings across studies. Lastly, research to better understand the relationship between SI joint pain and dysfunction and other spinal disorders will help further elucidate cause and effect mechanisms.

ES 5. Conclusion

Among patients meeting diagnostic criteria for SI joint pain or dysfunction and who have not responded adequately to conservative management, minimally invasive SI joint fusion surgery is probably more effective than conservative management for reducing pain, improving function, improving quality of life at 6 months follow-up and at 1 to 2 years of follow-up, and is likely cost-effective though the certainty of this evidence varies from very low to moderate and varies by different follow-up timepoints. This evidence also suggests that adverse events up to 6 months are higher from minimally invasive SI joint surgery than conservative management, though the certainty of this evidence is very low. Minimally invasive SI joint fusion surgery may be more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay, but the certainty of this evidence is very low. Based on evidence from uncontrolled studies, serious adverse events from minimally invasive SI joint surgery may be higher in usual practice compared to what is reported in RCTs. The incidence of revision surgery is likely no higher than 3.8% at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or across different minimally invasive devices and procedures.

Full Technical Report

1. Background

We conducted this health technology assessment (HTA) update to assist the State of Washington's independent Health Technology Clinical Committee with determining coverage for sacroiliac (SI) joint fusion.

1.1 Condition Description

SI joint fusion is a surgical treatment used by some clinicians to address chronic pain that is believed to originate from the joint between bones in the spine and hip (sacrum and ilium). The SI joint is a diarthrodial joint with 2 surfaces and a fibrous capsule containing synovial fluid.[1,13] Functionally, the SI joint supports the upper body and dampens forces related to walking. Numerous ligaments support the joint and provide it with strength but also limit its mobility. The clinical presentation of chronic SI joint pain varies from patient to patient, but buttock pain extending into the posterolateral thigh is the most common pattern.[1] The etiology of SI joint pain is thought to be related to degenerative sacroiliitis or SI joint dysfunction from axial loading and rotation. Studies suggest the entire SI joint complex (i.e., capsule, ligaments, subchondral bone) is innervated with nociceptors providing multiple sources of pain.[1,2,13] Aside from major trauma events resulting in serious pelvic injury, several predisposing factors for SI joint pain and dysfunction exist, including leg length discrepancies, gait abnormalities, persistent strain/low-grade trauma (i.e., running), scoliosis, pregnancy, and prior spine surgery, particularly spinal fusion.[1]

1.2 Disease Burden

SI joint pain is thought to be the primary source of pain for approximately 10% to 38% of cases of mechanical low back pain, and its frequency may be higher among persons with new or ongoing pain after lumbar fusion because of stress transfer from the lumbar spine to the SI joint after such surgery.[2-12] However, estimating an accurate prevalence of SI joint pain is challenging and studies that attempt to estimate the prevalence are limited by conflicts of interest and lack of a consistent case definition. History and physical exam are limited for establishing a diagnosis of SI joint pain. Provocative physical exam tests (e.g., distraction test, thigh thrust, compression test, **F**lexion **A**bduction, **E**xternal **R**otation [FABER or Patrick] test, Gaenslen's maneuver) that stress the SI joint have a role as part of a stepwise approach to diagnosis.[3,4] The current reference standard for diagnosis is relief of pain following anesthetic SI joint injections, typically under imaging guidance to ensure intraarticular placement.[2] However, this diagnostic standard is invasive and may not be widely available. Imaging is generally not helpful in establishing a diagnosis of SI joint pain or dysfunction but may be helpful in ruling out other etiologies of low back pain.[2]

Although diagnosis can be challenging, the impact of SI joint pain on quality of life is significant. When compared to a nationally representative sample of free-living adults, patients who were enrolled in 2 trials of minimally invasive SI joint fusion had significantly worse

quality of life at study entry as measured by the Short-Form 36 survey and the EuroQol-5D index measures.[12] Further, the decrement in quality of life among patients with SI joint pain was similar to the decrement associated with hip osteoarthritis and a chronic obstructive pulmonary disease exacerbation.[12]

1.3 Technology Description

Several treatments for SI joint pain and dysfunction are available: pelvic belts and girdles; analgesics and anti-inflammatory medications; physical therapy to address strength, flexibility, or biomechanical deficits; manual manipulation; therapeutic joint injection; prolotherapy; radiofrequency denervation; and fusion surgery.[3,13,88,89] SI joint fusion procedures are typically reserved for persons who fail less invasive treatments. The goal of SI joint fusion is to relieve excessive motion at the joint, which is hypothesized to then minimize pain and improve function.

Fusion of the SI joint can be performed as an open procedure, or since the late 1990s, as a minimally invasive procedure, which is the predominant procedure now used in clinical practice for this condition. Numerous proprietary surgical systems for SI joint fusion exist. These systems typically consist of 2 to 3 specialized implants or screws inserted to span the SI joint and create immediate fixation. The device implants or screws used in some systems have specialized designs or coatings to promote bone growth onto and into the implant or screw to achieve fusion. Other systems combine decortication and insertion of a bone graft with immediate fixation to promote solid bone growth across the joint space for what some consider to be a 'true' fusion of the joint space.[13]

Some systems are designed exclusively for use in a minimally invasive procedure with small incisions and insertion of the implants or screws with fluoroscopic or 3-D imaging guidance. The surgical approach is either a lateral transarticular approach or is a posterior approach that sometimes involves removal of a portion of the interosseous SI ligament.[90] Other surgical systems are designed exclusively for an open approach or can be used with either an open or minimally invasive approach. Practitioners report that intraoperative times, bleeding, and hospital length of stay are higher with the open approach when compared to a minimally invasive approach.[90] According to a survey of members of the International Society for the Advancement of Spine Surgery and the Society for Minimally Invasive Spine Surgery, the percent of fusion procedures that were performed using minimally invasive techniques increased from 39% in 2009 to 88% in 2012.[14] Most SI joint fusion procedures are performed unilaterally, though a bilateral SI joint fusion may occasionally be indicated and would typically be performed in sequence rather than simultaneously.[90]

1.4 Regulatory Status

We identified 34 products with U.S. Food and Drug Administration (FDA) 510k clearance, Title 21 CFR Part 1271 FDA approval, or both that are currently marketed in the United States specifically for SI joint fusion (***Table 1***). The 510(k) clearance process for medical devices is based on evidence that the device is "substantially equivalent" to a device that FDA has already cleared or that was marketed before 1976. None of the devices currently marketed for SI joint fusion were required to use the FDA premarket approval (PMA) pathway, which is the process

for scientific and regulatory review for the safety and effectiveness of Class III medical devices and is the most stringent FDA pathway for device approval. Products marketed as structural allografts (i.e., implants made of mineralized bone) and demineralized bone allografts designed to be used with SI joint devices require FDA approval under Title 21 CFR Part 1271, which governs the manufacture, storage, and use of human cells, tissues, and cellular- and tissue-based products.

Table 1. FDA clearance or approval status of available sacroiliac joint fusion systems or devices

Company	Product	Clearance or Approval Type	Date[a]	510k Clearance Number/ Federal Establishment Identifier[b]	Company or Product Link(s)
Advanced Research Medical LLC	Trident SI Screw System	510k	January 22, 2021	k203373	Trident SI Screw System
Aegis Spine	ZESPIN SI Joint Fusion System	510k	February 16, 2021	k210035	Aegis Spine
	PathLoc-SI Joint Fusion System	510k	November 14, 2016 July 16, 2018	k153656 k181600	PathLoc-SI
Alevio Spine	SiCure Sacroiliac Fusion System	510k	Unable to determine	Unable to determine[c]	SiCure
	Re-Live Multi-Point Structural Allograft Sacroiliac Joint Fusion System	21 CFR Part 1271	Unable to determine	3013684126	Re-Live
Biofusion Medical	SI-Restore Sacroiliac Joint Fixation System	510K	January 25, 2019 April 17, 2020	k182919 k200868	SI-Restore
Camber Spine	Siconus SI Joint Fixation System	510k	January 18, 2017	k162121	Siconus
	Prolix SI Fusion System (structural allograft used in conjunction with Siconus system)	21 CFR Part 1271	Unable to determine	3010197239	Prolix
Captiva Spine	TransFasten Posterior Sacroiliac Fusion System	21 CFR Part 1271	Unable to determine	510k not required (structural allograft) 3006082533	TransFasten
CoreLink, LLC	Entasis Sacroiliac Joint Fusion System	510k	February 4, 2016	k152237	Entasis
Cutting Edge Spine, LLC	EVOL-SI Joint Fusion System	510k	August 12, 2019	k190025	EVOL-SI Joint Fusion
Foundation Fusion Systems	CornerLoc	21 CFR Part 1271	Unable to determine	510k not required (structural allograft) 3013912820	CornerLoc
Genesys Spine	Genesys Spine Sacroiliac Joint Fusion System	510k and 21 CFR Part 1271	September 26, 2019	k191748 3008455034	Genesys Spine
Globus Medical, Inc.	SI-LOK Sacroiliac Joint Fixation System, Navigation Instruments, ExcelsiusGPS Instruments	510k and 21 CFR Part 1271	December 9, 2011 February 6, 2019	k112028 k183119 3004142400	SI-LOK
Ilion Medical Inc/ SIGNUS Medizintechnik .	NADIA SI Fusion System/ Distraction Interference Arthrodesis of the Sacroiliac Joint (DIANA)	510k	August 5, 2020 September 18, 2009	k190580 k091122	NADIA DIANA device
KIC Ventures/Spine Frontier, Inc LES	Sacrix (SacroFuse)	510k	April 24, 2015	k150017	Sacrix
Life Spine	Tri-Fin Sacroiliac Joint Fixation Screw System	510k and 21 CFR Part 1271	February 22, 2015 June 15, 2018	k141246 k180749	SImpact

Company	Product	Clearance or Approval Type	Date[a]	510k Clearance Number/ Federal Establishment Identifier[b]	Company or Product Link(s)
	SIMPACT Sacroiliac Joint Fixation System		September 18, 2020	k201538 3006138406	
Medacta International SA	M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System	510k	August 2, 2017 January 13, 2021	k171595 k203671	M.U.S.T.
Medtronic	Rialto SI Fusion System	510k and 21 CFR Part 1271	May 29, 2012 August 12, 2016	k110472 k161210 3002600221	Rialto
NuTech Spine and Biologics	SIFix Sacroiliac Intra-articular Fusion Allograft	21 CFR Part 1271	Unable to determine	3008865245	SIFix
Omnia Medical	PsiF System	21 CFR Part 1271	December 28, 2017	510k not required (structural allograft) 3013159344	PsiF
Orthofix Inc.	FIREBIRD SI Fusion System	510k and 21 CFR Part 1271	April 2, 2020	k200696 k203138 0002183449	FIREBIRD SI
	Samba Screw System SambaScrew 3D SI Fusion System	510k and 21 CFR Part 1271	August 20, 2012 April 30, 2019	k121148 k183342 0002183449	SambaScrew 3D
Painteq, LLC	LinQ SI Joint Stabilization System	21 CFR Part 1271	Unable to determine	510k not required (structural allograft) 3015341611	LinQ SI Joint Stabilization System
Pantheon Surgical/ Osseus	Orion SI Joint System/ Blue Topaz	510k	October 3, 2018	k181881	Orion Blue Topaz
RTI Surgical, Inc.	SImmetry Sacroiliac Joint Fusion System	510k	December 14, 2010 August 5, 2015	k102907 k151818 3002719998	SImmetry
SI-Bone, Inc.	iFuse -TORQ	510k & 21 CFR Part 1271	March 4, 2021	k203247	iFuse
	iFuse Implant System iFuse 3-D Implant	510k & 21 CFR Part 1271	March 31, 2020 March 10, 2017 November 26, 2008	k162733/3014436635 k193524 k080398	iFuse
SICAGE, LLC	SICAGE Bone Screw System	510k	May 5, 2017	k170475	SICAGE
Tenon Medical, Inc.	Catamaran Sacroiliac Joint Fusion System (CAT SIJ Fixation System)	510k	June 13, 2018	k180818	Catamaran
VGI Medical, LLC	SiJoin	21 CFR Part 1271	January 17, 2018	510k not required (structural allograft)	SiJoin

Company	Product	Clearance or Approval Type	Date[a]	510k Clearance Number/ Federal Establishment Identifier[b]	Company or Product Link(s)
				3006982954	
XTant Medical/ Zimmer Biomet	Silex Sacroiliac Joint Fusion System / TriCor Sacroiliac Joint Fusin System	510k and 21 CFR Part 1271	March 11, 2013 March 25, 2014	k123702 k140079 3005168462	Silex TriCor
Zavation Medical Products, LLC	SI Screw System	510k	March 16, 2018	k173752	SI Screw System

Notes: a. Date of most recent clearance document and original device clearance document.
b. Refers to identifier for Title 21 CFR 1271 approval for structural allografts or devices used with bone tissue allografts**.**
c. Query sent to the company for more information; update pending response from the company.

Abbreviations: CFR = Code of Federal Regulations; FDA = U.S. Food and Drug Administration.

In addition to the devices specifically marketed for SI joint fusion, several cannulated screw products designed for use across a wide variety of orthopedic fixation procedures also have 510k clearance for use in SI joint fusion.

1.5 Policy Context

The State of Washington Health Care Authority selected SI joint fusion in 2018 as a topic for an HTA based on high concerns for efficacy, safety, and cost (https://www.hca.wa.gov/assets/program/si-fusion-final-rpt-20181130.pdf). SI joint fusion was selected for a re-review based on a signal search report conducted in 2020 (https://www.hca.wa.gov/assets/program/si-joint-fusion-signal-search-20201110.pdf), petition, and public comments received on the topic. This HTA update was conducted to assist the State of Washington's independent Health Technology Clinical Committee in determining coverage for SI joint fusion procedures to treat SI joint pain related to degenerative sacroiliitis and/or SI joint disruption.

1.6 Washington State Agency Utilization Data

The State of Washington Health Care Authority provided data on SI joint fusion utilization in the State of Washington from 2017 to 2020. This data is provided in ***Appendix A***. The data provided includes utilization and costs for Medicaid (fee for service and managed care organization), Department of Labor and Industries Workers' Compensation Program, and the Public Employee Benefit Board Uniform Medical Plan, including Medicare.

2. Methods

This section describes the methods we used to conduct this HTA update.

2.1 Research Questions and Analytic Framework

We used the following research questions and analytic framework (***Figure 1***) to guide the systematic evidence review of primary research studies; no changes were made to the framework or questions compared to the prior HTA:

Efficacy Question 1 (EQ1). What is the effectiveness and comparative effectiveness of sacroiliac joint fusion surgery on health outcomes?

> **Effectiveness Question (EQ1a):** What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

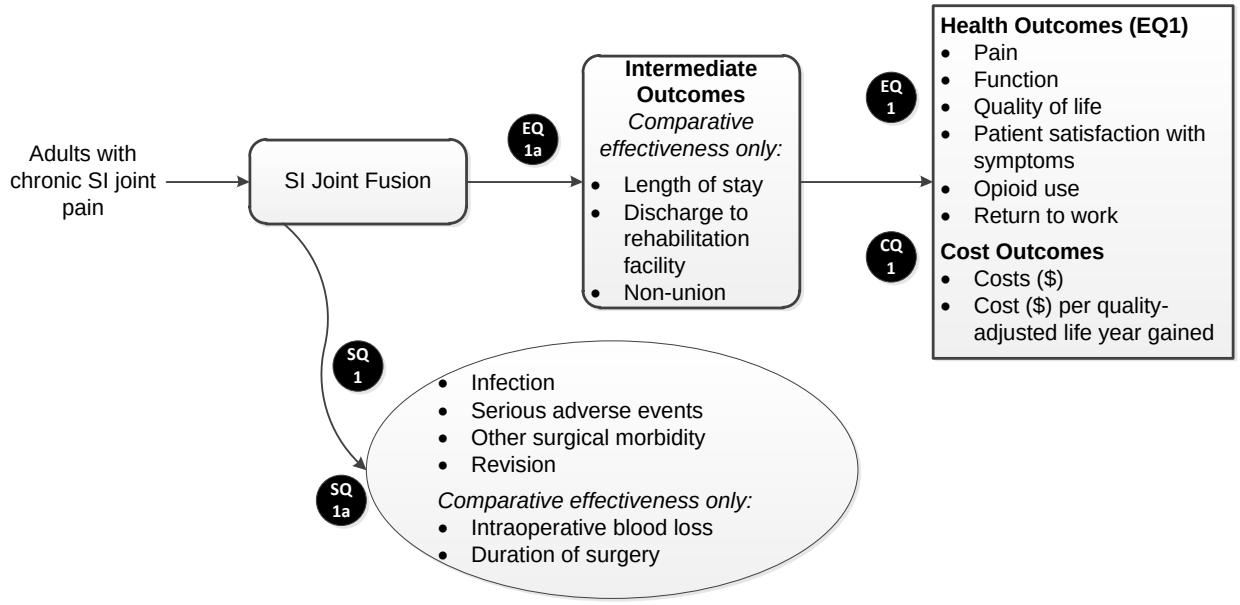
Safety Question 1 (SQ1). What is the safety of sacroiliac joint fusion surgery?

> **Safety Question 1a (SQ1a):** What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

Cost Question 1 (CQ1). What is the cost and cost-effectiveness of sacroiliac joint fusion surgery?

The State of Washington HTA Program posted a draft of these research questions with study selection criteria for public comment from January 27, 2021, through February 11, 2021. The final key questions and response to public comments on the draft key questions are available at the Program's website.[91] A draft version of this evidence report was reviewed by two independent, external peer reviewers and was posted for public comment from April 2, 2021, until May 3, 2021. Feedback from peer reviewers and from public comments was incorporated into the Final Evidence Report. Responses to public and peer-review comments were summarized in a separate document also available at the Program's website.[91]

Figure 1. Analytic framework for HTA on sacroiliac joint fusion



Abbreviations: CQ=cost question; EQ=efficacy question; SI = sacroiliac; SQ=safety question.

In addition, we addressed the following contextual question:

1. What are the recommended ways to diagnose SI joint pain or disruption and what is the accuracy of various diagnostic tests?

The contextual question was not systematically reviewed and is not shown in the analytic framework.

2.2 Data Sources and Searches

We searched MEDLINE (via PubMed), Embase, Cochrane, and a clinical trials registry (clinicaltrials.gov) for relevant English-language studies. Date ranges for the PubMed and Embase searches ranged from January 1, 2018, through January 31, 2021, with active surveillance of the literature through March 5, 2021. We searched the Centers for Medicare & Medicaid Services and FDA websites, selected payer and health care professional society websites, and websites of other organizations that conduct and disseminate HTAs. In addition, we reviewed the reference lists of relevant studies, systematic reviews, practice guidelines, other

HTAs, and comments submitted to the state to identify any relevant primary research studies not found through the electronic search. The detailed search strategy is in ***Appendix B***.

In brief, we used medical subject headings (MeSH terms) and text words associated with the "sacroiliac joint" and "fusion." We limited the search by eliminating studies indexed using terms for infants, children, or adolescents, and animals. We used MeSH terms to remove editorials, letters, and publication types that do not represent primary research studies from the search yield.

2.3 Study Selection

Table 2 summarizes the study selection criteria related to the population, intervention, comparator, outcomes, time period, study designs, and setting that defined the scope of this HTA; these are further described following the table. We screened titles and abstracts and full-text articles based on these study selection criteria. Two review team members independently screened all titles/abstracts and full-text articles; discrepancies in study selection at the full-text level were adjudicated by a senior investigator or, in some cases, consensus among the team.

Table 2. Population, intervention, comparator, outcome, timing, setting and other study selection criteria for HTA on sacroiliac joint fusion

Domain	Included	Excluded
Population	• Adults age 18 years and over with chronic (≥3 months) SI joint pain related to degenerative sacroiliitis and/or SI joint disruption • Diagnosis based on positive findings on provocative physical exam tests and reduction/amelioration of pain after local SI joint injection or leakage of contrast from joint	• Younger than 18 years old • Low back pain of other etiology (e.g., radiculopathy, neurogenic claudication) • SI joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis associated with inflammatory arthropathies • Patients without clear diagnosis of SI joint pain/disruption or diagnosis based on criteria other than those listed in the inclusion column
Intervention	• Open SI joint fusion • Minimally invasive SI joint fusion	Other spine surgeries, nonsurgical interventions to treat SI joint pain (e.g., radiofrequency ablation)
Comparator	*EQ1 and 1a:* • Active treatment - Physical therapy - Chiropractic therapy - Acupuncture - Analgesic and anti-inflammatory medication - Orthotics (e.g., pelvic girdles, belts) - Therapeutic joint injection - Neurotomy (e.g., radiofrequency ablation) - Fusion surgery • Placebo or sham surgery • No treatment	*EQ1 and 1a:* No comparator group
Outcomes	*EQ1:* • Pain • Physical functioning • Quality of life • Patient satisfaction with symptoms • Opioid use	Other outcomes not specifically listed as eligible Pain, quality of life, and functional outcomes not measured using valid and reliable instruments or scales[92,93]

Domain	Included	Excluded
	• Return to work *EQ1a only:* • Length of stay • Nonunion • Discharge to acute or subacute rehabilitation facility *SQ1:* • Infection • Serious adverse events (e.g., cardiovascular events, thromboembolism) • Other surgical morbidity • Revision surgery *SQ1a:* • Intraoperative blood loss • Duration of surgery *CQ1:* • Costs • Cost per quality-adjusted life-year gained • Cost per disability-adjusted life-year gained	
Study Design and Risk of Bias Rating	*EQ1 and 1a and SQ1a:* RCTs, CCTs, CCSs, and SRs of RCTs, CCTs, or CCSs with similar scope as this HTA *SQ1:* RCTs, CCTs, CCSs, uncontrolled studies (e.g., case series, single-arm clinical trials or cohort studies), and SRs of any study type with similar scope as this HTA *CQ1*: CCA, CEA, CUA, or CBA performed from the societal or payer perspective Any risk of bias rating	Editorials, comments, letters, narrative reviews, case reports *EQ1 and 1a and SQ1a only:* Uncontrolled studies (e.g., case series, single-arm clinical trials or cohort studies)
Setting	Inpatient or outpatient settings in countries categorized as "very high" on the 2020 UN Human Development Index[a].[15]	Studies conducted in countries not categorized as "very high" on the 2020 UN Human Development index.[15]

Note. a. Andorra, Argentina, Australia, Austria, Bahamas, Bahrain, Barbados, Belarus, Belgium, Brunei Darussalam, Bulgaria, Canada, Chile, Costa Rica, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Montenegro, Netherlands, New Zealand, Norway, Oman, Palau, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Arab Emirates, United Kingdom, United States, Uruguay

Abbreviations: CBA= cost-benefit analysis; CCS = controlled cohort study, CCT = controlled clinical trial; CEA = cost-effectiveness analysis; CUA = cost-utility analysis; HTA = health technology assessment; RCT = randomized controlled trial; SR = systematic review.

2.3.1 Population

Studies were selected if they enrolled adults ages 18 years or over with chronic SI joint pain related to degenerative sacroiliitis and/or SI joint disruption. Studies that enrolled participants with low back pain of any other etiology (e.g., radiculopathy, neurogenic claudication), those with SI joint pain related to recent major trauma or fracture, infection, cancer, or sacroiliitis

associated with inflammatory arthropathies, or those without a clear diagnosis of SI joint pain/disruption were excluded.

2.3.2 Intervention and Comparator

For efficacy questions, comparative studies where at least 1 study group included an SI joint fusion intervention were eligible for selection. All types of SI joint fusion surgery, including minimally invasive approaches or open procedures, were eligible. Studies with comparison groups that were placebo or sham surgery, no treatment comparators, or active treatment comparators were eligible for selection. Active treatment comparators could include nonsurgical management (e.g., analgesics, physical therapy, chiropractic therapy, orthotics, neurotomy) or an alternative type of fusion surgery. For the main safety question (SQ1), we required no comparator group.

2.3.3 Outcomes

For the research question on efficacy (EQ1), studies that reported outcomes related to pain, physical functioning, quality of life, patient satisfaction, opioid use, and return to work were eligible for selection, and we required studies to use valid and reliable measures of these constructs (e.g., Short Form 36 [SF-36], visual analog scale) for use within our certainty of evidence ratings. Additionally, hospital length of stay, non-union, and discharge to rehabilitation facility were eligible for EQ1a (comparative effectiveness on intermediate outcomes). For the research questions on safety (SQ1, SQ1a), studies that reported on perioperative or postoperative morbidity and mortality and revision surgery were eligible for selection. Additionally, intraoperative blood loss and duration of surgery were eligible outcomes for SQ1a (comparative safety on intermediate outcomes). For the research question on cost (CQ1), studies that reported costs or cost-effectiveness measures, specifically cost per quality-adjusted life-year (QALY) gained or cost per disability-adjusted life-year (DALY) gained were eligible for selection.

2.3.4 Settings

Studies conducted in any inpatient or outpatient clinical setting were eligible for selection. Studies that were conducted in countries with a development rating designated as "very high" by the United Nations Human Development Programme were eligible for selection because these countries (e.g., Canada, Europe, Australia, New Zealand, Japan, S. Korea, Singapore, Hong Kong and others) are like the United States with respect to standards of medical practice.[15] We excluded studies conducted in countries with a development rating designated as less than "very high."

2.3.5 Study Design

Randomized controlled trials (RCTs), nonrandomized controlled clinical trials (CCTs), controlled cohort studies (CCSs), and systematic reviews of trials or nonrandomized controlled studies were eligible for selection for both our efficacy (EQ1, EQ1a) and safety questions (SQ1, SQ1a). Additionally, uncontrolled studies (e.g., case series, single-arm clinical trials, single-arm cohort studies) were eligible to address our safety question (SQ1). Case reports, editorials, comments, letters, and narrative reviews were not eligible for selection.

2.3.6 Time Period

We did not restrict included studies based on year conducted or published.

2.4 What is Excluded from This HTA

This review did not include studies published in languages other than English or conducted in countries that are not very highly developed based on the United Nations Human Development Index.[15] This review did not include studies conducted among children or adolescents. It was designed to focus on SI joint fusion surgery to treat chronic SI joint pain related to degenerative sacroiliitis and/or SI joint disruption, and we excluded studies evaluating surgical interventions focused on addressing other etiologies of low back pain or SI joint surgery related to acute trauma, infection, or cancer. This review also excluded case reports because they provide the weakest evidence for assessing benefit or safety. Lastly, this study did not use data from the Manufacturer and User Facility Device Experience (MAUDE) database because of limitations with this passive surveillance system including incomplete, inaccurate, untimely, and unverified data.[16] Further, the incidence and prevalence of events cannot be determined from this data source because it has no information about the frequency of device use.

2.5 Data Abstraction and Risk of Bias Assessment

Two team members extracted relevant study data from new studies into a structured abstraction form, and a senior investigator checked those data for accuracy. We rechecked data previously abstracted for completeness and accuracy. We contacted some study authors to clarify discrepancies within or across articles. When multiple publications were published for a study (i.e., studies published outcomes with longer follow-up), we reported eligible outcome data from the most recent publication.

We used the Cochrane Risk of Bias (RoB 2.0) tool to assess the risk of bias for each included RCT.[17] Domains assessed with this tool include: bias arising from randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result. Risk of bias was assessed as "high," "some concerns," or "low" at the study level, unless different outcomes within a single study required outcome-level risk of bias ratings.

We used the ROBINS-I tool to assess risk of bias for nonrandomized comparative studies.[18] As with RCTs, risk of bias for these studies was assessed as "high," "some concerns," or "low" at the study level, unless different outcomes within a single study required outcome-level risk of bias ratings.

We used a checklist for critical appraisal of uncontrolled studies that we based on several existing instruments.[20,21] Risk of bias for safety outcomes reported by these studies was assessed as "high," "some concerns," or "low."

We used the Quality of Health Economic Studies Instrument to assess the risk of bias of included cost analyses.[19] We considered studies with scores on this instrument of 90 or above to have low

risk of bias, studies with scores between 60 and 89 to have some concerns for bias, and studies with scores below 60 to have high risk of bias.

Two team members conducted independent risk of bias assessments on all newly included studies; discrepancies were resolved by discussion. We reassessed the risk of bias for previously included studies and made adjustments to some study assessments for improved consistency in application of the assessment across the new and previously included studies.

2.6 Data Synthesis and Certainty of Evidence Rating

We qualitatively synthesized study characteristics and results for each research question in tabular and narrative formats. We synthesized studies comparing the surgical interventions to nonsurgical interventions separately from studies comparing alternative surgical interventions. We summarized continuous outcome measures as absolute mean differences (AMDs) between treatment groups where possible. When studies did not report the AMD, we calculated it when the appropriate data were reported in the article (e.g., mean, standard deviation [SD] for each group). We summarized categorical outcomes using differences in proportions, absolute risk differences (ARD) and risk ratios (RR). For efficacy outcomes, we calculated the ARD and RR when studies did not report them and the study provided the appropriate data. We used OpenEpi (version 3.01) to calculate estimates and associated 95% confidence intervals (CI). These calculations are specified as "calculated" in the report and tables.

To determine whether quantitative synthesis was appropriate, we assessed the number of studies and the clinical and methodological heterogeneity present based on established guidance.[94,95] We required 3 or more studies with similar intervention and comparator with same outcome measure at approximately the same follow-up time point to calculate a pooled treatment effect; we did not have enough studies reporting similar interventions, comparators, and outcomes to conduct a quantitative synthesis.

We graded the certainty of evidence for each comparison using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.[96] We updated the GRADE ratings from the previous HTA to reflect the incorporation of new studies and additional data from previously included studies. With GRADE, the certainty of evidence can be graded as "very low," "low," "moderate," or "high." ***Table 3*** offers definitions for these levels based on the strength of evidence rating system developed by the Agency for Healthcare Research and Quality, a rating system very similar to GRADE.[97] We graded bodies of evidence from RCTs separately from other study designs. Bodies of RCT evidence begin with a 'high' rating and are downgraded based on domains relating to study limitations (i.e., risk of bias), inconsistency, imprecision, indirectness, and other considerations, such as publication bias. Bodies of observational evidence begin with a "low" rating and can be downgraded for the same domains as used to evaluate RCTs but can also be upgraded from low for other considerations (e.g., large effect, evidence of dose-response).

Table 3. Suggested definitions for GRADE certainty of evidence levels (adapted from Berkman et al, 2014[97])

Grade	Suggested Interpretation
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable, that is, another study would not change the conclusions.
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Very Low	**We have very limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has numerous major deficiencies. We believe that substantial additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect. (This level is referred to as "Insufficient" within the AHRQ strength of evidence rating system.[97]

To assess the consistency domain within GRADE, we evaluated both the consistency in the direction and magnitude of treatment effect. For efficacy outcomes related to pain and physical function, we determined if the effect was consistent based on whether the evidence consistently supported a minimally important difference (MID) between intervention and comparator groups, or consistently supported no meaningful difference. We identified the range of MIDs for key outcomes a priori based on the literature.

To assess the precision domain within GRADE, we evaluated whether optimal information size (OIS) criteria were met.[98] To do this, we calculated the sample size requirement for a single, adequately powered trial (based on 80% power, alpha level of 0.05, and two-tailed tests) to detect a MID for continuous measures (using average SDs reported by studies) or a relative risk reduction of at least 20% for categorical measures using OpenEpi version 3.01. We downgraded bodies of evidence that did not meet OIS criteria for imprecision. If OIS criteria were met but the confidence intervals were either not provided or could not exclude a meaningful benefit or harm, then we also downgraded for imprecision.

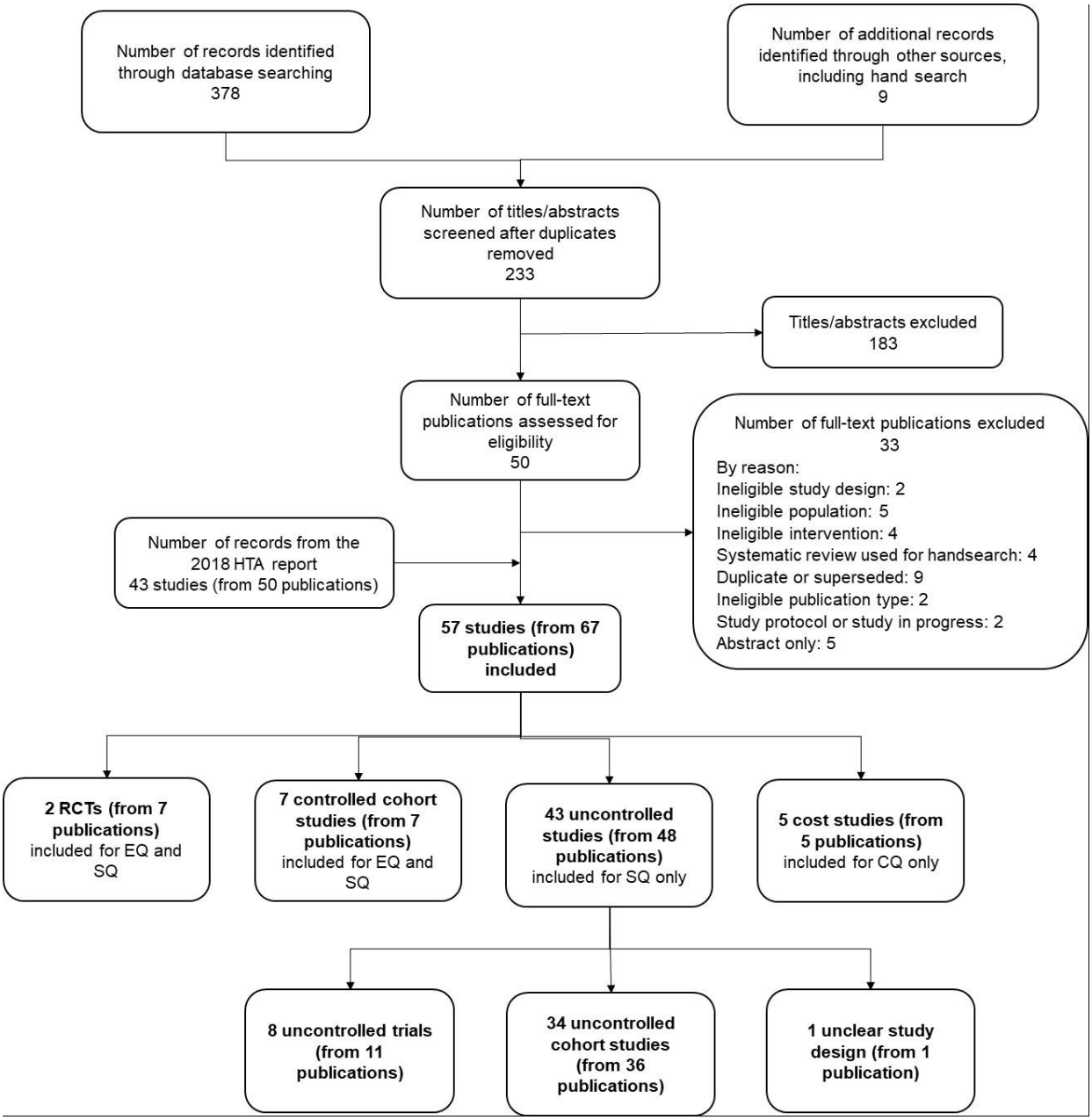
3. Results

3.1 Literature Search

Figure 2 depicts the study flow diagram, which updates the search from the previous HTA. We identified and screened 233 unique citations in an updated search. We excluded 183 citations after title and abstract review. We reviewed the full text of 50 articles and included a total of 57 studies reported in 67 publications published between 1987 and January 2021; 43 of these studies (50 publications) were included in the previous 2018 HTA report. Nine studies (2 randomized controlled trials [RCTs], 7 controlled cohort studies [CCSs]) provided evidence on efficacy or comparative effectiveness (EQ1) and safety (SQ1), 43 uncontrolled studies (8 uncontrolled trials, 34 uncontrolled cohort studies, 1 unclear study) provided evidence on safety (SQ1), and 5 studies provided evidence on costs or cost-effectiveness (CQ1). Individual study and population characteristics and findings for all included studies are summarized in ***Appendix C***. The list of

articles we screened at the full-text stage, but which we excluded, is provided in ***Appendix D***. Note that articles may have been excluded for more than 1 reason, but we report only 1 reason. We report our individual study risk of bias assessments for included studies in ***Appendix E***.

Figure 2. Study flow diagram for the HTA update on sacroiliac joint fusion



Abbreviations: CQ = cost question; EQ = efficacy question; HTA = Health Technology Assessment; RCT = randomized controlled trial; SQ = safety question.

Table 4 summarizes the most common outcomes used to report pain, physical functions, and quality of life among the included SI joint fusion studies. The table includes how the outcome is assessed, the range of possible scores, and the minimally important clinical difference reported in the literature.

Table 4. Summary of efficacy outcomes reported by included studies, including score range, and minimally important clinical difference

Instrument	Domain	Administration	Score Range	Minimally Important Difference from Literature[a]
Visual Analog Scale (VAS) 100 mm[b] Leg or Back Pain	Pain	Patient reported	0 to 100 Higher scores represent more severe symptoms	Between 7 to 11 points[99,100]
Oswestry Disability Index	Physical Function	Patient reported, 10 items with 6-point Likert Scale	0 to 100 Higher scores represent worse functional status	Between 30% to 50% relative difference, or absolute difference of 8 to11 points[101] (though some studies report range from 5 to 17 points)[99,102,103]
EuroQol 5 Dimensions (EQ-5D)	Quality of Life	Patient reported	0 to 1 Higher score represents better health states	0.18[104] (ranges from 0.03 to 0.52)[105]
SF-36 Physical Component Summary	Quality of Life	Patient reported, scores multiplied by subscale factor score coefficients and summed over all 8 subscales	0 to 100 (norm-based: mean 50, SD (10)) Higher scores represent less severe symptoms	2 points for PCS 3 points for MCS[99,106]
SF-36 Mental Component Summary	Quality of Life			

[a] From the broader musculoskeletal pain literature
[b] Also applicable to VAS 10 cm, between-group differences in VAS 100 mm can be divided by 10 to be applicable to VAS 10 cm.
Abbreviations: MCS = mental component summary score; PCS = physical component summary score; SF-36 = Short Form 36; SD = standard deviation; VAS = visual analog scale.

The rest of the results section is organized as follows. First, we synthesize the efficacy and safety of SI joint fusion from controlled studies. We synthesize findings from minimally invasive fusion or open fusion to conservative management and then synthesize findings comparing minimally invasive fusion to open fusion. Next, we synthesize findings comparing alternative minimally invasive fusion procedures. Each of the sections describing these comparisons begins with a GRADE summary of findings table, followed by tables and text describing study characteristics and results. After summarizing the evidence from controlled studies, we synthesize the evidence for safety from uncontrolled studies of open and minimally invasive fusion. Next, we synthesize the evidence on cost-effectiveness. Last, we summarize the evidence to address the contextual question related to diagnosis of SI joint pain and dysfunction.

3.2 Sacroiliac Joint Fusion Compared to Conservative Management

We identified 2 RCTs[22,23] and 1 CCS[24] that compared minimally invasive SI joint fusion with the iFuse Implant System to conservative management and 1 CCS[25] that compared open fusion to no treatment. Conservative management in the 2 trials included components such as optimization of medical therapy, physical therapy; 1 of the trials also allowed therapeutic SI joint injections and radiofrequency nerve ablation if other measures failed.[23] The certainty of evidence (GRADE rating) for efficacy and safety outcomes comparing iFuse to conservative management is provided in ***Table 5*** and comparing open fusion to no surgery is provided in ***Table 6***.

Table 5. Summary of findings and certainty of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) with conservative management

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in pain at 6 months (Visual Analog Scale; MID = 7 to 11 mm)						
2 RCTs[22,23]	Serious[a]	Not serious	Not serious	Not serious	Total N=249. Significantly larger improvement with MI SIJF compared to conservative management; calculated between-group difference -40.5 mm (95% CI, -50.1 to -30.9) in 1 study[23] and -38.1 mm (95% CI NR, *P*<0.0001) in other study.[22]	⊕⊕⊕◯ MODERATE Favors MI SIJF
Change in pain at 6 months to 3.5 years (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[24]	Very serious[b]	Not serious[c]	Not serious	Not serious[d]	Total N=137. Significantly larger improvement with MI SIJF compared to SI denervation (between-group difference: -45 mm, *P*<0.001) and to conservative management (between-group difference: -60 mm, *P*<0.001).	⊕◯◯◯ VERY LOW Favors MI SIJF
Change in pain at 1 year (Visual Analog Scale; MID = 7 to 11 mm)						
2 RCTs[26,27]	Very serious[k]	Not serious	Not serious	Not serious	Total N=234. Compared with conservative management, significantly larger improvements for MI SIJF in 1 study[22] (between-group difference -27.6 mm, *P*<0.0001). In other study,[23] significantly larger improvements for MI SIJF compared to conservative management participants who did not cross over (between-group difference -32.6 mm, 95% CI, -58.7 to -6.6, *P*=0.01) and no difference when compared to conservative management participants who crossed over (-5.7 mm, 95% CI, -17.1 to 5.7, *P*=0.32).	⊕⊕◯◯ LOW Favors MI SIJF
Threshold improvement in pain at 2 years (at least 20-mm improvement on Visual Analog Scale)						
2 RCTs[28,29]	Very serious[k]	Not serious	Not serious	Not serious	Total N=218. Compared with conservative management, a significantly higher proportion of participants achieved a threshold improvement with MI SIJF compared to conservative management. In 1 study,[29] 79% vs. 24% (calculated RR 3.3, 95% CI, 1.92 to 5.6); in other study,[28] 83% vs.10% (calculated RR 8.3, 95% CI, 3.3 to 21.2).	⊕⊕◯◯ LOW Favors MI SIJF
Change in physical function at 6 months (Oswestry Disability Index; MID = 8 to 11 points)						
2 RCTs[22,23]	Serious[a]	Not serious	Not serious	Not serious	Total N=249. Significantly larger improvement with MI SIJF compared to conservative management, between-group difference -25.4 points (calculated) (95% CI, -32.5 to -18.3, *P*<0.0001) in 1 study[23] and -19.8 (95% CI NR, *P*<0.0001) in other study.[22]	⊕⊕⊕◯ MODERATE Favors MI SIJF

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in physical function at 1 year (Oswestry Disability Index; MID = 8 to 11 points)						
2 RCTs[26,27]	Very serious[k]	Serious[l]	Not serious	Not serious	Total N=234. Compared to conservative management, significantly larger improvements for MI SIJF in 1 study[22] (calculated between-group difference -20.1 points, *P*<0.0001); no difference in other study[23] for MI SIJF compared to conservative management participants who crossed over (calculated between-group difference -1.1, 95% CI, -8.9 to 6.7, *P*=0.78) and conservative management participants who did not cross over (calculated between-group difference -0.4, 95% CI, -18.5 to 17.7, *P*=0.97)	⊕◯◯◯ VERY LOW Mixed findings
Threshold improvement in physical function at 2 years (at least 15-point improvement on Oswestry Disability Index)						
2 RCTs[28,29]	Very serious[k]	Not serious	Not serious	Not serious	Total N =218. Compared to conservative management, a significantly higher proportion of participants achieved a threshold improvement with MI SIJF compared to conservative management. In 1 study,[29] 64% vs. 24% (calculated RR 2.7, 95% CI, 1.5 to 4.7); in other study,[28] 68% vs. 8% (calculated RR 9.1, 95% CI, 3.0 to 27.2).	⊕⊕◯◯ LOW Favors MI SIJF
Change in physical function at 6 months to 3.5 years (Oswestry Disability Index; MID = 8 to 11 points)						
1 CCS[24]	Very serious[b]	Not serious[c]	Not serious	Not serious[e]	Total N=137. Significantly larger improvement with MI SIJF compared to SI denervation (between-group difference -17 points [*P*<0.001]) and to conservative management (between-group difference -24 points [*P*<0.001]).	⊕◯◯◯ VERY LOW Favors MI SIJF
Change in quality of life at 6 months (EQ-5D [MID = 0.18] and SF-36 [MID = 2 to 3 points])						
2 RCTs[22,23]	Serious[a]	Not serious	Not serious	Not serious	Total N=249. Significantly larger improvement with MI SIJF compared to conservative management; EQ-5D between-group difference 0.24 (calculated) (95% CI, 0.16 to 0.32) in 1 study[23] and 0.21 (95% CI NR, *P*<0.0001) in other study.[22] Calculated between-group difference on SF-36 PCS 11.5 (95% CI, 8.1 to 14.9) and MCS 5.6 (95% CI, 1.8 to 9.4) in 1 study.[23]	⊕⊕⊕◯ MODERATE Favors MI SIJF
Change in quality of life at 1 to 2 years (EQ-5D [MID = 0.18] and SF-36 PCS [MID = 2 points])						
2 RCTs[22,23,26-29]	Very serious[k]	Not serious	Not serious	Not serious	Total N=234. Significantly larger improvements persisted with MI SIJF compared to conservative management; EQ-5D calculated between-group difference 0.22 (*P*=0.0009) at 1 yr. and 0.24 (*P*<0.001) at 2 yrs. in 1 study.[26,29] In other study,[27,28] EQ-5D calculated change from baseline (SD) at 1 yr. for MI SIJF participants compared to conservative management participants who crossed over to surgery was 0.01, and for those who did not cross over was 0.11;	⊕⊕◯◯ Low Favors MI SIJF

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
					these values persisted at 2 yrs. A similar pattern was observed for SF-36 PCS.	
Opioid use at 6 months						
1 RCT[23]	Serious[a]	Not serious[f]	Not serious	Very serious[g]	Total N=148. No significant difference in percentage of participants using opioids; calculated within group difference -9% among MI SIJF participants and 8% among conservative management participants (reported *P*=0.08).	⨁◯◯◯ VERY LOW Favors MI SIJF
Opioid use at 1 to 2 years						
2 RCTs[27-29]	Very serious[k]	Serious[m]	Not serious	Not serious	Total N=233. In one study,[29] calculated change in percentage of participants using opioids -23% among MI SIJF participants and -1.4% among conservative management participants at 2 yrs. (calculated RR 0.75, 95% CI, 0.45 to 1.24). In other study,[27,28] calculated change in percentage of participants using opioids -16.6% among MI SIJF participants at 1 yr. and 20.3% at 2 yrs. and -8.0% among conservative management participants (unclear which group included the crossovers; *P* NR).	⨁◯◯◯ VERY LOW Favors MI SIJF
Opioid use at 6 months to 3.5 years						
1 CCS[24]	Very serious[b]	Not serious[f]	Not serious	Not serious	Total N=137. Significant difference (*P*<0.001) between groups in oral morphine equivalents used at the time of last follow-up: MI SIJF (3.1 mg/day), SI denervation (32.2 mg/day), conservative management (38.5 mg/day).	⨁◯◯◯ VERY LOW Favors MI SIJF
Adverse events at 6 months						
2 RCTs[22,23]	Serious[a]	Serious[n]	Not serious	Serious[h]	Total n=249. In one study, 129 events among 102 MI SIJF participants and 49 events among 46 conservative management participants; [23]# severe events related to the device or procedure 6 vs. 1.[23,28] In other study, 20 events among 52 MI SIJF participants and 17 events among 51 conservative management participants; # severe events related to device or procedure 4 vs. 0.[22,29] Unable to determine direction of effect beyond 6 months because data for CM participants not reported by crossover status.	⨁◯◯◯ VERY LOW Favors CM
1 CCS[24]	Very serious[b]	Not serious[f]	Not serious	Very serious[i]	Total N=137. No serious adverse events reported in either group.	⨁◯◯◯ VERY LOW No difference

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Revision surgery						
2 RCTs[22,23,26-29]	Serious[a]	Not serious	Not serious	Not serious	Total N=249. In one study, incidence 3.4% at 2 yrs. among 89 MI SIJF participants with follow-up data and 2.6% among 39 conservative management participants who crossed over to surgery.[23] In other study, incidence 3.8% at 2 yrs. among 52 MI SIJF participants and 4.8% among 21 conservative management participants who crossed over to surgery.[22]	⊕⊕⊕◯ MODERATE Favors CM
1 CCS[24]	Very serious[b]	Not serious[f]	Not serious	Very serious[j]	Total N=137. No revision surgery reported among participants who received MI SIJF at 6 months to 3.5 years.	⊕◯◯◯ VERY LOW Favors CM

Notes: a. Some concerns for bias because of no masking of treatment allocation.
b. High concerns for bias because of large amounts of missing data at timepoints greater than 1 year and use of repeated measures analysis through all timepoints; some concerns for selection bias, confounding, and measurement of outcome.
c. Not applicable as is a single study body of evidence but findings are consistent with the 2 RCTs.
d. Data not provided to estimate 95% CI, but based on Figure 3 in original publication, the treatment effect confidence intervals for iFuse do not overlap with the confidence intervals for the 2 control groups.
e. Data not provided to estimate 95% CI, but based on Figure 4 in original publication, the treatment effect confidence intervals for iFuse do not overlap with the confidence intervals for the 2 control groups.
f. Not applicable, single study body of evidence.
g. Requires a sample size of 386 to meet OIS criteria (RR = 0.8, power = 0.8, alpha = .05); CI spans a range from moderate benefit to no effect.
h. Somewhat infrequent events, requires a sample size of 4,168 to meet OIS criteria (RR = 1.2, power = 0.8, alpha = 0.05); unable to calculate confidence intervals because number of participants with events was not reported.
i. Zero events reported in both groups, OIS criteria not met.
j. Zero revisions reported in intervention group, OIS criteria not met.
k. High concern for bias because of no masking of treatment allocation and extensive crossover from conservative management to surgery after 6 mos. One study[23,27,28] did not clearly state which participants were included in 1 year outcomes and did not report 2 year outcomes for the CM group; the other study[22,26,29] used the last observation carried forward method to estimate outcomes after 6 mos. for those assigned to conservative management.
l. One study[26] reported a significant improvement, and the other study[27] observed no difference between the groups.
m. One study[29] did not calculate the significance of the difference between the groups and the other study[27] observed no difference between the groups.
n. Similar direction of effect, but absolute number of events higher in INSITE compared to iMIA, partially but not entirely explained by differences in treatments used in control groups.

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; EQ-5D = EuroQOL measure of generic health status; MI SIJF = minimally invasive sacroiliac fusion; MID = minimally important difference; mm = millimeters; mo(s). = months; N=number of participants; NA = not applicable; NR = not reported; OIS = optimal information size; RCT = randomized controlled trial; RR = relative risk; SF-36 = Short Form 36-item Survey Physical Health Component Score (PCS) and Mental Health Component Score (MCS); yr(s). = year(s).

Table 6. Summary of findings and certainty of evidence comparing open sacroiliac joint fusion with no surgery

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Pain at 11 to 23 years (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[c]	Total N=78. No significant between-group difference (calculated): -6 mm (95% CI, -10.2 to 22.2).	⊕◯◯◯ VERY LOW No difference

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Physical function at 11 to 23 years (Oswestry Disability Index; MID = 8 to 11 points)						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[d]	Total N=78. No significant between-group difference (calculated): -4 points (95% CI, -9.1 to 17.1).	⨁◯◯◯ VERY LOW No difference
Quality of life at 11 to 23 years (SF-36)						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[e]	Total N=78. No significant between-group differences in any of the 8 subscale scores.	⨁◯◯◯ VERY LOW No difference
Adverse events						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[f]	Total N=78. Incidence 10% among 58 open surgery participants; adverse events not reported in the no surgery group.	⨁◯◯◯ VERY LOW NA
Revision surgery						
1 CCS[25]	Very serious[a]	Not serious[b]	Not serious	Serious[g]	Total N=78. Incidence 8.4% of joints among 50 open surgery participants. No revision surgery reported among participants who received no surgery.	⨁◯◯◯ VERY LOW NA

Notes: a. High or some concerns in multiple domains including confounding, selection bias (both enrollment methods and high attrition) and outcome measurement.
b. Not applicable, single study body of evidence.
c. Requires a sample size of 344 (mean difference 10 mm, power = 0.8, alpha = .05, SD estimate from studies) to meet OIS criteria; confidence intervals around mean difference are wide and include a clinically meaningful increase and decrease.
d. Requires a sample size of 202 (mean difference 10 points, power = 0.8, alpha = 0.05, SD estimate from studies) to meet OIS criteria; confidence interval spans a clinically meaningful decrease and increase.
e. CIs around subscale estimates were wide and overlapping between groups.
f. Somewhat infrequent events; events were not reported for the no-surgery group.
g. Somewhat infrequent events; unable to calculate confidence intervals because number of participants with events was not reported; revisions were not reported for the no-surgery group.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MID = minimally important difference; mm = millimeters; N=number of participants; OIS = optimal information size; SD = standard deviation; SF-36 = Short Form 36-item survey.

3.2.1 Study Characteristics

Table 7 describes study and population characteristics, including the methods used to diagnosis SI joint pain. Detailed characteristics for the 2 RCTs are in ***Appendix C***, ***Table C-1***; detailed characteristics for the 2 CCSs are in ***Appendix C***, ***Table C-6***.

Two RCTs compared the iFuse Implant System to conservative management.[22,23] One study called INSITE enrolled participants at 19 U.S. centers and analyzed 148 participants.[23] The other study, called iMIA, enrolled participants at 9 centers in Belgium, Germany, Italy, and Sweden and analyzed 101 participants.[22] Just over a third of both studies enrolled participants with a prior history of lumbar fusion and both studies used the same diagnostic criteria for study enrollment. These criteria included a combination of a history consistent with SI joint pain, positive provocative physical exam findings, and improvement in pain following a diagnostic joint injection.

Table 7. Study and population characteristics of the 2 randomized controlled trials and 2 controlled cohort studies evaluating sacroiliac joint fusion compared to conservative management

Author (Year); Study Name; Country	Study Design; Risk of Bias	Population Characteristics	Method of Diagnosis	Intervention (N Analyzed)	Comparator (N Analyzed)
INSITE (2015)[23,27,28] U.S.	RCT, some concerns for outcomes ≤ 6 mos.; high for outcomes > 6 mos.	19 centers, 2013 to 2014 Mean age iFuse: 50.2 Conservative management: 54.0 Mean duration (range) of pain, years iFuse: 7.0 (0.5 to 40.7) Conservative management: 5.0 (0.48 to 38.9) N (%) with prior lumbar fusion iFuse: 39 (38.2) Conservative management: 17 (37.0)	History of SI joint pain, provocative exam findings (at least 3 of 5), ≥ 50% reduction in pain after SI joint block	iFuse, machined implant (102 treated, 101 at 6 mos., 100 at 12 mos., 89 at 2 yrs.)	Conservative management (46 treated, 44 at 6 mos. [39 crossovers], 40 at 1 yr., 36 at 2 yrs.) Intervention included pain medications, physical therapy, intraarticular SI joint injections, radiofrequency nerve ablation all delivered in stepwise fashion under direction of site investigator; crossovers allowed after 6 mos. and by 2 yrs. 88.6% crossed over to surgery
iMIA (2016)[22,26,29,107] Multiple European Countries	RCT, some concerns for outcomes ≤ 6 mos.; high for outcomes > 6 mos.	9 centers, 2013 to 2015 Mean age iFuse: 49.4 Conservative management: 46.7 Mean duration (range) of pain, years iFuse: 4.9 (0.58 to 44) Conservative management: 4.5 (0.45 to 23) N (%) with prior lumbar fusion iFuse: 18 (34.6) Conservative management: 19 (37.3)	Positive Fortin finger test, provocative exam findings (at least 3 of 5), ≥ 50% reduction in pain after SI joint block	iFuse, machined implant (52 treated, 52 at 6 mos., 48 at 12 mos. 47 at 2 yrs.)	Conservative management (51 treated, 49 at 6 mos. [21 crossovers], 46 at 1 yr., 46 at 2 yrs.) Intervention included optimization of medical therapy, physical therapy, information and reassurance, cognitive behavioral therapy at some site. SI joint injections and nerve ablation were NOT part of management; crossovers allowed after 6 mos. and by 1 yr. 42.9% crossed over to surgery

Author (Year); Study Name; Country	Study Design; Risk of Bias	Population Characteristics	Method of Diagnosis	Intervention (N Analyzed)	Comparator (N Analyzed)
Vanaclocha et al. (2018)[24] Spain	CCS, high	Single center, 2007 to 2015 Mean age iFuse: 48.0 SI denervation: 48.0 Conservative management: 51.4 Mean duration of pain, years iFuse: 1.6 SI denervation: 2.9 Conservative management: 4.6 N (%) with prior lumbar fusion iFuse: 2 (7.4) SI denervation: 16 (34.0) Conservative management: 27 (42.9)	Positive Fortin finger test, ≥ 3 provocative exam findings, ≥ 50% pain relief after SI joint block	iFuse, machined implant (27)	1) SI denervation (47) 2) Conservative management (63)
Kibsgard et al. (2013)[25] Norway	CCS, high	Single center, 1977 to 1998 Mean age Open fusion: 58 Nonsurgery: 52 Mean duration of pain, years Open fusion: 5 (range 1 to 21) Nonsurgery: NR N (%) with prior lumbar fusion NR	Tenderness at the superior and inferior posterior iliac spines; pain with active and passive straight leg raise, Patrick Fabere's test, passive hip rotation, forcible inward rotation and extension of the hip joint; normal spinal x-rays and radiculography.	Open fusion with dorsal approach (50)	No surgery, no specific intervention specified (28)

Abbreviations: CCS = controlled cohort study; mo(s). = month(s); N=number of participants; NR = not reported; RCT = randomized controlled trial; SI = sacroiliac; U.S. = United States; yr(s). = year(s).

Although the surgical intervention was the same in both studies (iFuse Implant system using machined solid triangular titanium-coated implants), INSITE used a stepwise approach to conservative management that included therapeutic SI joint blocks and radiofrequency nerve ablation while iMIA excluded these treatments in the conservative management group. iMIA required at least 6 months of conservative treatment before enrollment, INSITE did not specify the length of conservative treatment before enrollment. Both studies allowed participant crossover from conservative management to surgery after 6 months; by 1 year, 42.9% and 79.5% crossed over in the iMIA and INSITE trials, respectively. We rated the 6-month and earlier outcomes from both RCTs as having some concerns for bias because treatment and outcome assessment was not blinded. We considered outcomes reported after 6 months as high risk of bias because of extensive unplanned crossovers. The INSITE trial reported outcomes separately for participants who crossed over and those who did not; iMIA used the last observation (prior to crossover) carried forward method to estimate outcomes after 6 months for those assigned to conservative management.

One CCS[24] conducted at a single center in Spain compared the iFuse Implant System to SI denervation and to conservative management, which consisted of counseling for smoking cessation and weight control, physiotherapist consultation, use of nonsteroidal anti-inflammatory medication, and SI joint injections with steroids. Over a third of participants had prior lumbar fusion. The diagnostic criteria that this study used were similar to criteria used in the 2 RCTs previously described. We rated the risk of bias for this study as high because repeated measures were used throughout all timepoints despite a high level of missing data at timepoints greater than 1 year and some concerns related to confounding, selection of participants, classification of intervention, and measurement of outcomes.

One CCS[25] conducted at a single center in Norway compared an open fusion procedure using a dorsal approach to a group of participants who did not have surgery. This study was conducted from 1977 to 1998 and study authors provided no details regarding control group treatment. Further, comparative outcomes are reported only for long-term follow-up (11 to 32 years). The methods of diagnosis in this study were primarily from physical exam and imaging (x-rays and radiculography). We rated the risk of bias for this study as high because of confounding, selection bias (both because of methods of enrollment and because of attrition), and outcome measurement.

3.2.2 Findings-Efficacy Outcomes

All 4 studies reported efficacy outcomes. ***Table 8*** summarizes the key efficacy outcomes of interest for this HTA that the studies reported (pain, physical function, quality of life, opioid use). These studies reported several other efficacy outcomes, which are described in the text, with full details in ***Appendix C***, ***Tables C-2*** and ***C-3*** for the 2 RCTs and in ***Appendix C***, ***Tables C-7*** and ***C-8*** for the 2 CCSs. We contacted the INSITE study authors to clarify minor discrepancies in data that were reported in different publications reporting outcomes; although our query was acknowledged, we did not receive any clarification regarding those discrepancies at the time of this draft report publication. When there were discrepancies, we report the data from the most recent study.

Table 8. Key efficacy outcomes from the 2 randomized controlled trials and 2 controlled cohort studies evaluating sacroiliac joint fusion compared to conservative management or no treatment (EQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Pain, VAS[a]	Oswestry Disability Index[b]	Quality of Life[c]	Opioid Use
		Mean Difference or Difference in Proportion Between Groups			
INSITE (2015)[23,27,28] U.S.	RCT; some concerns, for outcomes ≤ 6 mos.; high for outcomes > 6 mos.	iFuse compared to CM (calculated): 1 mo. -35.9 mm (*P*<0.0001) 3 mos. -38.0 mm (*P*<0.0001) 6 mos. -40.5 mm (95% CI, -50.1 to -30.9, *P*<0.0001) 1 yr. (crossovers): -5.7 mm (95% CI, -17.1 to 5.7; *P*=0.32) 1 yr. (no crossovers): -32.6 (95% CI, -58.7 to -6.6; *P*=0.01) 2 yrs. Unable to determine	iFuse compared to CM (calculated): 1 mo. -13.7 points (*P*<0.0001) 3 mos. -19.2 points (*P*<0.0001) 6 mos. -25.4 points (95% CI, -32.5 to -18.3, *P*<0.0001) 1 yr. (crossovers) -1.1 (95% CI, -8.9 to 6.7; *P*=0.78) 1 yr. (no crossover) -0.4 (95% CI, -18.5 to 17.7; *P*=0.97) 2 yrs. Unable to determine	iFuse compared to CM at 6 mos. (calculated): SF-36 PCS 11.5 (95% CI, 8.1 to 14.9) SF-36 MCS 5.6 (95% CI, 1.8 to 9.4) EQ-5D 0.24 (95% CI, 0.16 to 0.32)	iFuse compared to CM: Calculated change in percentage using 6 mos. iFuse: -9% CM: 7.5% (*P*=0.08) 1 yr. I: -16.6% C: -8.0% (*P*=0.61, but unclear whether this includes crossovers) 2 yr. I: -20.3% C: NR
iMIA (2016)[22,26,29,107] Multiple European Countries	RCT, some concerns, for outcomes ≤ 6 mos.; high for outcomes > 6 mos.	iFuse compared to CM (calculated): 1 mo. -35.3 mm (*P* NR) 3 mos. -38.6 mm (*P* NR) 6 mos. -38.1 mm (*P*<0.0001) 1 yr. -27.6 mm (*P*<0.0001)[d] 2 yrs.: -34 (*P*<0.0001)	iFuse compared to CM: 6 mos. -19.8 points (*P*<0.0001) 1 yr. (calculated): -20.1 points (*P*<0.0001)[d] 2 yrs. (calculated): -18 points (*P*<0.0001)	iFuse compared to CM: EQ-5D 6 mos. 0.21 (*P*<0.0001) 1 yr. (calculated): 0.22 (*P*=0.0009)[d] 2 yrs. (calculated): 0.24 (*P*<0.0001)	Change in percentage using at 2 yrs. iFuse: -23% (*P*=0.009 vs. baseline) CM: -1.4% (*P*=1.0 vs. baseline) Calculated RR 0.75 (95% CI, 0.45 to 1.24)
Vanaclocha et al. (2018)[24] Spain	CCS, high	At 6 mos. to 3.5 yrs. iFuse compared to SI denervation: RM difference: -45 mm (*P*<0.001) iFuse compared to CM: RM difference: -60 mm (*P*<0.001)	At 6 mos. to 3.5 yrs. iFuse compared to SI denervation: RM difference: -17 points (*P*<0.001) iFuse compared to CM: RM difference: -24 points (*P*<0.001)	NR	Oral morphine equivalents in mg/day (range) at last follow-up iFuse: 3.1 (0 to 60) Denervation: 32.2 (0 to 133) CM: 38.5 (0 to 98) *P*<0.001
Kibsgard et al. (2013)[25] Norway	CCS, high	Open fusion difference from no surgery at 11 to 32 yrs. (calculated) VAS in AM: -6 mm (95% CI, -13.0 to 25.0, *P*=0.54) VAS in PM: -6 mm (95% CI, -10.2 to 22.2; *P*=0.50)	Open fusion difference from no surgery at 11 to 32 yrs. (calculated) -4 points (*P*=0.54)	Across SF-36 subscales, score differences between open fusion and no surgery ranged from -3 to 10; all between-group differences reported as NS	NR

Notes: a. Scores range from 0 to 100 mm, a higher score indicates worse pain. A negative difference between groups means that fusion surgery resulted in a greater improvement than the comparator.
b. Score ranges from 0 to 100; higher scores indicate greater disability. A negative difference between groups means that fusion surgery resulted in a greater improvement than the comparator.
c. EQ-5D scores range from 0 to 1, with higher scores representing higher utilities (i.e., better quality of life). SF-36 scores range from 0 to 100, with higher scores representing better quality of life. For both, a positive difference between groups means that fusion surgery resulted in a greater improvement in quality of life than the comparator.
d. For participants who crossed over from conservative management to surgery, the last observation carried forward method was used to impute their 1-yr. follow-up data.

Abbreviations: AM = morning; ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; CM = conservative management; EQ-5D = EuroQOL measure of generic health status; mg = milligrams; mm = millimeters; mo(s). = month(s); NR = not reported; NS = nonsignificant; PM = evening; RCT = randomized controlled trial; RM = repeated measures; RR = risk ratio; SD = standard deviation; SF-36 = Short Form 36-item Survey Physical Health Component Score (PCS) and Mental Health Component Score (MCS); SI = sacroiliac; U.S. = United States; VAS = visual analog scale; yr(s). = year(s).

Pain

Both RCTs[22,23] and the CCS[24] comparing iFuse to conservative management reported a statistically significant, larger improvement in pain as measured by a visual analog scale (VAS). At 6 months follow-up, the 2 RCTs reported a calculated difference of -40.5 mm (INSITE[23]) and -38.1 mm (iMIA[22]) compared to conservative management, both above a typical MID for this measure (i.e., 7 to 11 mm). The CCS[24] reported a difference using repeated measures from 6 months to 3.5 years and observed a similar treatment effect when compared to SI denervation, and an even larger effect when compared to conservative management. Both RCTs also reported a statistically significant larger percentage of participants with at least a 20-mm improvement on VAS at 6 months among participants allocated to surgery (***Appendix C Table C-2***). The iMIA trial reported no between-group differences in VAS pain among subgroups defined by prior lumbar fusion, bilateral pain, or pregnancy-related pain at 6 months.[22] The INSITE trial prespecified several subgroup analyses and also reported no differences based on etiology (degenerative sacroiliitis vs. SI joint disruption), prior lumbar fusion, or bilateral procedure at 6 months.[23]

Both RCTs also reported VAS pain measures beyond 6 months. Because extensive crossovers occurred, these findings have a high risk of bias given their deviation from the randomized assignment in the intent-to-treat analyses. As-treated analyses introduce confounding because participants who crossed over had higher 6-month mean VAS compared to participants who did not cross over. Additionally, the last observation carried forward (LOCF) method to impute a participant's previous values also leads to biased estimates.[108] In the iMIA trial,[22,26] the LOCF method was used to impute data at time points beyond 6 months for participants who crossed over. A significant between-group difference in VAS low back pain scores persisted at 1 year (-27.6 mm) and 2 years (-34 mm) compared to conservative management ($P<0.0001$ at both time points).[26,29] The difference in VAS pain reported at 1 year was similar in the INSITE trial,[23,27] which reported findings separately for those who crossed over and those who did not (i.e., as-treated analysis). When compared to participants allocated to fusion, the between-group difference with participants who remained in the conservative management group without crossing over was -32.6 mm (95% CI, -58.7 to -6.6, $P=0.01$).[27] The between-group difference was -5.7 mm (95% CI, -17.1 to 5.7, $P=0.32$) compared to those assigned to conservative management who did cross over.[27] The statistically significant larger percentage of participants

with at least a 20-mm improvement on VAS pain scores among participants allocated to surgery was sustained at 1 and 2 years.

The CCS[25] comparing open fusion to no surgery reported a nonsignificant difference in VAS scores at follow-up between 11 and 32 years; the calculated mean difference in the evening VAS was -6 mm (95% CI, -10.2 to 22.2). This difference in mean change did not achieve the MID for this measure.

Physical Functioning

Both RCTs[22,23] and the CCS[24] comparing iFuse to conservative management reported a statistically significant, larger improvement in function as measured by the Oswestry Disability Index (ODI). At 6 months follow-up, the 2 RCTs reported a difference of -25.4 points (calculated) (INSITE[23]) and -19.8 points (iMIA[22]) compared to conservative management; the mean difference in both RCTs achieved the MID (8 to 11 points). The significant difference in ODI between participants allocated to iFuse compared to conservative management persisted for iFUSE participants in the iMIA trial[22] at 1 year (calculated difference -20.1 points, $P<0.0001$) and at 2 years (calculated difference -18 points, $P<0.0001$). However, the INSITE trial[23] did not observe a clinically meaningful or significant difference between the iFuse participants compared to conservative management participants at 1 year. Both RCTs reported a statistically significant larger percentage of participants with at least a 15-point improvement on ODI at 6 months among participants allocated to surgery (***Appendix C, Table C-2***); this difference was sustained at 1 year and at 2 years. In the iMIA trial,[29] 64% of participants allocated to surgery had at least a 15-point improvement on ODI compared to 24% of participants allocated to conservative management at 2 years (calculated RR, 2.7; 95% CI, 1.5 to 4.7). Similarly at 2 years in the INSITE trial,[28] 68% of participants allocated to surgery had at least a 15-point improvement on ODI compared to 8% of all participants originally allocated to conservative management (calculated RR, 9.1; 95% CI, 3.0 to 27.2). The CCS[24] reported similar statistically significant and clinically meaningful treatment effects in a repeated measures analysis over 6 months to 3.5 years when comparing surgery to both SI denervation and to conservative management.

The CCS[25] comparing open fusion to no surgery reported a nonsignificant difference in ODI scores at follow-up between 11 and 32 years: the calculated adjusted mean difference (AMD) between groups was -4 points (95% CI, -9.1 to 17.1). This difference in mean change did not achieve the MID for physical function.

Quality of Life

Both RCTs[22,23] reported quality of life using the EuroQOL instrument (EQ-5D) and both reported statistically significant larger improvements in quality of life at 6 months for participants allocated to iFuse compared to conservative management; both RCTs were above the MID for EQ-5D (0.18). In the iMIA trial, statistically significant larger improvements in the EQ-5D were sustained at 1 year and at 2 years for participants allocated to iFuse compared to conservative management (both $P<0.001$). In the INSITE trial, participants allocated to surgery also sustained improvements in the EQ-5D at 1 year and at 2 years. Improvements in EQ-5D at 1 year for conservative management participants who crossed over to surgery were similar to the

scores observed in patients allocated to surgery, while EQ-5D at 1 year was lower for participants who remained in conservative management. The INSITE trial[23] also reported the physical health (PCS) and mental health (MCS) component scores of the Short-Form 36 survey (SF-36). The trial reported statistically significant improvements in both scores for participants allocated to iFuse compared to conservative management at 6 months and these scores both achieved their respective MIDs (2 points for PCS and 3 points for MCS). Like the EQ-5D, improvements in both components of the SF-36 were sustained at 1 and 2 years for participants allocated to surgery and for conservative management patients who crossed over to surgery at 1 year, while scores were lower for participants who remained in conservative management.

The CCS[25] comparing open fusion to no surgery reported all SF-36 subscales. The differences between participants who received surgery compared to no surgery ranged from -3 to 10 and authors observed no statistical differences between treatment groups.

Opioid Use

The INSITE and iMIA trials both reported on change in opioid use.[22,23] In the INSITE trial, the percentage of participants using opioids decreased from 68.6% to 58.4% between baseline and 6 months in the surgery group and increased from 63.0% to 70.5% in the conservative management group though the difference in change between groups was not statistically significant (P=0.08). At 1 and 2 years, the proportion using opioids continued to decrease among participants who were allocated to surgery (52.0 % at 1 year, 48.3% at 2 years).[27] The percentage of opioid use observed among the CM group was 55% at 1 year, but the authors do not specify whether this is specific to participants who crossed over, did not cross over, or includes both.[27,28] Opioid use at 2 years was not reported for the CM group; however, the authors did report that the proportion of cross-over participants using opioids 12 months after crossover.[28] The iMIA trial reported opioid use at 2 years using the last observation carried forward for participants who crossed over; the percentage of participants using opioids decreased from 56% to 33% in the surgery group (P=0.009) and decreased from 47.1% to 45.7% in the conservative management group (P=1.0) (calculated RR, 0.75; 95% CI, 0.45 to 1.24).

The CCS comparing iFuse to SI denervation or conservative management reported on the mean amount of oral morphine equivalents (mg/day) that participants were using at the time of last follow-up. A significant difference among groups was observed (fusion 3.1 mg/day, SI denervation 32.2 mg/day, conservative management 38.5 mg/day, P<0.001).

Return to Work

The iMIA trial was the only study that reported a return to work outcome.[22,107] At baseline, 44.2% of participants in the iFuse group were not working because of low back pain, and 52.9% in the conservative management group were not working. At 6 months, these proportions were 39.2% and 57.1%, respectively (P=0.07). The iMIA trial also reported that work status improved significantly over time through year 2 (P=0.001) in the iFuse group.[29]

Other Efficacy Outcomes

The INSITE trial reported a measure of global recovery as its primary study endpoint using a Bayesian analysis.[23] This measure was defined as a reduction in VAS of 20 mm, absence of

device-related serious adverse events, absence of neurologic worsening related to sacral spine, and absence of surgical reintervention for pain. Using this measure, success was achieved in 81.4% of participants (95% Credible Interval, 72.4% to 88.4%) allocated to surgery and 23.9% of participants (95% Credible Interval, 12.6% to 38.8%) allocated to conservative management. Study authors determined the probability that the success rate was higher in the iFuse group compared to conservative management was greater than 0.999. The iMIA trial also reported a measure of global recovery; at 6 months, 39.2% of participants allocated to iFuse reported that they were "much better" compared to 8.2% of participants allocated to conservative treatment ($P<0.0001$).

Both the INSITE trial[23] and the iMIA trial[22] measured self-reported treatment satisfaction (***Appendix C, Table C-2***). In INSITE, 77.2% of participants allocated to iFuse reported being 'very satisfied' with treatment at 6 months compared to 27.3% of participants allocated to conservative management.[22] This level of satisfaction was durable at 1 and 2 years among participants allocated to iFuse.[27,28] At 1 year, a similar proportion (71.0%) of participants who crossed over from conservative management to iFuse reported being very satisfied.[27] The percentage of participants allocated to iFuse that reported being very satisfied was lower in the iMIA trial (54.9%), but was still significantly larger than the percentage reported by participants allocated to conservative management (18.4%).[22]

3.2.3 Findings-Safety Outcomes

All 3 studies comparing iFuse to a control group also reported safety outcomes **(*Table 9***). The 2 RCTs (INSITE[23], iMIA[22]) observed no significant difference between iFuse and conservative management in mean number of events per participant at 6 months. However, the absolute number of events reported in both groups in INSITE was much larger than what was reported in iMIA. By 6 months in the iMIA trial, 20 events among 16 participants occurred in the iFuse group compared to 17 events among 15 participants in the conservative management group.[22] whereas 129 events were reported in the surgery group for INSITE and 49 for the conservative management group. Some of the difference in the conservative management group might be because of the use of therapeutic joint injections and nerve ablation in the control group of the INSITE trial. The absolute number of severe events was larger in both surgery groups (even accounting for differences in size of groups for INSITE) and the absolute number of events determined to be related to the intervention (iFuse or conservative management) was also larger in the surgery groups compared to control groups. Adverse events were reported in each of the 3 to 4 publications associated with each trial but these data were not consistent across these publications. We contacted study authors for clarification of the inconsistencies and our query was acknowledged by study authors but we did not receive any clarifications for these data.

Adverse events reported after 6 months are more challenging to interpret because study authors did not specify whether events in the conservative management group occurred in participants who crossed over or did not cross over. At 2 years in the iMIA trial, 54 events occurred in the iFuse group compared to 47 in the conservative management group; 39 events (72% of events) in the group allocated to iFuse were considered severe compared to 27 events (57% of events) in the group allocated to conservative management.[22,29] However, interpretation of the data beyond 6 months is complicated by author reporting of events among participants who crossed over to

surgery in their original allocation group (conservative management). In the INSITE trial, 22 severe adverse events occurred in the iFuse group by 6 months compared to 8 severe events in the conservative management group (*P*=0.60). At 2 years, 55 severe adverse events were reported in the iFuse group compared to 23 severe adverse events in the conservative management group; the 23 events among conservative management participants included events occurring among participants who crossed over to surgery. No serious adverse events were reported in the CCS comparing iFuse to conservative management.[24]

Table 9. Safety outcomes from the 2 randomized controlled trials and 1 controlled cohort study evaluating minimally invasive sacroiliac joint fusion (iFuse Implant System) compared to conservative management (SQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Serious Adverse Events	Revision Surgery
INSITE (2015)[23,27,28] U.S.	RCT; some concerns	Serious adverse events at 6 mos. iFuse: 22 events Conservative management: 8 events (*P*=0.60) Adverse events related to device at 6 mos. iFuse: 3 (2.9%) Conservative management: NA Adverse events related to treatment procedure(s) at 6 mos. iFuse: 16 (15.7%) Conservative management: 4 (8.7%) (*P* NR) Serious adverse events at 2 yrs. iFuse: 55 events (5 related to device or procedure; 9.1% of events) Conservative management: 23 events (NR related to device or procedure)	At 2 yrs.: iFuse: 3 (3.4%, among 89 with follow-up) Conservative management: 1 (2.6%, among 39 who crossed over to surgery); *P*=0.87 Calculated ARD 0.8% (95% CI, -5.4% to 7.0%) Calculated RR 1.32 (95% CI, 0.14 to 12.24)
iMIA (2016)[22,26,29,107] Multiple European Countries	RCT, some concerns	Serious adverse events at 6 mos. iFuse: 16 events (4 related to device or procedure; 25% of events) Conservative management: 11 events Serious adverse events at 2 yrs. iFuse: 39 events (4 related to device or procedure; 10.3% of events) Conservative management: 27 events (1 related to device in a patient who crossed over to surgery; 3.7% of events)	At 2 yrs.: iFuse: 2 (3.8%) (1 implant revision, 1 post-operative hematoma evacuation) Conservative management: 1 (4.8% among 21 who crossed over to surgery); *P*=0.66 Calculated ARD 1.8% (95% CI, -4.8% to 8.4%) Calculated RR 1.89 (95% CI, 0.18 to 20.13)
Vanaclocha et al. (2018)[24] Spain	CCS, high	Serious adverse events: iFuse: NR SI denervation: 0 Conservative management: 0 Temporary postoperative sciatic pain due to advancement of pin into sacral foramen: iFuse: 2 (7.4%)	Time point unspecified iFuse: 0

Abbreviations: CCS = controlled cohort study; mo(s). = month(s); NA = not applicable; NR = not reported; RCT = randomized controlled trial; SI = sacroiliac; U.S. = United States.

Both RCTs[22,23] also included information on whether the adverse events were device or treatment related. In the INSITE trial,[23] treatment-related adverse events at 6 months occurred in 15.7% of participants allocated to iFuse compared to 8.7% of those allocated to conservative management, and device-related adverse events at 6 months occurred in 2.9% of participants allocated to iFuse. At 2 years, 9.1% of serious adverse events in participants allocated to iFuse were events related to the device or treatment procedure. In the iMIA trial, 10.3% of serious adverse events in participants allocated to iFuse were device or treatment procedure related compared to 3.7% in participants allocated to conservative management (due to a crossover patient).

The incidence of revision surgery at 2 years was similar in the INSITE trial (3.4% among participations allocated to fusion, 2.6% among crossovers) and the iMIA trial (3.8% among participants allocated to fusion, 1.4% among crossovers,); no revisions were reported in the CCS comparing iFuse to conservative management. Reasons for revision surgery are reported in ***Appendix C, Table C-4***.

The CCS[25] comparing open fusion to no surgery did not report whether any serious adverse events occurred (***Appendix C, Table C-4***); postoperative complications occurred in 10% of participants allocated to open surgery and were not reported in participants allocated to the no-surgery group. Revision surgery was performed on 8.4% of the joints in participants allocated to the open surgery group.

3.3 Minimally Invasive Fusion Compared With Open Fusion

We identified 3 CCSs that compared minimally invasive fusion with open fusion. The certainty of evidence for efficacy and safety outcomes is provided in ***Table 10***.

Table 10. Summary of findings and certainty of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) to open fusion

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in pain over 2 years (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[30]	Very serious[a]	Not serious[b]	Not serious	Not serious	Total N=263. Significantly larger improvement for MI SIJF compared to open fusion (between-group repeated measures difference -30 mm [95% CI, -40 to -21]).	⊕◯◯◯ VERY LOW Favors MI SIJF
Change in physical function at 13 to 15 months (Oswestry Disability Index; MID = 8 to 11 points)						
2 CCS[31,32]	Very serious[a]	Serious[c]	Not serious	Serious[d]	Total N=83; mixed findings. Compared with open fusion, significantly larger improvements for MI SIJF in 1 study[31] (calculated between-group difference -33 points, *P*<0.0008); no difference in other study[32] (calculated between-group difference 4.9 points, *P*=0.272).	⊕◯◯◯ VERY LOW Mixed findings
Length of hospital stay						
3 CCS[30-32]	Very serious[a]	Not serious	Serious[e]	Not serious	Total N=346. Significantly shorter length of stay for MI SIJF participants compared to open fusion participants; range of differences were 1.3 to 3.8 days across studies.	⊕◯◯◯ VERY LOW Favors MI SIJF

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Adverse events						
3 CCS[30-32]	Very serious[a]	Serious[f]	Not serious	Very serious[g]	Total N=346. No intraoperative complications reported in any study; frequency of postoperative complications similar between groups and ranged from 14% to 35% across groups.	⨁◯◯◯ VERY LOW No difference
Revision surgery						
3 CCS[30-32]	Very serious[a]	Very serious[h]	Not serious	Very serious[g]	Total N=346. Infrequent revision in both groups in 2 studies (1 to 2 per group)[31,32]; significantly fewer revisions in MI SIJF in third study (calculated ARD -40.8% [95% CI, -49.5% to -32.1%]; calculated RR 0.08 [95% CI, 0.03 to 0.21]).[30]	⨁◯◯◯ VERY LOW Mixed findings

Notes: a. High risk or some concerns for bias in multiple domains, including confounding, selection bias (both because of methods of enrollment and attrition), and outcome measurement.
b. Not applicable, single study body of evidence.
c. One study[32] observed similar improvements and the other study[31] shows significantly larger improvements.
d. Based on SDs observed for measure at follow-up in Ledonio et al.[32]; a sample size of 1,040 participants would be required to meet OIS criteria for a difference of 3.38 points, which represents a small effect size (0.2 SDs).
e. Unclear whether length of stay has a direct correlation to clinical status versus reflecting surgeon or hospital preferences.
f. The incidence of adverse events was highly varied suggesting differences in monitoring or reporting of events or heterogeneity in underlying population.
g. Infrequent events in 2 of the 3 studies.
h. Similar frequency of revision surgery among groups in 2 studies[31,32]; large difference between iFuse and open surgery in third study.[30]

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; MI SIJF = minimally invasive sacroiliac fusion; mm = millimeters; N = number of participants; OIS = optimal information size; RR = risk ratio; SD = standard deviation.

3.3.1 Study Characteristics

The study characteristics for the 3 CCSs included are summarized in ***Table 11***. All were conducted in the U.S.; 1[32] was conducted at a single center. All 3 evaluated the iFuse Implant System in 1 study group; two of the studies used an anterior ilioinguinal approach for open fusion for the comparator group[31,32] and the third study used a posterior approach to open fusion for the comparator group. All used similar methods of diagnosing SI joint pain. The patients who received iFuse were more than 10 years older compared to participants who received open surgery in 2 studies.[30,31] No studies reported the mean duration of symptoms. Notably, the proportion of participants who had a prior lumbar fusion was higher among participants who received iFuse in all 3 studies, and notably higher in the Smith et al.[30] study (74.4% vs. 23.5%). We rated these studies as having a high risk of bias, because of confounding, selection bias, high and/or differential attrition, and the methods of outcome measurement.

Table 11. Study and population characteristics of the 3 controlled cohort studies evaluating minimally invasive sacroiliac joint fusion (iFuse Implant System) compared to open fusion

Author (Year); Country	Study Design; Risk of Bias	Population and Setting Characteristics	Method of Diagnosis	Intervention (N)	Comparator (N)
Ledonio et al. (2014)[32] U.S.	CCS, High	Single center, 2006 to 2011 Mean age iFuse: 47.9 Open: 51 Mean duration of symptoms: NR N (%) with prior lumbar fusion iFuse: 14 (64) Open: 11 (60)	History, provocative physical exam findings, diagnostic SI joint injections	iFuse N treated: NR[a] N analyzed: 22	Open anterior ilioinguinal approach N treated: NR[a] N analyzed: 22
Ledonio et al. (2014)[31] U.S.	CCS, High	2 centers, 2006 to 2012 Mean age iFuse: 66 Open: 51 Mean duration of symptoms: NR N (%) with prior lumbar fusion iFuse: 14 (82) Open 11 (50)	History, provocative physical exam findings, diagnostic SI joint injections	iFuse N treated: NR[b] N analyzed: 17	Open anterior ilioinguinal approach N treated: NR[b] N analyzed: 22
Smith et al. (2013)[30] U.S.	CCS, High	7 centers, 1994 to 2012 Mean age iFuse 57.4 Open: 45.8 Mean duration of symptoms: NR N (%) with prior lumbar fusion iFuse: 54 (74.4) Open: 35 (23.5)	History, ≥ 3 findings on physical provocation tests, diagnostic imaging to rule out other pathology, intraarticular SI joint block	iFuse N treated: NR N analyzed:114	Open posterior approach N treated: NR N analyzed: 149

Notes: a. A total of 63 participants were treated but only 44 had data available for analysis.
b. A total of 49 participants were treated but only 39 had data available for analysis. The open fusion group in this study[31] is the same open fusion group reported in Ledonio et al.[32]

Abbreviations: CCS = controlled cohort study; N=number of participants; NR = not reported; SI = sacroiliac; U.S. = United States.

3.3.2 Findings: Efficacy Outcomes

Table 12 summarizes key efficacy outcomes reported by 3 studies comparing minimally invasive SI joint fusion to open fusion.

Table 12. Key efficacy outcomes from the 3 controlled cohort studies evaluating minimally invasive sacroiliac joint fusion (iFuse Implant System) compared to open fusion (EQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Pain	Physical Functioning	Length of Stay (days)
Ledonio et al. (2014)[32] U.S.	CCS, High	NR	Oswestry Disability Index[a] iFuse calculated difference from open fusion: 13 to 15 months: 4.9 points (*P*=0.272)	Mean (SD) iFuse: 2 (1.5) Open: 3.3 (1.1) (*P*=0.002)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Pain	Physical Functioning	Length of Stay (days)
Ledonio et al. (2014)[31] U.S.	CCS, High	NR	Oswestry Disability Index[a] iFuse calculated difference from open fusion: 15 months: -33 points (*P*<0.0008) N (%) meeting MID threshold (12.8 points) iFuse 14 (82%) Open: 10 (45%) (*P*=0.02)	Mean (range) iFuse: 1 (1 to 2) Open: 3 (2 to 6) (*P*<0.0001)
Smith et al. (2013)[30] U.S.	CCS, High	VAS (mm)[b] iFuse difference from open fusion 1 year: -36 (95% CI NR) 2 year: -37 (95% CI NR) Adjusted RM[c]: -30 (95% CI, -20.7 to -39.9)	NR	Mean (SD) iFuse: 1.3 (0.5)[d] Open: 5.1 (1.9) (*P*<0.0001)

Notes: a. Score ranges from 0 to 100; higher scores indicate greater disability. A negative difference between groups means that fusion surgery resulted in a greater improvement than the comparator.
b. Scores range from 0 to 100 millimeters; a higher score indicates worse pain. A negative difference between groups means that fusion surgery resulted in a greater improvement than the comparator.
c. Repeated measures over all follow-up adjusted for age, sex, prior lumbar fusion.
d. This estimate is based on only 30 of the 114 participants in this group.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; cm = centimeter; MID = minimally important difference; NR = not reported; RM = repeated measures; SD = standard deviation; U.S. = United States; VAS = visual analog scale.

Pain

Only 1 of the 3 studies reported a pain outcome. Smith et al.[30] reported pain using the VAS (in millimeters) at baseline, 1 year, and 2 years follow-up. At both 1 and 2 years, participants who received iFuse had larger improvements in pain, and a repeated measures analysis over all follow-up found a statistically significant 30-mm larger improvement for iFuse participants compared to open fusion. This difference in mean change achieved the MID for this measure (i.e., 7 to 11 points). In a subgroup analysis of participants by prior lumbar fusion surgery status, no differences in effect were observed.[30]

Physical Functioning

Two of the 3 studies reported a physical functioning outcome; both reported this outcome using the ODI. These studies observed mixed findings. One study observed similar improvements in the iFuse and open fusion groups (calculated between-group difference 4.9, $P=0.272$) and did not achieve the MID (8 to 11 points)[32] whereas the other study observed significantly larger improvements in the iFuse group (calculated between-group difference -33, $P<0.0008$) that exceeded the MID.[31] Of note, the open fusion groups used in both these studies were the same set of participants, suggesting underlying differences in the populations or surgical techniques used in the iFuse groups.

Length of Stay

All 3 studies reported significantly shorter length of hospital stay among participants in the iFuse groups compared to open surgery. The range of difference in length of stay between iFuse and open fusion was 1.3 to 3.8 days.

3.3.3 Findings-Safety Outcomes

Table 13 summarizes safety outcomes reported by the 3 studies comparing minimally invasive SI joint fusion to open fusion.[30-32] All 3 studies reported no intraoperative complications in the iFuse group; only 1 of the 3 studies explicitly reported no intraoperative complications in the open fusion group. Postoperative complications reported by studies ranged from 13.6% to 35.3%, suggesting variability in monitoring or reporting of these events. No significant differences in adverse events were observed. Both studies by Ledonio et al. reported few revisions in either the iFuse or open groups and no significant differences were observed;[31,32] however, we note that the same set of participants was used for the open fusion group in both studies. Smith et al. reported significantly fewer revisions among participants who received iFuse (3.5%) compared to participants who received open fusion (44.3%) (calculated ARD -40.8% [95% CI, -49.5% to -32.1%].

Table 13. Safety outcomes from the 3 controlled cohort studies evaluating minimally invasive sacroiliac joint fusion (iFuse Implant System) compared to open fusion (SQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Adverse Events	Revision Surgery	Interoperative Blood Loss	Duration of Surgery
Ledonio et al. (2014)[32] U.S.	CCS, High	Intraoperative iFuse 0; Open NR Postoperative iFuse 3 (13.6%); Open 3 (13.6%); *P*=1.00	iFuse: 2 (9.1%); Open 2 (9.1%); *P*=1.00	Mean (SD) iFuse: 40.5 mL (31.4) Open: 681.8 mL (479.0) *P*<0.001	Mean (SD) iFuse: 68.3 mins. (26.8) Open: 128.0 mins. (27.9) *P*<0.001
Ledonio et al. (2014)[31] U.S.	CCS, High	Intraoperative iFuse 0; Open NR Postoperative iFuse 6 (35.3%); Open 3 (13.6%), *P*=0.14	iFuse: 1 (5.9%); Open 2 (9.1%); *P*=0.77 Calculated ARD -3.2% (95% CI, -19.6% to 13.2%) Calculated RR 0.65 (95% CI, 0.06 to 6.55)	NR	Mean (range) iFuse: 27 mins. (18 to 72) Open: 128 mins. (73 to 180) Calculated between-group difference (iFuse-Open) -101 mins. *P*<0.0001
Smith et al. (2013)[30] U.S.	CCS, High	Intraoperative 0 in either arm; Postoperative iFuse: 20 (18%); Open: 34 (23%); *P*=0.30	iFuse: 4 (3.5%); Open: 66 (44.3%); *P<0.001*	Mean (SD) iFuse: 33 mL (27) (based on 66 of 114 patients) Open: 288 mL (182) (based on 138 of 149 patients) *P*<0.0001	Mean (SD) iFuse: 70 mins. (24) (based on 63 of 114 patients) Open: 163 mins. (25) (based on 100 of 149 patients) *P*<0.0001

Abbreviations: ARD = risk difference; CCS = controlled cohort study; CI = confidence interval; min(s). = minute(s); mL = milliliters; NR = not reported; RR = risk ratio; U.S. = United States.

All 3 studies also reported on intermediate safety outcomes, interoperative blood loss, and duration of surgery. Two of the 3 studies reported on interoperative blood loss, and both reported significantly less blood loss among participants in the iFuse group compared to the open surgery group. The difference in blood loss between the iFuse and open surgery groups ranged from 255 mL ($P<0.0001$)[30] to 641.3 mL ($P<0.001$).[32] All 3 studies reported on duration of surgery and reported significantly shorter surgery durations among participants in the iFuse group compared to the open surgery group. The difference in surgery duration between the iFuse and open surgery groups range from 60 to 101 minutes.

3.4 Comparative Effectiveness of Alternative Minimally Invasive Fusion Procedures

We identified 2 CCSs comparing the effectiveness of alternative minimally invasive fusion procedures. One CCS, new to this update, compared the minimally invasive posterior oblique approach with Rialto (a cylindrical threaded implant) to the minimally invasive lateral transiliac approach with the iFuse Implant System (a triangular dowel implant).[33] The other CCS compared minimally invasive fusion with the iFuse Implant System to percutaneous screw fixation.[34] The study that compared minimally invasive fusion with the iFuse Implant System to percutaneously screw fixation did not report any eligible efficacy outcomes. The certainty of evidence (GRADE rating) for efficacy and safety outcomes comparing iFuse to Rialto is provided in ***Table 14***, and the certainty of evidence for safety outcomes comparing iFuse to percutaneously screw fixation is provided in ***Table 15***.

Table 14. Summary of findings and certainty of evidence ratings comparing minimally invasive sacroiliac joint fusion using the iFuse Implant System to the Rialto Implant System

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Change in pain at 6 months to 1 year (Visual Analog Scale; MID = 7 to 11 mm)						
1 CCS[33]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N=156; no significant differences between Rialto and iFuse (between-group difference 4.3 mm [95% CI, -8.7 to 17], *P*=0.53 at 6 mos.; -3.7 mm [95% CI, -23 to 15], *P*=0.70 at 1 yr.)	⊕◯◯◯ VERY LOW No difference
Change in physical function at 6 months to 1 year (Oswestry Disability Index; MID = 8 to 11 points)						
1 CCS[33]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N=156; no significant differences between Rialto and iFuse (between-group difference 3.0 [95% CI, -2.1 to 8.1], *P*=0.25 at 6 mos.; -2.1 [95% CI, -9.2 to 4.9], *P*=0.55 at 1 yr.)	⊕◯◯◯ VERY LOW No difference
Change in quality of life at 6 months to 1 year (SF-12)						
1 CCS[33]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N=156; no significant differences between Rialto and iFuse (between-group difference 1.7 [95% CI, -1.5 to 4.9], *P*=0.28 at 6 mos.; 3.0 [95% CI, -0.48 to 6.5], *P*=0.09 at 1 yr.)	⊕◯◯◯ VERY LOW No difference
Length of stay						
1 CCS[33]	Serious[a]	Not serious[b]	Serious[c]	Not serious	Total N=156; no significant differences between Rialto (1.7 days) and iFuse (1.8 days) (*P*=0.42)	⊕◯◯◯ VERY LOW No difference
Revision surgery						
1 CCS[33]	Serious[d]	Not serious[b]	Not serious	Serious[e]	Total N=156; no significant differences between Rialto (6.1%) and iFuse (2.4%); calculated ARD -5.7% (95% CI, -12.7% to 1.4%), calculated RR 0.30 (95% CI, 0.06 to 1.44).	⊕◯◯◯ VERY LOW No difference

Notes: a. Serious or moderate concerns for bias because of confounding, selection, and outcome measurement.
b. Not applicable, single study body of evidence.
c. Unclear whether length of stay has a direct correlation to clinical status versus reflecting surgeon, hospital, or insurer preferences.

d. High or some concerns for bias in multiple domains, including confounding, selection bias (both because of methods of enrollment and attrition), and outcome measurement.
e. Somewhat infrequent events.

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; mL = milliliter; mm = millimeters; mo(s). = month(s); N=number of participants; RR = risk ratio; yr(s). = year(s).

Table 15. Summary of findings and certainty of evidence ratings comparing minimally invasive sacroiliac joint fusion with implants (iFuse) to screw fixation

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY/ Direction of Effect
Revision surgery at 2.8 to 4.6 years						
1 CCS[34]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N=292; significantly fewer revisions with MI SIJF (4.6%) compared to screws (65.5%); calculated ARD -61.0% (95% CI, -78.4% to -43.5%); calculated RR 0.07 (95% CI, 0.04 to 0.13).	⊕◯◯◯ VERY LOW Favors MI SIJF

Notes: a. Some concerns for bias because of confounding and differential attrition.
b. Not applicable, single study body of evidence.

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; MI SIJF = minimally invasive sacroiliac fusion; N=number of participants; RR = risk ratio.

3.4.1 Study Characteristics

The study characteristics for the 2 CCSs evaluating alternative minimally invasive fusion procedures are summarized in ***Table 16***. Both studies were conducted in the United States at a single center. Both evaluated the iFuse Implant System in 1 group. One CCS compared SI joint fusion using the iFuse System (a triangular dowel implant system placed using a lateral transiliac approach) to using the Rialto Fusion System (a cylindrical threaded implant system placed using a posterior oblique approach).[33] Over three-fifths of participants had prior lumbar fusion. The diagnostic criteria that this study used to diagnose SI joint pain was based on physical examination, positive provocative tests, imaging, and 2 consecutive injections demonstrating ≥ 60% improvement in baseline pain scores. We rated the risk of bias for this study as high because of confounding, selection, and outcome measurement.

Table 16. Study and population characteristics of the 2 controlled cohort studies evaluating alternative minimally invasive fusion procedures

Author (Year); Study Name; Country	Study Design; Risk of Bias	Population and Setting Characteristics	Method of Diagnosis	Intervention (N)	Comparator (N)
Spain et al. (2017)[34] U.S.	CCS, Some concerns	Single center, 2004 to 2016 Mean age: iFuse: 54.3 Screw fixation: 46.6 Mean duration of symptoms NR N with prior lumbar fusion NR	NR	iFuse N treated: 274 N analyzed: 263	Percutaneous fixation with screws (Synthes) N treated: 38 N analyzed: 29

Author (Year); Study Name; Country	Study Design; Risk of Bias	Population and Setting Characteristics	Method of Diagnosis	Intervention (N)	Comparator (N)
Claus et al. (2020)[33] U.S.	CCS, High	Single center, 2012 to 2018 Mean age: Rialto: 58.4 iFuse: 55.7 Mean duration of symptoms NR N (%) with prior lumbar fusion: Rialto: 48 (64.9%) iFuse: 51 (61.0%)	Diagnosis based on 1) physical examination, 2) positive provocative tests, 3) imaging studies that ruled out other lumbosacral pathology, and 4) confirmation of diagnosis was established with 2 consecutive injections demonstrating ≥60% improvement in baseline pain scores.	Rialto N treated: NR N analyzed: 74	iFuse N treated: NR N analyzed: 82

Abbreviations: CCS = controlled cohort study; N=number of participants; NR = not reported; U.S. = United States.

One CCS compared SI joint fusion with the iFuse System to SI joint percutaneous fixation with screws.[34] The number of participants with prior lumbar fusion and the method of diagnosis were not reported in the study. We rated the risk of bias for this study as having some concerns for bias because of confounding and differential attrition.

3.4.2 Findings—Efficacy Outcomes

The 1 CCS comparing minimally invasive SI joint fusion with iFuse to percutaneous screw fixation did not report any efficacy outcomes.[34] The 1 CCS comparing Rialto to iFuse reported pain, physical functioning, quality of life, and length-of-stay efficacy outcomes.[33] ***Table 17*** summarizes the efficacy outcomes for minimally invasive SI joint fusion with the Rialto System compared to the iFuse System.

Pain

The CCS comparing Rialto with iFuse reported pain using VAS for back and leg pain at baseline, 6 months, and 1 year follow-up. In both the Rialto and iFuse groups, there was a significant improvement in VAS (in millimeters) for back and leg pain compared to baseline values at 6 months.[33] However, authors observed no significant differences between groups for back pain (between-group difference 4.3, P=0.53 at 6 months; -3.7, P=0.70 at 1 year) or leg pain (between-group difference 3.6, P=0.64 at 6 months; 2.1, P=0.84 at 1 year) at either follow-up time point. In both the Rialto and iFuse groups, there was a significant improvement in VAS for back and leg pain compared to baseline values at 6 months.[33]

Table 17. Key efficacy outcomes from the 1 controlled cohort study evaluating alternative minimally invasive fusion procedures (EQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Pain, VAS[a]	Oswestry Disability Index[b]	Quality of Life	Length of Stay
		Mean Difference or Difference in Proportion Between Groups			
Claus et al. (2020)[33] U.S.	CCS, High	Rialto compared to iFuse VAS-back 6 mos.: 4.3 mm (95% CI, -8.7 to 17; P=0.53)	Rialto compared to iFuse 6 mos.: 3.0 (95% CI, -2.1 to 8.1; P=0.25) 1 yr.: -2.1 (95% CI, -9.2 to 4.9; P=0.55)	Rialto compared to iFuse SF-12 PCS 6 mos.: 1.7 (95% CI, -1.5 to 4.9; P=0.28) 1 yr.: 3.0 (95% CI, -0.48 to 6.5; P=0.09)	Length of stay (days), mean (SD) Rialto: 1.7 (0.93) iFuse: 1.8 (0.93) P=0.42

Author (Year); Study Name; Country	Study Design; Risk of Bias	Pain, VAS[a]	Oswestry Disability Index[b]	Quality of Life	Length of Stay
		Mean Difference or Difference in Proportion Between Groups			
		1 yr.: -3.7 mm (95% CI, -23 to 15; *P*=0.70) VAS-leg 6 mos.: 3.6 mm (95% CI, -11 to 19; *P*=0.64) 1 yr.: 2.1 mm (95% CI, -19 to 23; *P*=0.84)			

Notes: a. Scores range from 0 to 100 mm; a higher score indicates worse pain.
b. Score ranges from 0 to 100; higher scores indicate greater disability.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; EQ = efficacy question; MID = minimally important difference; mm = millimeter; NR = not reported; SD = standard deviation; SF-12 PCS = Short Form Survey 12 item, physical component score; U.S. = United States; VAS = visual analog scale.

Physical Functioning

The CCS comparing Rialto with iFuse reported physical functioning using ODI at baseline, 6 months, and 1 year follow-up. [33]Similar to pain outcomes, authors observed no significant differences between groups in ODI at either follow-up time point (between-group difference 3.0 points, *P*=0.25 at 6 months; -2.1 points, *P*=0.55 at 1 year). In both the Rialto and iFuse groups, there was a significant improvement in ODI compared to baseline values at 6 months.[33]

Quality of Life

The CCS comparing Rialto with iFuse reported quality of life using SF-12 (PCS) at baseline, 6 months, and 1 year follow-up. In both the Rialto and iFuse groups, there was a significant improvement in SF-12 compared to baseline values at 6 months.[33] Consistent with pain and functioning outcomes, authors observed no significant differences between groups in SF-12 at either follow-up time point (between-group difference 1.7 points, *P*=0.28 at 6 months; 3.0 points, *P*=0.09 at 1 year). In both the Rialto and iFuse groups, there was a significant improvement in SF-12 compared to baseline values at 6 months.[33]

Length of Stay

The CCS comparing Rialto with iFuse reported a similar length of hospital stay for both groups: 1.7 days for Rialto and 1.8 days for iFuse (*P*=0.42).

3.4.3 Findings-Safety Outcomes

Table 18 summarizes safety outcomes reported by the 2 CCS comparing different minimally invasive SI joint fusion procedures.[33,34] Both studies reported the number of revision surgeries, but neither reported the number of complications apart from those associated with a revision surgery. The CCS comparing Rialto with iFuse also reported the duration of surgery. The CCS comparing iFuse to percutaneous screw fixation reported significantly fewer revisions among participants who received iFuse (4.6%) compared to participants who received percutaneous

screw fixation (65.6%).[34] The CCS comparing Rialto with iFuse reported fewer revisions in the iFuse group (2.4%) than the Rialto group (6.1%), but this difference was not statistically significant.[33]

Table 18. Safety outcomes from the 2 controlled cohort studies evaluating alternative minimally invasive sacroiliac joint fusion procedures (SQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Adverse Events	Revision Surgery	Interoperative Blood Loss	Duration of Surgery
Spain et al. (2017)[34] U.S.	CCS, Some concerns	Postoperative complications resulting in revision surgery iFuse: 12 (4.6%) Screw fixation: 19 (65.5%); *P*<0.001	iFuse: 12 (4.6%) [occurring at a mean follow-up of 2.8 years (SD 3.2)] Screw fixation: 19 (65.5%) [occurring at a mean follow-up of 4.6 years (SD 4.9)]; *P*<0.001	NR	NR
Claus et al. (2020)[33]	CCS, High	Postoperative complications resulting in revision surgery iFuse: 2 (2.4%) Rialto: 6 (6.1%); *P*=0.11	iFuse: 2 (2.4%) Rialto: 6 (6.1%); *P*=0.11	Estimated blood loss in mL, mean (SD) Rialto: 39.6 (26.3) iFuse: 50.9 (44.1)	Surgery length (minutes), mean (SD) Rialto: 60.0 (18.8) iFuse: 41.2 (12.5)

Abbreviations: ARD = absolute risk difference; CI = confidence interval; CCS = controlled cohort study; mL = milliliters; NR = not reported; RR = risk ratio; SD = standard deviation; SQ = safety question; U.S. = United States.

The CCS comparing Rialto with iFuse also reported two intermediate outcomes: interoperative blood loss and duration of surgery. There were no significant differences between groups in interoperative blood loss; the mean blood loss for participants allocated to Rialto was 39.6 mL compared to 50.9 mL for participants allocated to iFuse (P=0.054). Surgery duration was significantly shorter for participants in the iFuse groups compared to the Rialto groups; the mean surgery length for participants allocated to Rialto was 60.0 minutes compared to 41.2 minutes for participants allocated to iFuse (P<0.0005).

3.5 Safety Outcomes from Uncontrolled Studies

In addition to the 2 RCTs and 7 CCSs evaluating SI joint fusion, we identified 43 uncontrolled studies that reported safety outcomes from various SI joint fusion procedures; 11 uncontrolled studies are new to this update.[35-46] We report a complete description of each study in ***Appendix C, Table C-11*** and provide detailed findings in ***Appendix C, Table C-12.***

3.5.1 Study Characteristics

Eight studies[35,49,51,54,55,109-111] were uncontrolled trials; 4 studies[37,38,56,112] were uncontrolled prospective cohorts; 28 studies[39-48,52,53,59-68,113-118] were uncontrolled retrospective cohorts; 2 studies[50,119] were uncontrolled cohorts, but we were unable to determine whether they were conducted prospectively or retrospectively; and 1 uncontrolled study[58] used a design we were unable to categorize because of limited information provided by the study. The sample size among these studies ranged from 4 to 14,210; 13 studies were multicenter,[35,42,54-56,62,65-68,109,119,120] 2 studies did not report the setting,[37,46] and the rest were conducted at a single center. These studies were conducted from 1987 to 2021. The types of procedures evaluated varied and

are summarized in ***Table 19***. Nine studies[37,47-54] evaluated open fusion procedures, and the rest evaluated various minimally invasive fusion procedures. We rated 27 studies as having a high risk of bias, 14 as having some concerns for bias, and 2 as having a low risk of bias (***Appendix E, Tables E-13, E-14,*** and ***E-15***).

Table 19. Summary of fusion procedures evaluated in 43 uncontrolled studies

Procedure	Number of Studies
Open fusion	9 studies total: 2 studies using posterior approach[47,48] 3 studies using anterior approach[37,49,50] 1 study using anterior approach with symphysiodesis[51] 1 study using Verral and Pitkin technique(bilateral)[52] 1 study using modified Smith-Petersen technique[53] 1 study using distraction interference arthrodesis[54]
iFuse Implant System (triangular, titanium coated implants) [Minimally invasive]	20 studies total: 19 studies using iFuse only[35,36,39,40,42-45,55-66,68,120] 1 study using iFuse or Samba[115]
SImmetry System (titanium cannulated and antirotational implants with surface roughness) [Minimally invasive]	3 studies[109,117,119]
Percutaneous fusion using hollow modular anchorage screw [Minimally invasive]	3 studies[112,113,116]
SI-LOK Sacroiliac Joint Fusion System [Minimally invasive]	3 studies[38,46,110]
Rialto system (cylindrical threaded implants) [Minimally invasive]	1 study[41]
INTERFIX system (single-threaded titanium cage filled with rhBMP-2) [Minimally invasive]	1 study[114]
Fusion using dual fibular dowel allografts [Minimally invasive]	1 study[118]
Fusion using threaded fusion cages [Minimally invasive]	1 study[111]
Various types of minimally invasive procedures based on insurance claims using CPT code 27279	1 study[67]

Abbreviations: CPT = Current Procedural Terminology; rhBMP-2 = recombinant human Bone Morphogenetic Protein-2.

The way in which study authors defined and monitored adverse events, including timeframe over which participants were followed, varied highly among studies. Prospective uncontrolled trials were more likely to actively monitor participants and report all adverse events participants experienced during the study time frame, regardless of whether the event was device- or procedure-related.[55-57,120] Non-device or procedure related events were events classified as being unrelated to the SI joint fusion (e.g., myocardial infarction, headache, respiratory infection). Some studies only reported events that were considered "severe" or "serious." Some studies reported only whether major complications of surgery occurred. Some study authors made a distinction between intraoperative and postoperative adverse events, and some did not. Some studies reported only the number of events but did not report the number of participants experiencing those events. Some studies reported only the number of revision surgeries and not the number of adverse events. Of the studies that reported on the frequency of revision surgery, some did not report the timeframe over which participants were monitored for revision surgery.

3.5.2 Findings—Safety Outcome

Among the 9 studies evaluating open fusion procedures, the frequency of adverse events ranged from 5.3% to 75% experiencing complications. The frequency of revision surgery, which was reported only among 7 of the 9 studies, ranged from 4.0% to 64.7%. The frequency of adverse events and revisions from most of these studies was higher than reported in the 1 CCS[25] evaluating open fusion. Kibsgard reported 10% of participants allocated to fusion experiencing complications (6% related to the fusion surgery and 4% not) and 8.4% of joints requiring revision.[25]

Among the 20 studies evaluating the iFuse Implant system, the frequency of adverse events ranged from 0% to 92%; however, when limited to adverse events definitely or probably related to the device or procedure, the range was from 0% to 30% across the studies reporting an overall frequency of adverse event.[35,39,40,42-45,55,56,58-66] The frequency of severe or serious adverse events ranged from 0% to 46%. One study reported that 33% of serious events were device related at 6 months;[55] the frequency of severe adverse events that were device or procedure related decreased to less than 10% of severe adverse events after 1 or more years of follow-up.[35,55,56] The uncontrolled trials reported a similar frequency of adverse events compared to those observed in the 2 RCTs,[22,23] while the other uncontrolled studies reported a lower frequency, similar to the frequency observed in the 1 CCS.[24] Among the 16 uncontrolled cohort studies reporting revision surgeries, the frequency of revision surgery ranged from 0% to 8%; among the 3 uncontrolled trials, the frequency of revision surgery ranged from 3% to 5%. One of the largest of these studies reported the incidence of revision based on the manufacturer's postmarket surveillance database over the years 2009 to 2014. Of 11,388 participants who underwent an initial procedure with iFuse, 320 (2.8%) underwent a revision and 63% of the revisions occurred within the first year postoperatively.[68] Another study that was new to this update that used the same postmarket surveillance database over the years 2015 to 2018 observed that 3.1% of the 14,210 participants with surgery during that time period had a revision with the 1-year cumulative rate of revision estimates at 1.0% (iFuse-3D) and 1.5%(iFuse).[42] The frequency of revision observed in the uncontrolled studies was similar to the frequencies observed in the 2 RCTs comparing iFuse to conservative management.[22-24]

Among the 3 studies evaluating the SImmetry system, the frequency of adverse events varied. One study reported 2 serious events among 50 participants[109] over 2 years, 1 study reported 4 operative complications among 17 procedures,[117] and 1 study reported no procedure complications or serious events but did report 6 nonserious events over 2 years among 19 participants.[119] The frequency of revision was 0% in 1 study,[117] 2% in 1 study,[109] and not reported in the third study.[119]

Among the 3 studies evaluating percutaneous fusion using a hollow modular anchorage screw, 1 study reported 1 adverse event among 9 participants,[113] 1 study reported 2 events among 55 participants,[112] and 1 study reported 0 events.[116] The number of revisions was 2 among 55 participants (3.6%) in 1 study,[112] 0 in 1 study,[116] and not reported in the third study.[113]

Among the 3 studies evaluating the SI-LOK system, the 1 study reported 2 adverse events among 32 participants,[110] 1 study reported 6 events among 33 participants,[38] and 1 study reported 3

events among 33 participants.[46] The frequency of revision was 6% in 1 study,[110] 12% in 1 study,[38] and not reported in the third study.[46]

One study evaluating the Rialto system reported 5 adverse events (21%) among 24 participants and 1 revision (4%).[121] This frequency of revisions observed in the uncontrolled study was similar to the frequency of revisions observed among Rialto patients in the CCS comparing participants allocated to the Rialto group to those in the iFuse group.[33]

One study[67] retrospectively evaluated the frequency of adverse events after minimally invasive SI joint fusion using an insurance claims database from 2007 to 2014. Study authors could not report the specific procedures or systems used based on available data. The overall incidence of complications was 13.2% at 90 days and 16.4% at 6 months among 469 claimants that received surgery. The most prevalent complication reported involved the nervous system (i.e., neuritis, radiculitis, sciatica, neuralgia) (6.2% at 6 months).

3.6 Cost and Cost-Effectiveness

Five studies reported on cost outcomes.[69-72,122] Four compared minimally invasive SI joint fusion surgery to conservative management,[69-72] and 1 reported costs for an uncontrolled study of SI joint fusion based on administrative claims data.[122] ***Table 20*** summarizes cost outcomes for the 4 comparative studies.

Table 20. Summary of findings and certainty of evidence ratings comparing costs and cost-effectiveness of minimally invasive sacroiliac joint fusion to conservative management

№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	CERTAINTY
Costs over 3 to 5 years in a commercially insured population						
1 CCA[69]	Not serious	Not serious[a]	Not serious	Serious[b]	Minimally invasive SI joint fusion with iFuse costs $14,545 more over 3 years and $6,137 more over 5 years.	⨁◯◯◯ VERY LOW
Lifetime costs in a Medicare population						
1 CCA[70]	Not serious	Not serious[a]	Not serious	Serious[b]	Minimally invasive SI joint fusion with iFuse costs $3,358 less than nonoperative care.	⨁◯◯◯ VERY LOW
Cost-effectiveness over 5 years						
2 CEA[71,72]	Not serious	Not serious[b]	Not serious	Serious[c]	Minimally invasive SI joint fusion with iFuse costs range from $2,697 to $13,313 per QALY gained.	⨁◯◯◯ VERY LOW

Notes: a. Not applicable, single study body of evidence.
b. Although the magnitude of the incremental cost-effectiveness ratios were not entirely consistent, they were in the same direction, and the inconsistency is likely explained by differences in cost between the United States and the United Kingdom and in differences in costing methods used in the studies.
c. No information provided (e.g., standard error, standard deviations, confidence intervals) in the studies to be able to judge precision of estimates.

Abbreviations: CCA = comparative cost analysis; CEA = cost-effectiveness analysis; QALY = quality-adjusted life-year; SI = sacroiliac.

3.6.1 Study Characteristics

Study characteristics are summarized in ***Table 21***. We rated 4 studies[69-72,122] as low risk of bias and 1 study[122] as some concerns for bias (***Appendix E, Tables E-16, E-17,*** and ***E-18***). Two studies were comparative cost analyses,[69,70] 2 were cost-effectiveness analyses,[71,72] and 1 was a retrospective observational analysis of low back pain costs before and after SI joint fusion surgery with a cumulative cost model based on a counterfactual assumption of continued cost trends if nonsurgical management had been continued.[122]

Table 21. Study characteristics for studies reporting cost or cost-effectiveness (CQ1)

Author (Year) Country Risk of Bias	Intervention	Comparator	Key Analysis Parameters	Outcomes
Ackerman (2014)[69] U.S. Low	Minimally invasive SI joint fusion (unilateral, device not specified)	Nonoperative care	Comparative cost analysis based on model 2012 U.S. dollars, discount rate 3% Payer perspective Time horizon 3 and 5 years Commercially insured study population, with mean age 45.2 years Costs: Truven Health MarketScan	Mean per-patient 3-year costs: Fusion: $30,884 Nonoperative care: $16,339 Difference: -$14,545 Mean per-patient 5-year costs: Fusion: $31,810 Nonoperative care: $25,673 Difference: -$6,137
Ackerman (2013)[70] U.S. Low	Minimally invasive SI joint fusion (unilateral, device not specified)	Nonoperative care	Comparative cost analysis based on model 2012 U.S. dollars, discount rate 3% Payer perspective Time horizon: lifetime costs Medicare study population, starting at age 70 with life expectancy of 84 years Costs: Medicare 5% SAF	Mean per-patient lifetime costs: Fusion: $48,185 Nonoperative care: $51,543 Difference: $3,358
Blissett (2020)[72] U.K. Low	Minimally invasive SI joint fusion (iFuse)	Nonoperative care (3 strategies)[a]	Cost-effectiveness analysis based on Markov model 2018 GBP[b], discount rate 3.5% Payer perspective Mean age: 50 Time horizon: 5 years Costs: NHS cost schedule Utility measure: EQ-5D	Base case at 5 years costs (converted to 2015 USD[b]) Surgery: $10,415 Stepped care: $8,573 PT/injections or RFA: $8,179 RFA only: $8,199 Base case at 5 years QALYs Surgery: 2.98 Stepped care: 2.30 PT/injections or RFA: 2.26 RFA only: 2.28 ICERs Surgery vs. stepped care: $2,697/QALY gained Surgery vs. PT/injections or RFA: $3,075/QALY gained Surgery vs. RFA only: $3,138/QALY gained

Author (Year) Country Risk of Bias	Intervention	Comparator	Key Analysis Parameters	Outcomes
Buysman (2018)[122] U.S. High	SI joint fusion based on administrative claims (CPT codes 27279, 27280)	None (but counterfactual trend used for cumulative cost model)	Retrospective analysis of actual costs with cumulative cost model for low back pain-related costs (2016 U.S. dollars) Payer perspective Time horizon: 1 yr. before and 1 yr. after fusion Most patients age 45 to 64 Costs: Claims from large U.S. health insurer 2010 to 2017 (N=302)	Mean (SD) low back pain costs Before: $16,803 ($32,144) After: $13,297 ($28,122) *P*=0.095 Median (IQR) low back pain costs Before: $5,849 ($2,423 to $14,287) After: $2,269 ($606 to $8,855) *P*<0.001 Break-even time point for fusion vs. continued nonsurgical management: 7.25 years
Cher (2016)[71] U.S. Low	Minimally invasive SI joint fusion (iFuse)	Nonoperative care	Cost-effectiveness analysis based on Markov model 2015 U.S. dollars Payer perspective Time horizon: 5 years Costs: Data from INSITE trial using indirect cost-accounting method Utility measure: EQ-5D	Base case at 5 years cost Fusion: $22,468 Nonoperative care: $12,636 Difference: -$9,833 Base case at 5 years QALYs Fusion: 3.20 Nonoperative Care: 2.46 Difference: -0.74 ICER: $13,313 per QALY gained Breakeven costs at 13 years

Notes: a. One comparator strategy evaluated stepped care consisting of physical therapy and therapeutic joint injections followed by RFA for failures. A second comparator strategy evaluated involved half the population only receiving PT and therapeutic joint injections and the other half only receiving RFA. The third comparator strategy evaluated involved the entire population only receiving RFA.
b. Authors reported results in 2018 British pound sterling; we converted these data to 2016 U.S. dollars using the Department of Treasury mid-year exchange rate and the chain-weighted consumer price index. The original data reported by authors are included in ***Appendix Table C-13.***

Abbreviations: CPT = Current Procedural Terminology; CQ = cost question; EQ-5D = EuroQOL instrument for measuring generic health status; GB*P*=British pound sterling; NR = not reported; ICER = incremental cost-effectiveness ratio; IQR = interquartile range; NHS = National Health Service; PT = physical therapy; QALY = quality-adjusted life-year; RFA = radiofrequency ablation; SAF = standard analytic file; SI = sacroiliac; U.S. = United States.

The 2 comparative cost analyses (by the same author) used similar modeling methods to estimate differences in costs associated with unilateral, minimally invasive fusion versus nonoperative management. These studies differed in the base case considered (primarily age group and probability of nonoperative treatment success). One study involved a commercially insured population with a mean age of 45 years and assumed 50% of the nonoperative care group would experience chronic pain.[69] The second study considered a Medicare population (70 years old, with a life expectancy of 84 years) that was eligible for surgery; authors assumed 75% of the nonoperative group experienced chronic pain.[70] In both studies, the expected success rate of surgery was 82% (based on data from published trials for the iFuse Implant System), and authors estimated direct costs (health care utilization, diagnostic services, and medication) from existing payer (commercial or Medicare) databases.

Two cost-effectiveness analyses reported incremental costs and QALYs gained with surgical treatment with the iFuse Implant System compared to nonoperative care from a payer perspective at 5 years.[71,72] In 1 study,[71] direct health care costs were based on data from the INSITE RCT[23]) and the uncontrolled SIFI trial.[55] In the other study,[72] costs were based on the National Health Service reference cost schedule (United Kingdom). Both analyses measured quality of life with the EQ-5D health utility measure. In both studies, authors modeled outcomes in a population that was 50 years old at the time of surgery but used somewhat different assumptions regarding the surgical response rate.

Lastly, 1 retrospective observational study reported low back pain costs before and after SI joint fusion surgery using data from a large U.S. health insurer between 2010 and 2017.[122] Authors included patients age 18 to 64 with continuous enrollment in the health plan and with claims for the SI joint fusion procedure (N=302 included in the analysis). The mean age of the sample was 49.1, but 71% were 45 years or older; 72% were female.[122] Authors used claims data to determine costs related to low back pain for the year before surgery and for the year after surgery (excluding the quarters immediately before and after surgery).

3.6.2 Findings

Studies reported results over different time horizons and for populations that differed in age, which limits the ability to compare findings across studies.

The comparative cost analysis based on a younger, commercially insured population (mean age of 45) found higher costs (reported in 2012 U.S. dollars) in the surgery group than nonoperative group at 3 years (higher by $14,545) and 5 years post-surgery (higher by $6,137).[69] Subgroup analyses found similar results among those without prior lumbar spinal fusion (***Appendix C, Table C-13***). However, estimated costs were lower in the surgery group than nonoperative care group in the subpopulation with prior lumbar spinal fusion at 3 years (lower by $54,817) and 5 years post-surgery (lower by $100,493).[69] In the comparative cost analysis focused on an older population (70 years old) using Medicare costs, the estimated per-patient lifetime costs (14 years following surgery; also reported in 2012 U.S. dollars) were lower in the surgery group than nonoperative group for the overall population (lower by $3,358). These costs were also lower in the subgroup with prior lumbar fusion (lower by $63,705) and in the subgroup without prior lumbar fusion (lower by $1,033).[70]

The cost-effectiveness analysis using inputs from the INSITE and SIFI trials estimated an incremental cost-effectiveness ratio (ICER) over 5 years of $13,313 per QALY gained (reported in 2015 U.S. dollars) with surgery compared to nonoperative care in a population assumed to be 50 years old.[71] Sensitivity analyses consistently found ICERs less than $45,000 per QALY when a range of input values were varied (e.g., successful response to surgery and nonsurgical treatment, various cost inputs). Authors also found that ICERs were more favorable over longer time horizons (approximately $2,300/QALY gained over 10 years) with breakeven costs achieved at 13 years.[71] The cost-effectiveness analysis based on National Health Service reference costs estimated an ICER over 5 years of $2,697 per QALY/gained (converted to 2015 U.S. dollars) with surgery compared to stepped care (physical therapy and steroid joint infections followed by radiofrequency ablation [RFA] for failures).[72] ICERs for the other 2 nonsurgical

approaches evaluated were $3,075 and $3,138 per QALY gained for stepped care and for RFA only, respectively.[72] In sensitivity analyses, surgery had a more than 90% probability of being cost-effective at a willingness to pay threshold of $25,000 for all 3 nonsurgical management strategies evaluated.

Lastly, the retrospective observational study reported lower mean and median costs associated with low back pain after surgery compared to before surgery; however, this difference was only statistically significant for the median costs.[122] Authors estimated that the break-even point cost savings associated with surgery compared to nonsurgical management (based on a counterfactual estimate) was 7.25 years.[122]

3.7 Contextual Question

In addition to the key research questions, we sought evidence to address a contextual question related to the diagnosis of chronic SI joint pain or disruption (CQ1).

The diagnosis of SI joint pain or disruption is challenging since symptoms may be similar to other causes of low back and hip pain due to overlapping pain referral zones.[4,73] Further no pathognomonic finding (history, exam, or imaging) can definitively point to the SI joint as the source of low back pain. Experts recommend a diagnostic approach that includes history, physical exam, diagnostic joint block, and additional diagnostic tests (e.g., radiography) to rule out other pain contributors.[4,74] Pain in the buttock with radiation to the groin or upper legs is a typical history, and specific physical exam tests that stress the SI joint (listed in *Section 1.2*) can be performed in office settings.[4,73,74] These physical exam tests in combination are predictive of a positive response to intra-articular SI joint block and can indicate the SI joint as a source the low back pain.[4] No specific imaging findings are pathognomonic for the diagnosis of non-inflammatory, nontraumatic SI joint pain; thus, imaging is primarily used to rule out alternative diagnoses for the low back pain.[4,74]

Confirmation of suspected SI joint etiology for low back pain is achieved through temporary pain relief from an intra-articular SI joint block with no more than 2.5 mL of a local anesthetic under imaging guidance to assure intra-articular placement.[4,75,76] However, there is not agreement on the level of pain improvement that constitutes a positive diagnostic injection. Some experts recommend 75% temporary pain relief or more after SI joint injection,[73,75] and others recommend a lower range, such as 50% or greater as some studies have suggested no meaningful correlation between degree of improvement above a certain threshold and outcomes after fusion surgery (see *Section 3.7.1* below) arguing against the use of overly stringent pain relief criteria.[4,74,75,77] Several known limitations associated with SI joint injection as a reference standard for diagnosis is the potential for insufficient anesthesia of the entire joint (which reduces positive target specificity) or extravasation of the injectate outside of the joint (which may serve to anesthetize other structures in close proximity to the SI joint and increase negative target specificity).[77] We identified no placebo controlled trials of SI joint injection to estimate the degree of pain relief associated with a placebo response to the injection.

3.7.1 Data Regarding Accuracy of Clinical Tests For Diagnosis

Numerous studies have evaluated the role of diagnostic blocks as a reference test for confirming the SI joint as the source of low back pain or dysfunction. A 2015 systematic review reported on 39 studies of diagnostic SI join injection, including unblinded uncontrolled studies, blinded saline-controlled studies, and two-step approaches with an initial screening block followed by a confirmatory block a week or two later.[123] These studies used a range of 50% to 90% pain relief to consider a block as confirming the diagnosis. These studies also varied by the volume of injectate, and whether a mixed solution (anesthetic with steroids) was used; both of which could impact target-specificity, a key aspect for evaluating the validity of local blocks. Across these studies, the range of persons with a positive diagnostic block ranged from 10% to 70% (median 39%).[123] Studies requiring a confirmatory block and a higher threshold for pain relief reported a lower prevalence of positive blocks.

Related to the degree of pain relief following SI joint block, there is debate regarding correlation of pain response and potential benefit from surgical intervention with fusion. An analysis using combined data from 2 trials (1 RCT [INSITE[23,27,28]] and 1 uncontrolled trial [SIFI[55,124,125]], total N=320) found no relationship between level of immediate response to SI joint block (average percent decrease in pain after injection from 40% to 100%) and 6- and 12-month pain and disability scores among patients undergoing SI joint fusion.[77] In other words, persons with the highest levels of pain relief following a diagnostic block did not systematically have the highest levels of pain relief or improved function following fusion surgery. Potential reasons for this may include patient characteristics (presence of pain in other areas), procedure characteristics (differences in SI joint block procedure or fusion surgery), and others.[77]

We identified 1 systematic review[78] published in 2009 of diagnostic test accuracy of history and physical exam maneuvers for the diagnosis of SI joint dysfunction. Authors of this review included 18 studies that evaluated 1 or more history or physical exam tests (or combination of tests). Most studies were set in university or hospital spine centers, and many tests were assessed in only 1 study. All compared the index test with contrast-enhanced intraarticular injection with local anesthetics as a reference test. In the studies in this review, reference test administration varied in terms of the volume of injected medications and cut-off used for a positive test (e.g., 5 studies required 80% reduction in pain, some required 50% or 70%, and some did not specify a level).[78] The diagnostic test accuracy for the most widely cited history and physical exam maneuvers are summarized in ***Table 22***. A history of pain in the SI joint region alone had relatively poor accuracy based on 1 study identified by the 2009 systematic review, but asking patients to point to the pain with the finger had improved accuracy.[78] Pooled analyses of studies comparing 3 or more positive provocation tests had improved accuracy (sensitivity of 85% and specificity of 76%) compared to most single provocation tests.

Table 22. Diagnostic accuracy of common sacroiliac joint clinical tests compared to reference test (intraarticular injection)[a]

Clinical Test	Description	Diagnostic OR[b] (95% CI)	Sensitivity (%)[c] (95% CI)	Specificity (%)[d] (95% CI)
Pain in the SI joint region[e]	When asked to locate pain, patient points out the area adjacent to the superior posterior iliac spine	2.75 (0.99 to 7.93)	76 (65 to 85)	47 (35 to 57)

Thigh thrust test (pooled analysis)	A posterior shearing stress is applied to the SI joint through the femur	18.46 (5.82 to 58.53)	91 (79 to 97)	66 (53 to 77)
Compression test (pooled analysis)	A compression force is applied along the SI joint through the anterior aspect of the lateral ilium	3.89 (1.7 to 8.9)	63 (47 to 77)	69 (57 to 80)
Multiple tests (pooled analysis)	3 or more positive provocation tests (specific tests varied across studies)	17.16 (7.6 to 39)	85 (75 to 92)	76 (68 to 84)

Notes: a. Diagnostic test accuracy estimates are from a systematic review and meta-analysis by Szadek et al.[78]
b. General estimation of discrimination that is calculated as (true positive/false negatives) divided by (false positives/true negatives); the diagnostic odds ratio ranges from 1 (no discriminative power) to infinity (perfect test), and increases with increases in sensitivity and specificity; a test with 90% sensitivity and specificity has a diagnostic odds ratio of 81.
c. Proportion of subjects with positive reference test who are positive on the clinical test.
d. Proportion of subjects with negative reference test who are negative on the clinical test.
e. Also known as Fortin finger test.

Abbreviations: CI = confidence interval; OR = odds ratio; SI = sacroiliac.

4. Discussion

4.1 Summary of the Evidence

As depicted in ***Figure 3***, compared to conservative management, minimally invasive SI joint fusion surgery appears to improve pain and physical function (moderate certainty based on RCT outcomes at 6 months and very low certainty based on observational study outcomes between 6 months and 3.5 years). Minimally invasive SI joint fusion also may improve pain compared to conservative management at 1 and 2 years (low certainty of evidence). For physical function, findings from RCTs also appeared to favor surgery at 6 months (moderate certainty of evidence) and 2 years (low certainty of evidence) but were mixed for studies at 1 year (very low certainty of evidence). Quality of life was also probably improved compared to conservative management at 6 months and 1 year in 2 RCTs (moderate to low certainty of evidence). Similarly, opioid use may be improved at 6 months and 1 to 2 years (very low certainty of evidence). For adverse events, findings from RCTs suggest that minimally invasive SI joint fusion surgery increased the number of adverse events compared to conservative management at 6 months (very low certainty of evidence) but could not be determined for longer follow-up periods (very low certainty of evidence). The incidence of revision surgery based on the RCT evidence was likely no higher than 3.8% at 2 years (moderate certainty of evidence). Minimally invasive surgery with iFuse is associated with costs between $2,697 and $13,313 per quality of life-adjusted year gained compared to conservative management (very low certainty of evidence); an amount that most would consider cost-effective. This evidence is most applicable to persons who do not adequately respond to an initial period of nonsurgical management, such as medication, physical therapy, and therapeutic joint injections.

As depicted in ***Figure 4***, no differences were observed between open fusion and conservative management with respect to pain, function, and quality of life. based on very low certainty of evidence from 1 CCS that only measured very long-term outcomes (11 to 32 years). The incidence of adverse events was 10% among open surgery participants and not reported for the

no surgery group (not graded). Revision surgery was performed on 8.4% of the joints in open surgery participants (very low certainty of evidence).

As depicted in ***Figure 5***, minimally invasive SI joint fusion surgery appears to improve pain over 2 years and was associated with a shorter length of hospital stay compared to open fusion, but findings were inconsistent with respect to the impact on physical function. The incidence of adverse events appears similar for open fusion and minimally invasive SI joint fusion, but findings were mixed for the incidence of revision surgery. All findings related to this comparison are based on very low certainty of evidence.

Figure 3. Evidence map: sacroiliac joint fusion with iFuse compared to conservative management

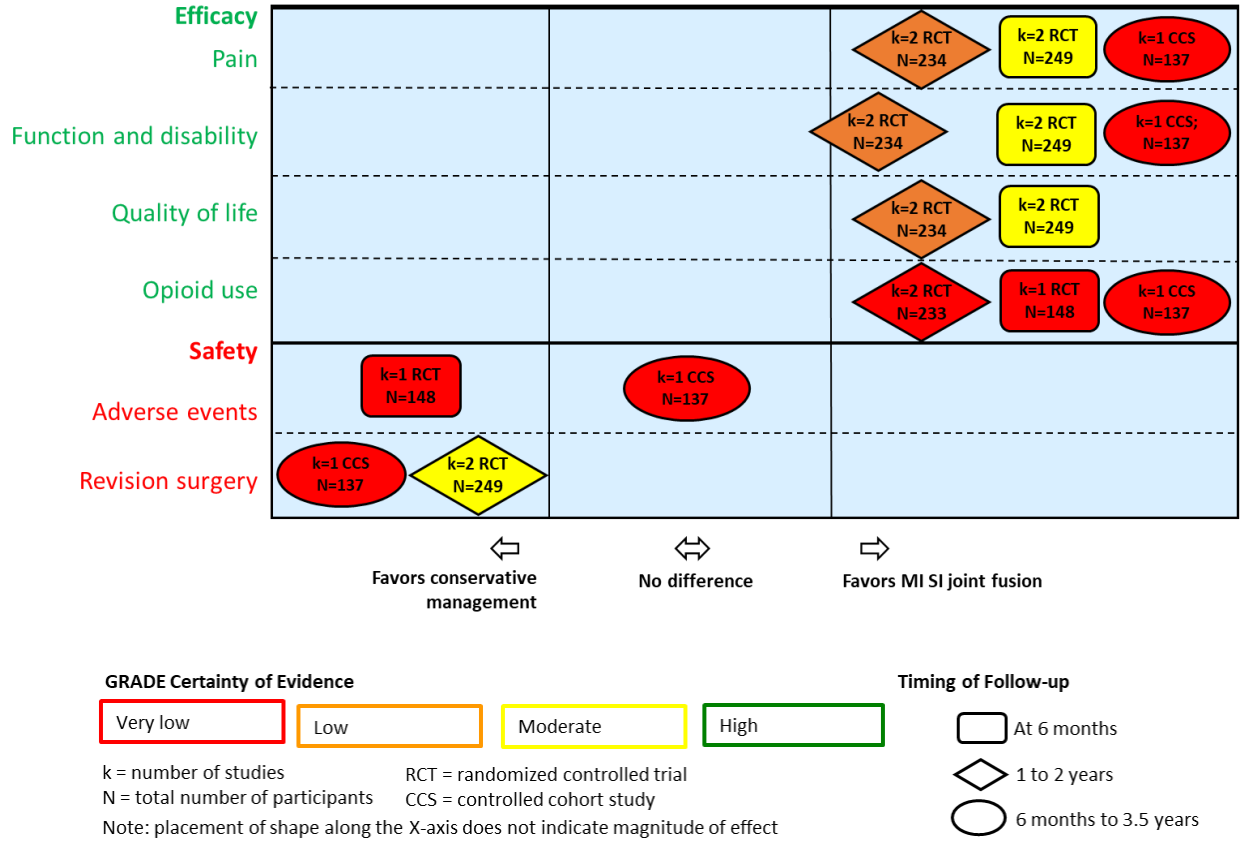


Figure 4. Evidence map: Open sacroiliac joint fusion compared to conservative management

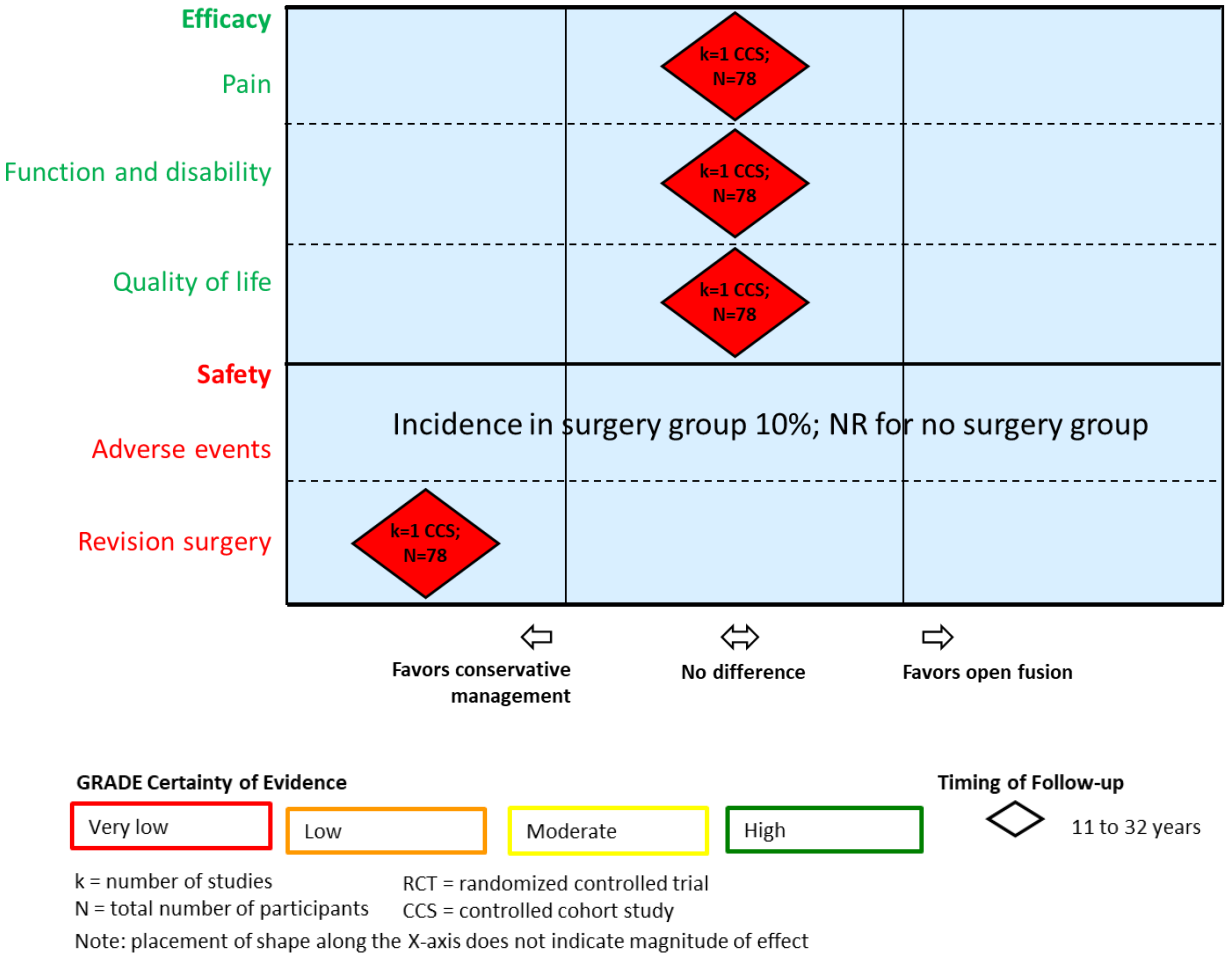
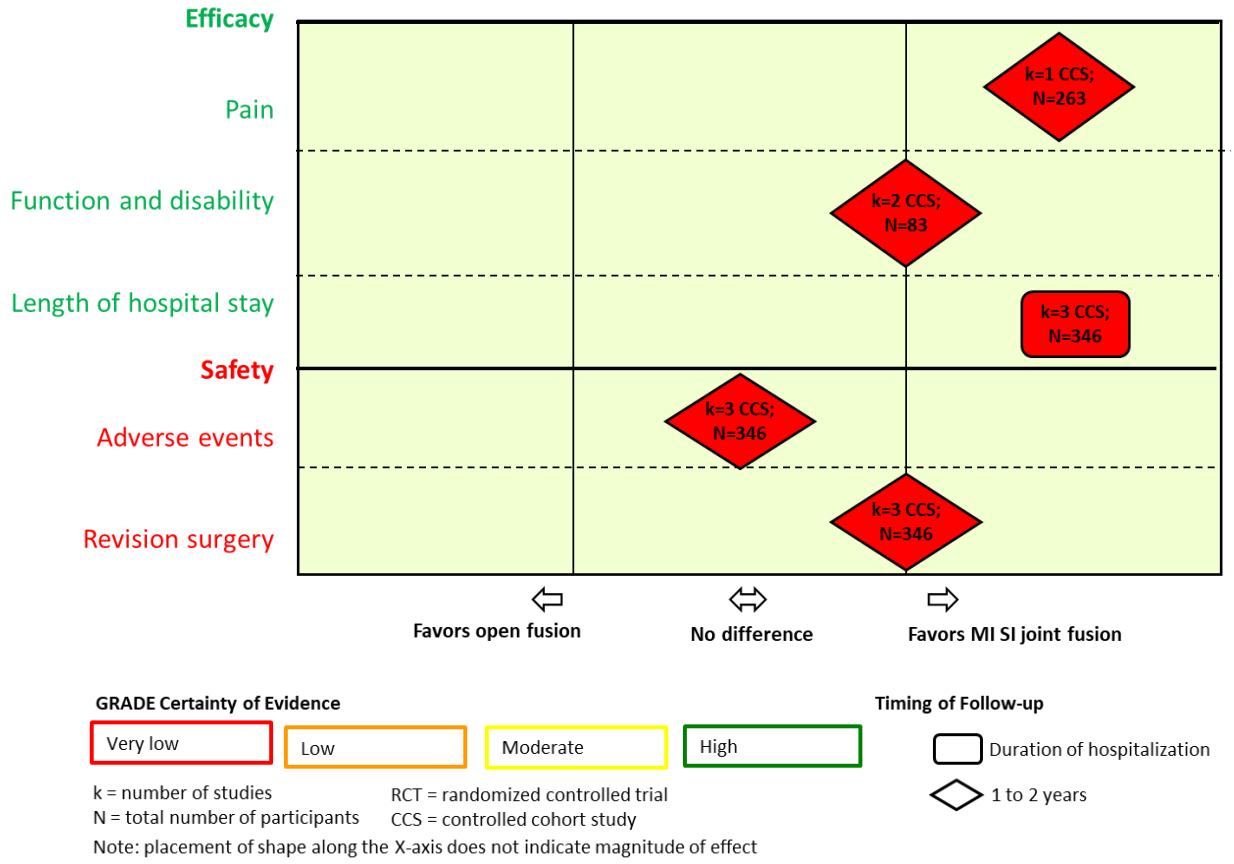


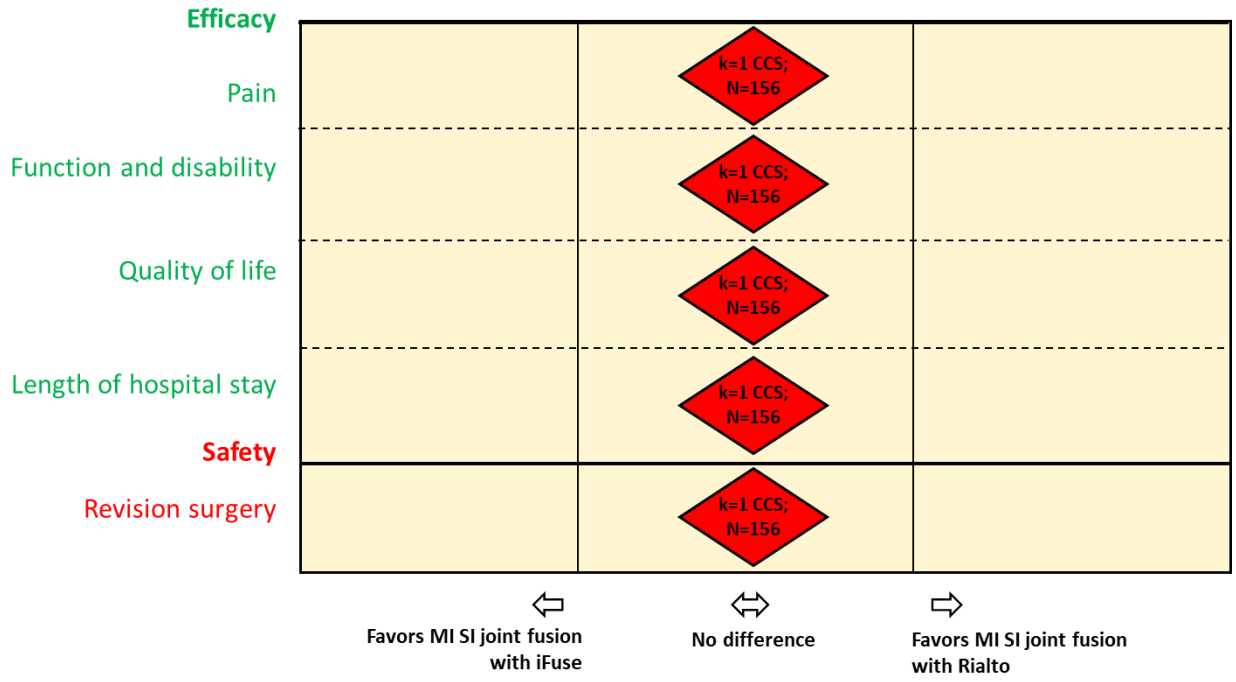
Figure 5. Evidence map: sacroiliac joint fusion surgery with iFuse compared to open fusion



As depicted in ***Figure 6***, no differences were observed between minimally invasive SI joint fusion surgery with the iFuse implant system and the Rialto implant system with respect to pain, function, quality of life, length of stay, and revision surgeries from 6 months to 1 year based on very low certainty of evidence from 1 CCS.

Lastly, compared to minimally invasive fusion with screw fixation, minimally invasive fusion with iFuse appears to result in fewer revisions (very low certainty of evidence; not depicted in a figure).

Figure 6. Evidence map: sacroiliac joint fusion surgery with iFuse compared to Rialto



Abbreviations: CCS = controlled cohort study.

We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events and revision surgery across the 9 uncontrolled studies evaluating open fusion limits our ability to draw definitive conclusions from this body of evidence. Similarly, the incidence of adverse events and revision surgery reported in the uncontrolled studies of minimally invasive surgery (iFuse and other devices) is also very heterogenous, likely reflecting differences in outcome definitions and ascertainment and heterogeneity in the study populations and follow-up times. The incidence of complications from minimally invasive fusion reported from an analysis of insurance claims is higher than the incidence reported in controlled studies and likely reflects the incidence in usual practice, outside of a study setting. The incidence of revision surgery reported using postmarket surveillance database was similar to the incidence reported in trials. Findings from the postmarket surveillance database study also suggest that longer follow-up time is needed to assess revision surgeries.

4.2 Limitations of the Evidence Base

The evidence we identified for inclusion in this HTA has several limitations.

Almost all of the included controlled studies and all the cost-effectiveness studies were sponsored by the manufacturer or authors reported financial ties to the manufacturer (consultancies or employment). Several analyses have documented more favorable outcomes and conclusions in studies with industry sponsorship and competing financial interests relative to

studies without competing interests.[79,126] This finding appears to be independent of study methodological quality (i.e., risk of bias) and design.

Most studies we identified were uncontrolled studies, which prevents a comparative assessment. Twelve studies (3 controlled cohort and 9 uncontrolled studies) evaluated an open approach to fusion; however, the outcomes reported from these studies were limited. Of the 8 controlled studies evaluating minimally invasive fusion, all evaluated the iFuse implant system, which limits generalizability of findings to other minimally invasive procedures; only 2 controlled studies compared iFuse with other minimally invasive procedures.

Many studies included a significant proportion of participants with prior lumbar fusion; however, most studies either did not prespecify subgroup analyses or sample sizes among subgroups were too small to conduct meaningful analyses. Studies that did evaluate this subgroup of participants observed no differences in efficacy based on a history of prior lumbar fusion.

All of the controlled observational studies we included had critical methodological flaws leading us to assess them as high risk of bias; specifically confounding and selection bias because of high attrition or because of only allowing participants with complete follow-up data into the analysis.

The 2 included RCTs had some concerns for bias since they were not blinded. Comparative outcomes reported after 6 months from these trials should be considered high risk of bias because of the extensive degree of crossovers from conservative management to surgery that occurred, despite analytic methods used by study authors to mitigate this issue. Authors attempted to mitigate the bias introduced by crossovers by imputing the last observation prior to crossover carried forward for subjects who crossed over to surgery,[26] or by considering all crossovers as failures in threshold analyses.[27] However, neither method fully mitigates potential biases. Comparisons among those allocated to fusion, those who crossed over to fusion, and those who remained in conservative management are no longer intent-to-treat analyses. Comparisons between participants who were allocated to fusion and those that remained in the conservative management group (i.e., excluding crossover participants) may underestimate the true difference because of confounding since participants who did not cross over had less severe symptoms. Considering all crossovers as failures or carrying the last observation forward may also bias the true difference; but the direction of this bias is uncertain and depends on the assumption that symptoms will not improve or deteriorate over time with conservative management, which may or may not be a valid assumption.

Last, small sample sizes and heterogeneity in the reporting of adverse events and incidence of revision surgery in the controlled studies limit the comparability of these outcomes across this body of evidence and drawing definitive conclusions. Further, inconsistencies in adverse events and revision surgery reported by the 2 RCTs across the various publications associated with these trials limits our certainty about these findings. We contacted study authors but did not receive any clarification by the time this report was finalized.

4.3 Clinical Practice Guideline Synthesis

We synthesized clinical practice guidelines (CPGs) to review the guidance that different organizations have provided on the provision of minimally invasive SI joint fusion for chronic SI joint pain. We searched for relevant CPGs and appraised each guideline using the Appraisal of Guidelines for Research & Evaluation II (AGREE) instrument.[80,81] With this instrument, 6 domains are assessed, and an overall score of between 1 (lowest quality) and 7 (highest quality) is assigned to reflect the overall quality of the guideline.

We identified several CPGs related to SI joint fusion. One developed by MCG Health (Milliman Care Guidelines) is proprietary and not publicly accessible and is not discussed further.[127] ***Table 23*** summarizes the publicly available guidelines related to this procedure, which includes 1 guidelines (1 general guideline for minimally invasive SI joint fusion and 1 iFuse-specific guideline) from the National Institute for Health and Care Excellence (United Kingdom), 1 from the North American Spine Society (NASS), one from AIM Specialty Health, 1 from eviCore, and 1 from the International Society for the Advancement of Spine Surgery (ISASS). We also identified a coverage policy recommendation from the NASS; however, this policy is only available by subscription, so we cannot assess whether it was a CPG.[128]

Table 23. Clinical practice guidelines related to sacroiliac joint fusion

Title/Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment
Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion [84] Quality rating: 3 out of 7 AIM Specialty Health	2020	Percutaneous/minimally invasive SI joint fusion with iFuse system may be considered medically necessary when all of the following criteria are met: • Persistent pain more than 6 months that interferes with function and has documented VAS of 50 mm or greater and ODI of 30 or greater • Failure of 6 months of conservative management • Confirmation of pain (typical pattern, positive Fortin test, absence of tenderness of similar severity elsewhere in the pelvic region, at least 3 positive provocative physical exam tests, and other causes excluded) • Imaging indicates evidence of injury/degeneration and excludes other sources • At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions	Not reported
Clinical Guidelines Spine Surgery [85] Quality rating: 3 out of 7 eviCore	2020	Minimally invasive SI joint fusion using titanium triangular implants (SI BONE [iFuse Implant]) for the treatment of lumbopelvic pain originating from the SI joint is considered medically necessary when all of the following are met:	Not reported

Title/Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment
		• Performed by an orthopedic surgeon or neurosurgeon with specific training in percutaneous sacroiliac joint fusion surgical techniques • Presence of nonradiating lumbopelvic pain caudal to L5, buttock, hip, and/or groin pain without radiation into the leg(s) that impairs physical activities • SI joint pain interfering with activities of daily living • Confirmation of pain (typical pattern, positive Fortin test, absence of tenderness of similar severity elsewhere in the pelvic region, at least 3 positive provocative physical exam tests, and other causes excluded) • At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions • Failure of 6 months of conservative management • Documentation of nicotine-free status • Absence of unmanaged significant behavioral health disorders • Imaging indicates evidence of injury/degeneration and excludes other sources	
International Society for the Advancement of Spine Surgery Policy 2020 Update—Minimally Invasive Surgical Sacroiliac Joint Fusion (for Chronic Sacroiliac Joint Pain): Coverage Indications, Limitations, and Medical Necessity[4] Quality rating: 4 out of 7 International Society for the Advancement of Spine Surgery	2020	Lateral transiliac minimally invasive surgical SI joint fusion may be considered medically necessary when all of the following criteria are met: • Persistent pain more than 6 months that does not respond to an appropriate course of nonsurgical treatment • Significant SI joint pain that affects quality of life or limits activities of daily living • Confirmation of pain (at least 3 positive provocative physical exam tests and confirmed with a diagnostic SI joint block [≥50% pain reduction following fluoroscopically guided diagnostic intra-articular SI joint block]) • Imaging indicates evidence of injury/degeneration and excludes other sources Minimally invasive surgical posterior (dorsal) SI joint fusion is not recommended because the procedure is, as of yet, unproven. There is limited published clinical evidence supporting the safety and	Lateral minimally invasive surgical SI joint fusion is based on 2 RCTs, 5 multicenter prospective studies, and several comparative retrospective case series. Quality of evidence assessment not performed. Posterior (dorsal) minimally invasive surgical SI joint fusion is based on 1 multicenter prospective study and a small number of case series. Quality of evidence assessment not performed.

Title/Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment
		effectiveness of posterior (dorsal) minimally invasive surgical SI joint fusion.	
Diagnosis and Treatment of Low Back Pain[86] North American Spine Society (NASS) Quality rating: 4 out of 7	2020	The systematic review yielded no studies to address the question regarding SI joint fusion compared to medical intervention for patients with SI joint dysfunction and no prior lumbar surgery and no lower limb pain. Therefore, a definitive statement favoring SI fusion over medical/interventional treatment in patients suffering with low back pain from an SI source cannot be made.	The systematic review of the literature yielded no studies with patients with no prior lumbar surgery and no lower limb pain to adequately address these questions.
iFuse for treating chronic sacroiliac joint pain[83] National Institute for Health and Care Excellence (United Kingdom) Quality rating: 4 out of 7	2018	"The case for adopting the iFuse implant system to treat chronic sacroiliac joint pain is supported by the evidence. Using iFuse leads to improved pain relief, better quality of life and less disability compared with non-surgical management. iFuse should be considered for use in people with a confirmed diagnosis of chronic sacroiliac joint pain (based on clinical assessment and a positive response to a diagnostic injection of local anesthetic in the sacroiliac joint) and whose pain is inadequately controlled by non-surgical management."	Based on 2 RCTs (n=251), 2 comparative studies, and 8 noncomparative studies. Quality of evidence assessment not performed.
Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578[82] National Institute for Health and Care Excellence (United Kingdom) Quality rating: 4 out of 7	2017	"Current evidence on safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption. This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and NICE expertise in minimally invasive SI joint fusion surgery for chronic SI pain."	Based on 2 RCTs, 2 SRs, 3 prospective cohort studies, and 2 retrospective case series. Quality of evidence assessment not performed.

Abbreviations: AIM = acronym not defined; NICE = National Institute for Health and Care Excellence; mm = millimeters; ODI = Oswestry Disability Index; RCT = randomized clinical trial; SI = sacroiliac; SR = systematic review; VAS = visual analog scale.

4.4 Selected Payer Coverage Policies

An overview of selected payer coverage policies for SI joint fusion related to degenerative sacroiliitis and SI joint disruption is provided in ***Table 24***. Details for these coverage policies are provided in ***Table 25***.

Table 24. Overview of payer coverage policies for sacroiliac joint fusion for degenerative sacroiliitis, sacroiliac joint dysfunction, or sacroiliac joint pain

Medicare NCD	Medicaid	Aetna	Cigna	Humana	Kaiser Permanente	Noridian Healthcare Solutions (MAC)	Premera Blue Cross	Regence Blue Shield	Tri-care	UnitedHealth Care (Medicare Advantage)	UnitedHealth Care (Commercial)
—[a]	Covered in 44 states	✓[b]	✓[b]	✓[b]	✕	✓	✓[c]	✓[c]	✓	✓[b]	✓[d]

Notes: ✓ = covered; ✕ = not covered; — = no policy identified.
a. No national coverage determination identified but all 8 MACs consider coverage, at least on a case-by-case basis.
b. Covered when clinical criteria are met.
c. Covered when clinical criteria are met and only covered for minimally invasive fusion with triangular, titanium-coated implants (i.e., iFuse).
d. Does not manage a UnitedHealth policy specific to this procedure but has adopted MCG clinical coverage criteria for this procedure.

Abbreviations: MAC = Medicare Administrative Contractor; MCG = Medicare Milliman Clinical Guidelines; NCD = national coverage determination.

Table 25. Payer coverage policies for sacroiliac joint fusion procedures for any indication

Payer; Date	Policy
Aetna[129] September 22, 2020	SI joint fusion (e.g., iFuse) is considered medically necessary for sacroiliac joint syndrome interfering with activities of daily living when all of the following criteria are met: • Adults 18 years of age or older with SI joint pain for greater than 6 months • Diagnosis of the SI joint as the primary pain generator • Baseline lower back pain score of at least 5 on 0 to 10 points NRS • Member should have tried 6 months of adequate forms of conservative treatment with little or no response, including pharmacotherapy (e.g., NSAIDS), activity modification, and active therapy (including 3 or more months of physical therapy)
Cigna[130] January 15, 2021	SI joint fusion is not covered for ANY other indication, including the following, because it is considered experimental, investigational or unproven: 1. Mechanical low back pain 2. SI joint syndrome 3. Degenerative SI joint 4. Radicular pain syndromes Percutaneous SI joint fusion, using an FDA-approved implant, placed across the SI joint and intended to promote bone fusion, is considered medically necessary for the treatment of low back/buttock pain resulting from degenerative sacroiliitis or sacroiliac joint disruption when ALL of the following criteria are met: 1. Presence of nonradiating, unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain and that impairs physical activities 2. Statement from a licensed behavioral and/or medical health care provider attesting to the absence of EACH of the following a. Untreated, underlying mental health conditions/issues (e.g., depression, drug, alcohol abuse) as a major contributor to chronic back pain, generalized pain behavior (e.g., somatoform disorder), generalized pain disorder (e.g., fibromyalgia) 3. The individual is a nonsmoker 4. Presence of localized tenderness with palpation of the posterior sacroiliac joint in the absence of tenderness of similar severity elsewhere and no other obvious sources for their pain exists 5. Positive response to the thigh thrust test or compression test 6. Positive response to at least 2 of the following additional provocative tests: Gaenslen's maneuver, distraction test, and Patrick's sign 7. Failure of 6 consecutive months of physician-supervised conservative management 8. Diagnostic imaging studies confirm ALL of the following: imaging of the SI joint excludes the presence of destructive lesions or inflammatory arthropathy, imaging of the ipsilateral hip (plain radiographs) excludes the presence of osteoarthritis, imaging of the lumbar spine (CT or MRI) excludes neural compression or other degenerative conditions that can be causing low back or buttock pain 9. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced sacroiliac joint injection on 2 separate occasions, at least 2 months apart

Payer; Date	Policy
Humana[131] December 10, 2020	SI joint fusion through percutaneous minimally invasive approach (i.e., iFuse Implant System) is considered medically necessary when ALL of the following criteria are met: 1. Absence of contraindications listed in the policy's Coverage Limitations section 2. Chronic low back pain due to sacroiliac joint dysfunction 3. Failure of 6 consecutive months of conservative treatment within the past year 4. Imagining studies exclude the presence of other causes for SI joint dysfunction/pain including but not limited to: a. Acute fracture, concomitant hip osteoarthritis, destructive SI joint lesions (infection, tumors), inflammatory arthropathy, lumbar spine degenerative conditions or neural compression 5. Positive response (reproduction of individual's typical SI joint pain) to at least 3 of the following provocative tests/maneuvers including compression test, distraction test, FABER test, Gaenslen's maneuver, and/or thigh thrust test 6. Positive response to 2 diagnostic, image-guided SI joint injections, at intervals of no sooner than 2 weeks (a positive response is defined as at least a 50% reduction in pain and/or symptoms) SI joint fusion through percutaneous minimally invasive approach via the following devices is not covered because they are considered experimental/investigational: 1. Firebird SI Fusion System, Genesys Sacroiliac Joint Fusion System, LinQ, Rialto SI Fusion System, Sacrofuse SIJFuse, SI-DESIS, Siconus SI Joint Fixation System, SIFix, SIJoin, Silex Sacroiliac Joint System, SImmetry Sacroiliac Joint Fusion System SI joint fusion performed by an open surgical approach is not covered for ANY other indication including the following because they are considered not medically necessary: 1. Low back pain 2. Sacroiliac joint dysfunction/syndrome
Kaiser Permanente (Washington)[132] May 21, 2020	Open SI joint fusion is medically necessary when ALL of the following are met: 1. Appropriate imaging studies demonstrate localized SI joint pathology 2. The individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks before the planned surgery 3. And ONE of the following: a. Post-traumatic injury of the SI joint (e.g., following pelvic ring fracture) b. As an adjunctive treatment for SI joint infection or sepsis c. Management of sacral tumor (e.g., partial sacrectomy) d. When performed as part of multisegmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis) B. Open SI joint fusion is not covered for ANY other indication, including the following, because it is considered experimental, investigational or unproven: 1. Mechanical low back pain 2. SI joint syndrome 3. Degenerative SI joint 4. Radicular pain syndromes

Payer; Date	Policy
	C. Percutaneous or minimally invasive SI joint stabilization (e.g., iFuse Implant System, SImmetry SI Joint Fusion System) for SI joint fusion (CPT codes 0334T, 27279) are not covered for ANY indication because there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Noridian HealthCare Solutions	Covered, but specific details not available.
Premera (Blue Cross)[133] February 1, 2021	Premera may consider minimally invasive fixation/fusion of the SI joint using a titanium triangular implant (e.g., iFuse) when ALL of the following criteria are met: 1. Pain is at least 5 on a 0 to 10 rating scale that affects quality of life or limits activities of daily living 2. There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia) 3. Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program 4. Pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain 5. A thorough physical examination demonstrates localized tenderness with palpation over the sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere 6. There is a positive response to a cluster of 3 provocative tests including thigh thrust test, compression test, Gaenslen's maneuver, distraction test, Patrick test, and/or posterior provocation test 7. Diagnostic imaging studies include ALL of the following: a. Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; and imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; and imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; and imaging of the sacroiliac joint indicates evidence of injury and/or degeneration 8. There is at least a 75% reduction in pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection on 2 separate occasions 9. A trial of a therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed at least once
N's Regence (Blue Shield)[134] October 1, 2020	Regence may consider open SI joint fusion procedures medically necessary when 1 of the following criteria is met: 1. As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum; or 2. As an adjunct to the medical treatment of sacroiliac joint infection (e.g., osteomyelitis, pyogenic sacroiliitis)/sepsis; or 3. As a treatment for severe traumatic injuries associated with pelvic ring fracture Open SI joint fusion for any other indication not listed above is not considered medically necessary. Minimally invasive fusion/stabilization of the SI joint using an FDA-approved titanium triangular implant may be considered medical necessary when ALL of the following criteria have been met: 4. Clinical documentation that pain limits activities of daily living (ADLs). ADLs are defined as feeding, bathing, dressing, grooming, meal preparation, household chores, and occupational risks that are required for daily functioning; and 5. Patients have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SI joint, and hip including a home exercise program; and

Payer; Date	Policy
	6. There is at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intraarticular SI joint injection on 2 separate occasions; and 7. A trial of a therapeutic SI joint injection (i.e., corticosteroid injection) has been performed on at least 1 occasion; and 8. A thorough physical examination demonstrates findings consistent with sacroiliac joint disease including a positive response to a cluster of 3 provocative tests (e.g., thigh thrust test, compression test, Gaenslen's maneuver, distraction test, Patrick's sign, posterior provocation test); and 9. Diagnostic imaging studies include ALL of the following: Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; and imaging of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint and rules out concomitant hip pathology; and advanced imaging of the lumbar spine (CT or MRI) is performed to rule out neural compression or other degenerative conditions that can be causing low back or buttock pain and excludes the presence of destructive lesions or inflammatory arthropathy of the sacroiliac joint Fusion/stabilization of the SI joint for the treatment of back pain presumed to originate from the SI joint is considered investigational under all other conditions
Tricare[135] August 23, 2016	Minimally invasive surgery (CPT procedure code 27279) for treatment of sacroiliac joint pain is proven.
UnitedHealthcare Medicare Advantage[136] October 14, 2020	Percutaneous minimally invasive SI joint fusion/stabilization is indicated for the treatment of SI joint pain in patients who meet all of the following criteria: 1. Have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, and active physical therapy; AND 2. Patient's report of nonradiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SI joint, and consistent with SI joint pain; AND 3. Localized tenderness with palpation of the posterior SI joint in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx) and other obvious sources for their pain do not exist; AND 4. Positive response to the thigh thrust test OR compression test AND 2 of the following additional provocative tests: Gaenslen's maneuver, distraction test, and Patrick's sign; AND 5. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); AND 6. Diagnostic imaging studies that include ALL of the following: a. Imaging (plain radiographs and a CT or MRI) of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous SI joint fusion; b. Imaging of the pelvis (AP plain radiographs) to rule out concomitant hip pathology; c. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; AND 7. At least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced SI joint injection on 2 separate occasions.

Payer; Date	Policy
UnitedHealthcare Commercial[137] July 1, 2018	No policies specific to the coverage of surgeries for SI joint fusion identified, however, the CPT code for minimally invasive SI joint fusion (27279) is among the CPTs codes that requires preauthorization. Additional information obtained from payor indicates that they have adopted MCG clinical coverage criteria, which include: 1. Significant SI joint pain (at least 5 on a scale of 0 to 10) and/or significant activity limitations 2. Unilateral pain localized over SI joint 3. SI joint pain confirmed by 3 or more provocative physical exam maneuvers 4. Diagnostic SI joint injection with at least 75% pain relief 5. Failure to respond to at least 6 months of alternative treatments consisting of analgesics and 1 or more of the following: a. Physical therapy b. SI joint steroid injection c. Radiofrequency rhizotomy 6. Alternative or contributing diagnoses absent (e.g., hip osteoarthritis, L5-S1 spine degeneration, tumor, infection, fracture)

Abbreviations: ADL = activity of daily living; A*P*=anteroposterior; CPT = Current Procedural Terminology; CT = computed tomography; FDA = Food and Drug Administration; L5-S1 = lumbosacral joint; MCG = Milliman Care Guidelines; MRI = magnetic resonance imaging; NSAID = nonsteroidal anti-inflammatory; SI = sacroiliac.

The Centers for Medicare & Medicaid Services does not have a national coverage determination for SI joint fusion procedures. However, as of 2016, all 8 Medicare Administrative Contractors (MACs) cover the minimally invasive SI joint fusion procedure (Current Procedural Terminology code 27279).[138] At least 3 MACs have active local coverage determinations that specify clinical criteria for coverage.[87] According to information supplied to the state's HTA Program by the manufacturer of iFuse, 44 state Medicaid programs covered iFuse as of May 2018.

All commercial payers reviewed in this HTA update, except Kaiser Permanente of Washington, cover minimally invasive fusion when certain clinical criteria are met. Numerous Blue Cross Blue Shield Association payers from other states cover this procedure when clinical criteria are met, according to information provided by the manufacturer of iFuse. The Blue Cross Blue Shield Association Federal Employee Blue Focus plan covers this procedure but requires prior approval. Tricare also covers this procedure.

4.5 Limitations of This HTA

This HTA has several limitations related to the scoping and the processes we used to conduct the HTA. We limited the scope to English-language publications and we only searched 3 databases. We did not seek unpublished data and did not use data presented only in conference abstracts. We did not consider efficacy outcomes from uncontrolled studies and did not use GRADE to evaluate the body of evidence consisting of uncontrolled studies. We also did not use data from the FDA MAUDE database to assess safety because passive surveillance systems include incomplete, inaccurate, untimely, and unverified data.[16] Finally, the AGREE guideline appraisal instrument largely focuses on evaluating the processes through which a guideline is developed; it does not assess how well the evidence included in the guideline was evaluated and if it was interpreted correctly, or whether the conclusions of the guideline are consistent with the evidence. Thus, some guidelines may score artificially high and this explains why conclusions may differ between guidelines despite having nearly similar quality scores.

4.6 Ongoing Research and Future Research Needs

Four studies of minimally invasive SI joint fusion are ongoing; these studies are summarized in ***Table 26***. One includes an RCT comparing iFuse to a sham surgery control; this study is currently recruiting with an estimated completion date of August 2023.

Future comparative effectiveness research that assesses long-term (greater than 1 year) efficacy and safety outcomes is needed to confirm the durability of outcomes from shorter-term studies. As an emerging field, high quality clinical trials are needed to assess the efficacy and safety of the many SI joint fusion procedures currently marketed in the United States. Further, comparative effectiveness research is needed to assess the relative efficacy and safety of alternative minimally invasive SI joint fusion procedures. Continued standardization of diagnostic criteria and of reporting for outcomes and adverse events in future studies will also help to ensure comparability of findings across studies. Last, research to better understand the relationship between SI joint pain and dysfunction and other spinal disorders will help further elucidate cause and effect mechanisms.

Table 26. Summary of ongoing sacroiliac joint fusion studies

Registration Number	Sponsor	Description	Number of Participants	Status	Estimated Completion Date
NCT01861899	Globus Medical, Inc.	Uncontrolled trial of SI-LOK joint fixation system to treat SI joint dysfunction. Primary outcome: radiographic fusion Secondary outcomes: operative time, blood loss, transfusion, hospitalization time Other outcomes: pain (VAS), disability (ODI)	55	Completed, no results posted	8/2018
NCT02074761	Zyga Technology, Inc.	Prospective, nonrandomized postmarket study to collect data on SI joint fusion and patient back pain following implant of the SImmetry device. Primary outcomes: radiographic fusion, pain (VAS) at 6 mos. Secondary outcomes: pain (VAS) at 12 mos., disability (ODI), QoL	250	Active, not recruiting	11/2020
NCT04423120	Evolve Restorative Center	Prospective, multisite, single-arm study intended to collect clinical outcomes data associated with the treatment of sacroiliac disease with the LinQ fusion procedure. Primary outcomes: pain (VAS) at 6 mos., absence of device related SAE, absence of neurological worsening related to the lumbosacral nerve roots, absence of surgical reintervention for SI joint pain Secondary outcomes: pain (VAS) at 12 mos., disability (ODI), pain intensity (PROMIS-29), PGIC, morphine milligram equivalent	100	Enrolling by invitation	3/2022
NCT03507049	Oslo University Hospital	Prospective, double-blind randomized controlled multicenter study examining treatment of sacroiliac pain using SI Bone iFuse versus sham operation. Primary outcomes: NRS operated side at 6 mos. Secondary outcomes: Baseline NRS, Global NRS, NRS on non-operated side, NRS leg pain, ODI, pelvic girdle questionnaire, QoL (EQ-5D), device breakage.	60	Recruiting	4/2023

Abbreviations: EQ-5D = EuroQOL measure of generic health status; mo(s). = month(s); NRS = Numeric Rating Scale; ODI = Oswestry Disability Index; PGIC = Patient Global Impression of Change; QoL = quality of life; SAE = serious adverse event; SI = sacroiliac; U.S. = United States; VAS = visual analog scale.

5. Conclusion

Among patients meeting diagnostic criteria for SI joint pain or dysfunction and who have not responded adequately to conservative management, minimally invasive SI joint fusion surgery is probably more effective than conservative management for reducing pain, improving function, improving quality of life at 6 months follow-up and at 1 to 2 years of follow-up, and is likely cost-effective though the certainty of this evidence varies from very low to moderate and varies by different follow-up timepoints. This evidence also suggests that adverse events up to 6 months are higher from minimally invasive SI joint surgery than conservative management, though the certainty of this evidence is very low. Minimally invasive SI joint fusion surgery may be more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay, but the certainty of this evidence is very low. Based on evidence from uncontrolled studies, serious adverse events from minimally invasive SI joint surgery may be

higher in usual practice compared to what is reported in RCTs. The incidence of revision surgery is likely no higher than 3.8% at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or across different minimally invasive devices and procedures.

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Appendix A. State of Washington Health Care Authority Utilization Data

The State of Washington Health Care Authority provided this data and analysis for inclusion in this Health Technology Assessment (HTA).

Population
Data represent claims for procedures and services associated with a sacroiliac (SI) joint fusion between January 1, 2017 and December 31, 2020. Claims data from the following Washington State programs were assessed: Public Employees Benefit Board Uniform Medical Plan (PEBB/UMP), Apple Health managed care (MC) and fee-for-service (FFS), and the Department of Labor and Industries (L&I) Workers' Compensation Plan.

The assessment includes final paid and adjudicated claims; denied claims were excluded. Individuals that were dually eligible for both Medicare and Medicaid were excluded from the Medicaid program analysis. The PEBB/UMP experience focuses on claims for services provided to non-Medicare UMP enrollees.

Timeframe
Data are reported annually according to the state fiscal year.

Procedures related to SI joint fusion utilization
The assessment focuses on procedures and services related to SI joint fusion (e.g., implantation, removal, revision, monitoring) with a date of service between January 1, 2017 and December 31, 2020.

Individuals that had a qualifying procedure/service according to current procedural terminology (CPT) code during the period were extracted for analysis.

Code	Description
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed

SI joint fusion procedures with specific diagnosis codes (e.g., for acute fracture or cancer) were excluded based on the study selection criteria from the key questions. Procedures with the following diagnosis codes were excluded: C41.4, M47.26, M48.062, M48.37, M51.16, M54.16, M54.17, S32.009K, S32.10XA, S32.131A, S32.810A, S32.811A, S32.9XXA, S33.2XXA, S33.6XXA, S72.102A, S72.141A, S72.142A, and S82.141B.

Payments for procedures related to SI joint fusion
Payments include procedures related to implantation, revision, removal, analysis and medical devices in the inpatient and outpatient settings. Payments do not include physician services for assessment and maintenance that are not identifiably specific to the treatment. Paid amounts are summed for the procedure or service by year and for the 4-year measurement period.

The following tables provide utilization counts, age, and cost by CPT code for SI joint fusion (***Tables A-1, A-2,*** and ***A-3***).

Table A-27. Utilization of SI joint fusion and related procedures and services, by state health program (2017-2020)

Medicaid	2017	2018	2019	2020	Total (unique)
Fee for service (FFS)					
Individuals with at least one SI joint fusion-related procedure	0	0	0	0	**0**
Managed care (MC)					
Individuals with at least one SI joint fusion	NR	NR	13	NR	**33**
Number of encounters with SI joint fusion	NR	NR	29	31	**80**
Average encounters with SI joint fusion	NR	NR	2.2	NR	**2.4**
Amount paid (estimated), SI joint fusion	$692	$3,287	$20,121	$31,270	**$55,368**
Individuals with paid amounts >$0	NR	NR	NR	NR	**22**
Encounters with paid amounts >$0	NR	NR	20	29	**56**
Average payments per individual, paid amounts >$0	NR	NR	NR	NR	**$2,517**
Average payments per encounter, paid amounts >$0	NR	NR	$1,006	$1,078	**$989**
Median payments per encounter, paid amounts >$0	$692	$715	$622	$510	**$573**
Amount paid (estimated), SI joint fusion-related procedures	$32,956	$4,972	$59,720	$76,240	**$173,887**
Public Employees Benefit Board Uniform Medical Plan (PEBB/UMP)					
Individuals with at least one SI joint fusion-related procedure/service	14	14	15	13	**54**
Number of encounters with SI joint fusion	34	40	46	29	**149**
Average encounters with SI joint fusion	2.4	2.9	3.1	2.2	**2.8**
Amount paid, SI joint fusion	$41,889	$58,922	$155,254	$116,666	**$372,731**
Individuals with paid amounts >$0	13	14	14	13	**52**
Encounters with paid amounts >$0	29	38	42	29	**138**
Average payments per individual, paid amounts >$0	$3,222	$4,209	$11,090	$8,974	**$7,168**
Average payments per encounter, paid amounts >$0	$1,445	$1,551	$3,697	$4,023	**$2,701**
Median payments per encounter, paid amounts >$0	$138	$143	$249	$194	**$176**
Amount paid, SI joint fusion-related procedures	$171,162	$91,371	$261,671	$187,623	**$711,827**
Washington State Department of Labor and Industries (L&I)					
Individuals with at least one SI joint fusion-related procedure/service	NR	NR	NR	NR	**25**
Number of encounters with SI joint fusion	18	15	23	20	**76**
Average encounters with SI joint fusion	NR	NR	NR	NR	**3.0**
Amount paid, SI joint fusion	$77,262	$97,595	$133,780	$129,498	**$438,135**
Individuals with paid amounts >$0	NR	NR	NR	NR	**25**
Encounters with paid amounts >$0	16	14	20	19	**69**
Average payments per individual, paid amounts >$0	NR	NR	NR	NR	**$17,525**
Average payments per encounter, paid amounts >$0	$4,829	$6,971	$6,689	$6,816	**$6,350**
Median payments per encounter, paid amounts >$0	$1,234	$1,246	$1,312	$1,312	**$1,312**
Amount paid, SI joint fusion-related procedures	$86,806	$99,931	$156,157	$303,913	**$646,807**
Washington State – Combined Medicaid, PEBB/UMP, L&I					
Individuals with at least one SI joint fusion-related procedure/service	24	27	36	31	**112**
Number of encounters with SI joint fusion	57	70	98	80	**305**
Amount paid, SI joint fusion	$119,843	$159,804	$309,155	$277,434	**$866,234**
Amount paid, SI joint fusion-related procedures	$290,924	$196,274	$477,548	$567,776	**$1,532,521**

Abbreviations: - = no individuals were identified; L&I = Department of Labor and Industries; NR = not reported; PEBB/UMP = Public Employees Benefit Board Uniform Medical Plan; SI = sacroiliac

Data notes: Annual enrollment for Medicaid excludes members that are dually eligible for Medicaid and Medicare. NR = not reported; small numbers suppressed to protect patient privacy. Encounter defined as a date of service associated with at least one SI joint fusion procedure or service. Amount paid reflects all claims submitted with the procedure code for the service dates

(typically 1-2 days), and includes professional, facility and ancillary claims (such as durable medical equipment). Managed care amount paid reflects an estimate of the amount paid for the procedure. Individuals who had a procedure in more than one year are only counted once in the "Total" summary.

Table A-2. Demographics of Medicaid beneficiaries with at least one SI joint fusion-related procedure, SFY 2017-2020

Age	Total (count)
Less than 20 years	-
21-44 years	13
45 years and above	20
Total	**33**

Abbreviations: - = no individuals were identified; SFY = state fiscal year; SI = sacroiliac.

Table A-3. Cost by CPT code (maximum allowable), by state health program and setting

Code	Description	Medicaid FFS		L&I	
		Non-facility	Facility	Non-facility	Facility
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device	$510	$647	$1,650	$1,650
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed	$786	Not covered	$2,546	$2,546

Abbreviations: CPT = current procedural terminology; FFS = fee-for-service; L&I = Department of Labor and Industries
Data notes: Medicaid FFS from Fee Schedule (accessed April 21, 2021; available at https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-and-billing/provider-billing-guides-and-fee-schedules#P). L&I from provider fee schedule (accessed April 21, 2021; available at https://lni.wa.gov/patient-care/billing-payments/fee-schedules-and-payment-policies/). PEBB/UMP fees are confidential and not publicly available (proprietary).

Appendix B. Search Strategy

PubMed searched from 1/1/2018 to 1/31/2021

#1 ((Sacroiliac Joint/surgery[MeSH Terms] OR Sacroiliac Joint/therapy[MeSH Terms] OR (sacroiliac joint[Title/Abstract] AND fusion[Title/Abstract]) OR (sacroiliac joint[Title/Abstract] AND arthrodesis[Title/Abstract]) OR iFuse[Title/Abstract] OR SImmetry[Title/Abstract] OR SILOK[Title/Abstract] OR Siconus[Title/Abstract] OR Prolix[Title/Abstract] OR Silex[Title/Abstract] OR TriCor[Title/Abstract] OR M.U.S.T.[Title/Abstract] OR SIFix[Title/Abstract] OR SI-Fix[Title/Abstract] OR INTER FIX[Title/Abstract] OR Rialto[Title/Abstract] OR PathLoc [Title/Abstract] OR SIJFuse[Title/Abstract] OR Entasis[Title/Abstract] OR SiCure[Title/Abstract] OR Re-Live[Title/Abstract] OR SacroFuse[Title/Abstract] OR SImpact[Title/Abstract] OR Tri-Fin[Title/Abstract] OR SambaScrew[Title/Abstract] OR TransFasten[Title/Abstract] OR SiJoin[Title/Abstract] OR PSIF[Title/Abstract] OR (DIANA[Title/Abstract] AND Sacroiliac Joint[Title/Abstract]) OR SIDESIS[Title/Abstract] OR SICAGE[Title/Abstract]) NOT (Infant[MeSH Terms] OR Child[MeSH Terms] OR Pediatric[Title/Abstract] OR Children[Title/Abstract] OR Case Reports[Publication Type] OR Editorial[Publication Type] OR Letter[Publication Type] OR Patient Education Handout[Publication Type] OR News[Publication Type])) AND Humans[mh:noexp]

#2 ((Sacroiliac Joint/surgery[MeSH Terms] OR Sacroiliac Joint/therapy[MeSH Terms] OR (sacroiliac joint[Title/Abstract] AND fusion[Title/Abstract]) OR (sacroiliac joint[Title/Abstract] AND arthrodesis[Title/Abstract]) OR iFuse[Title/Abstract] OR SImmetry[Title/Abstract] OR SILOK[Title/Abstract] OR Siconus[Title/Abstract] OR Prolix[Title/Abstract] OR Silex[Title/Abstract] OR TriCor[Title/Abstract] OR M.U.S.T.[Title/Abstract] OR SIFix[Title/Abstract] OR SI-Fix[Title/Abstract] OR INTER FIX[Title/Abstract] OR Rialto[Title/Abstract] OR PathLoc [Title/Abstract] OR SIJFuse[Title/Abstract] OR Entasis[Title/Abstract] OR SiCure[Title/Abstract] OR Re-Live[Title/Abstract] OR SacroFuse[Title/Abstract] OR SImpact[Title/Abstract] OR Tri-Fin[Title/Abstract] OR SambaScrew[Title/Abstract] OR TransFasten[Title/Abstract] OR SiJoin[Title/Abstract] OR PSIF[Title/Abstract] OR (DIANA[Title/Abstract] AND Sacroiliac Joint[Title/Abstract]) OR SIDESIS[Title/Abstract] OR SICAGE[Title/Abstract]) NOT (Infant[MeSH Terms] OR Child[MeSH Terms] OR Pediatric[Title/Abstract] OR Children[Title/Abstract] OR Case Reports[Publication Type] OR Editorial[Publication Type] OR Letter[Publication Type] OR Patient Education Handout[Publication Type] OR News[Publication Type])) NOT Animals[mh:noexp]

#3 (#1 OR #2)

#4 (#1 OR #2) Filters: English

Yield: 141 (after removing duplicates)

Embase searched from 1/1/2018 to 1/31/2021

#1 ((‘sacroiliac joint fusion’/exp OR (‘sacroiliac joint’/exp AND ‘arthrodesis’/de) OR (‘sacroiliac joint’/exp AND ‘joint surgery’/de) OR (‘sacroiliac joint’/exp/mj AND ‘therapy’/mj) OR (‘sacroiliac joint’:ti,ab AND fusion:ti,ab) OR (‘sacroiliac joint’:ti,ab AND arthrodesis:ti,ab) OR iFuse:ti,ab OR SImmetry:ti,ab OR ‘SI-LOK’:ti,ab OR Siconus:ti,ab OR Prolix:ti,ab OR Silex:ti,ab OR TriCor:ti,ab OR ‘M.U.S.T.’:ti,ab OR SIFix:ti,ab OR ‘SI-Fix’:ti,ab OR ‘INTER FIX’:ti,ab OR Rialto:ti,ab OR PathLoc:ti,ab OR SIJFuse:ti,ab OR Entasis:ti,ab OR SiCure:ti,ab OR ‘Re-Live’:ti,ab OR SacroFuse:ti,ab OR SImpact:ti,ab OR ‘Tri-Fin’:ti,ab OR SambaScrew:ti,ab OR TransFasten:ti,ab OR SiJoin:ti,ab OR PSIF:ti,ab OR (DIANA:ti,ab AND ‘sacroiliac joint’:ti,ab) OR ‘SI-DESIS’:ti,ab OR SICAGE:ti,ab) NOT (‘infant’/exp OR ‘child’/exp OR Pediatric:ti,ab OR Children:ti,ab OR ‘case report’/exp OR ‘editorial’/exp OR ‘letter’/exp OR [editorial]/lim OR [letter]/lim)) AND (‘human’/exp OR [humans]/lim) 529

#2 ((‘sacroiliac joint fusion’/exp OR (‘sacroiliac joint’/exp AND ‘arthrodesis’/de) OR (‘sacroiliac joint’/exp AND ‘joint surgery’/de) OR (‘sacroiliac joint’/exp/mj AND ‘therapy’/mj) OR (‘sacroiliac joint’:ti,ab AND fusion:ti,ab) OR (‘sacroiliac joint’:ti,ab AND arthrodesis:ti,ab) OR iFuse:ti,ab OR SImmetry:ti,ab OR ‘SI-LOK’:ti,ab OR Siconus:ti,ab OR Prolix:ti,ab OR Silex:ti,ab OR TriCor:ti,ab OR ‘M.U.S.T.’:ti,ab OR SIFix:ti,ab OR ‘SI-Fix’:ti,ab OR ‘INTER FIX’:ti,ab OR Rialto:ti,ab OR PathLoc:ti,ab OR SIJFuse:ti,ab OR Entasis:ti,ab OR SiCure:ti,ab OR ‘Re-Live’:ti,ab OR SacroFuse:ti,ab OR SImpact:ti,ab OR ‘Tri-Fin’:ti,ab OR SambaScrew:ti,ab OR TransFasten:ti,ab OR SiJoin:ti,ab OR PSIF:ti,ab OR (DIANA:ti,ab AND ‘sacroiliac joint’:ti,ab) OR ‘SI-DESIS’:ti,ab OR SICAGE:ti,ab) NOT (‘infant’/exp OR ‘child’/exp OR Pediatric:ti,ab OR Children:ti,ab OR ‘case report’/exp OR ‘editorial’/exp OR ‘letter’/exp OR [editorial]/lim OR [letter]/lim)) NOT (‘animal’/de OR [animals]/lim OR ‘animal experiment’/exp OR ‘animal model’/exp) 570

#3 (#1 OR #2)

#4 (#1 OR #2) AND [english]/lim

#5 (#4 NOT (miRNA:ti,ab OR microRNA:ti,ab)) AND [english]/lim

#6 #5 AND [2018-2021]/py

Yield: 55 (after removing duplicates)

ClinicalTrials.Gov Search from 6/1/2018 to current date

Terms: sacroiliac joint AND fusion | Adult, Older Adult | Start date from 06/01/2018 to 01/31/2021

Yield: 6

Cochrane Search from inception to 1/29/2021

#1 ("Sacroiliac Joint" NEXT surgery OR "Sacroiliac Joint" NEXT therapy):kw
#2 ("sacroiliac joint" AND (fusion OR arthrodesis OR DIANA)):ti,ab
#3 ("iFuse" OR "SImmetry" OR "SI-LOK" OR "Siconus" OR "Prolix" OR "Silex" OR "TriCor" OR "M.U.S.T." OR "SIFix" OR "SI-Fix" OR "INTER FIX" OR "Rialto" OR "PathLoc" OR "SIJFuse" OR "Entasis" OR "SiCure" OR "Re-Live" OR "SacroFuse" OR "SImpact" OR "Tri-Fin" OR "SambaScrew" OR "TransFasten" OR "SiJoin" OR "PSIF" OR "SI-DESIS" OR "SICAGE"):ti,ab
#4 [mh Infant] OR [mh Child] OR (Pediatric OR Children):ti,ab OR ("Case Reports" OR Editorial OR Letter OR "Patient Education Handout" OR News):pt
#5 [mh Humans]
#6 (#1 OR #2 OR #3) NOT #4
#7 #5 AND #6
#8 [mh Animals] NOT [mh Humans]
#9 #6 NOT #8
#10 #7 OR #9
#11 #10 NOT miRNA OR microRNA):ti,ab

Yield: 30 (after removing duplicates)

Other Data

The following websites were searched using the terms sacroiliac joint, sacroiliac joint fusion, sacroiliac joint arthrodesis:

United States (U.S.) Food and Drug Administration

Centers for Medicare and Medicaid Services

Aetna

Cigna

UnitedHealth

Humana

BlueCross BlueShield (Premera and Regence)

Kaiser Permanente

National Institute for Health and Care Excellence (U.K.)

U.S. Agency for Healthcare Research and Quality

North American Spine Society

American Society of Interventional Pain Physicians

American Academy of Orthopaedic Surgeons

American Academy of Neurological Surgeons

American Pain Society

International Society for the Advancement of Spine Surgery

State of Colorado Department of Labor and Employment Division of Workers' Compensation

North American Spine Society (NASS)

Work Loss Data Institute

AIM Specialty Health

Milliman Care Guidelines

eviCore

ECRI Guidelines Trust

The International Network of Agencies for Health Technology Assessment

Cochrane

Google

Appendix C. Evidence Tables

Table C-1. Study characteristics of randomized controlled trials evaluating sacroiliac joint fusion

Author (Year) Study Name; Registry Number; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA; Multiple countries: Belgium, Germany, Italy, Sweden; SI-BONE, Inc.	N eligible: NR N randomized: 109 N treated: 103 N intervention (randomized/treated/analyzed): 55/52/52 N control (randomized/treated/analyzed): 54/51/49 N crossovers: 6 mos.: 0/51 (0%) 1 yr.: 21/49 (42.9%)	9 centers, participants enrolled between June 2013 and May 2015 Mean age (range) I: 49.4 (27 to 70) C: 46.7 (23 to 69) N (%) Female I: 38 (73.1) C: 37 (72.5) Mean duration of pain (range) I: 4.9 (0.58 to 44) yrs. C: 4.5 (0.45 to 23) yrs. N (%) with prior lumbar fusion I: 18 (34.6) C: 19 (37.3) *Key inclusion criteria:* Aged 21 to 70 years old with LBP caused primarily by the SI joint for >6 mos. (or >18 mos. for pregnancy-related pain); baseline ODI score ≥30; baseline LBP VAS ≥50 *Key exclusion criteria*: Severe LBP due to other causes; autoimmune sacroiliitis, history of recent (<1 yr.) pelvic fracture with documented malunion, nonunion of sacrum or ilium, or any type of internal fixation of pelvic ring; spine surgery in the past 1 yr.	SI joint pain diagnosis based on all 3 criteria: 1) positive Fortin Finger Test, 2) ≥3 positive findings on 5 physical exam maneuvers for SI joint pain, and 3) ≥50% pain reduction following SI joint block	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 7/52 bilateral 45/52 unilateral C: Conservative management consisting of 1) optimization of medical therapy, 2) individualized physical therapy focusing on mobilization and stabilization exercises for control and stability (at least twice per week for up to 8 wks.), and 3) adequate information and reassurance of the patient. Cognitive behavioral therapy was allowed, but not available at all participating sites. SI joint steroid injections and radiofrequency ablation of sacral nerve roots was NOT part of conservative management.
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28]	N eligible: NR N enrolled: 159 N randomized: 158	Participants enrolled between January 2013 and May 2014 at 19 spine surgery clinics	Combination of a history of SI joint pain, positive provocative testing on at least 3 of 5 tests	I: iFuse Implant System (triangular titanium implant coated with porous

Author (Year) Study Name; Registry Number; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
INSITE; NCT01681004; U.S.; SI-BONE, Inc.	N treated: 148 N intervention: 102 N control: 46 N crossovers: 6 mos. 0 of 46 (0%) 1 yr. 35 of 44 (79.5%) 2 yrs. 39 of 44 (88.6%) (protocol allowed crossovers after 6 mos.)	Mean age (SD) I: 50.2 (11.4) C: 54.0 (11.0) N (%) Female I: 75 (73.5) C: 28 (60.9) Mean duration of pain, years (range) I: 7.0 (0.5 to 40.7) C: 5.0 (0.48 to 38.9) N (%) with prior lumbar fusion I: 39 (38.2) C: 17 (37.0) *Key inclusion criteria:* Aged 21 to 70 yrs.; confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or sacroiliac joint disruption; at least 30% baseline score on the ODI and at least 50 on VAS pain score. *Key exclusion criteria:* Inability to diagnose pain related to SI joint, pain due to inflammatory conditions or thought to be due to other causes; involvement in litigation, on disability leave, or receiving workers compensation.	(distraction, compression, FABER test, thigh thrust, Gaenslen's maneuver), at least 50% decrease in SI joint pain 30 to 60 minutes after image-guided local anesthetic injection into the SI joint within 3 mos. prior to screening. Degenerative sacroiliitis defined as SI joint-mediated pain in the context of either radiographic evidence of SI joint degermation (sclerosis, osteophytes, subchondral cysts, or vacuum phenomenon) on imaging or a history of prior lumbar fusion. SI joint disruption defined as SI joint pain in the context of asymmetric widening of SI joints on CT or X-rays or the presence of significant contrast leakage during a diagnostic SI joint block.	titanium plasma spray); minimally invasive lateral transiliac approach 26/102 bilateral 76/102 unilateral Individualized physical therapy twice a week for 6 wks. beginning 1 to 3 wks. postoperatively. C: Nonsurgical management with pain medications as directed by site investigator, physical therapy following American Physical Therapy Association guidelines, intraarticular SI joint steroid injections, and radiofrequency ablation of sacral nerve roots, all of which were delivered in a stepwise fashion and tailored to each individual patient's need. In the first 6 mos., 45 (97.8%) underwent physical therapy, 34 (73.9%) underwent at least 1 steroid injection, 21 (45.7%) underwent radiofrequency ablation of the sacral nerve root lateral branches, 40 (87.0%) underwent at least 2 types of treatment.

Abbreviations: C = control group; CT = computed tomography; I = intervention group; iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; LB*P*=low back pain; mos. = months; N = number of participants; NR = not reported; ODI = Oswestry Disability Index; SD = standard deviation; SI = sacroiliac; U.S. = United States; VAS = visual analog scale; wk(s). = week(s); yr(s). = year(s).

Table C-2. Efficacy outcomes from randomized controlled trials evaluating sacroiliac joint fusion—Part I

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	VAS LBP in mm, mean (SD) I: Baseline: 77.7 (11.3) 1 mo.: 35.4 (28.4) Calculated change: -42.3 3 mos.: 33.6 (27.2) Calculated change: -44.1 6 mos.: 34.4 (23.9) Change: -43.3 (25.0) (*P*<0.0001) 1 yr.: 35.2 (25.5) Change: -41.6 (27.0) 2 yrs.: NR Change: -45.3 (95% CI, 37 to 54) C (LOCF used for crossovers for timepoints > 6 mos.): Baseline: 73.0 (13.8) 1 mo.: 66.0 (17.7) Calculated change: -7.0 3 mos.: 67.5 (22.3) Calculated change: -5.5 6 mos.: 67.8 (20.3) Change: -5.7 (24.4) (*P*=0.1105) 1 yr.: 58.9 (28.2) Change: -14.0 (33.4) Between-group differences (I-C) Calculated 1 mo.: -35.3 Calculated 3 mos.: -38.6 **Calculated 6 mos.: -38.1 (adjusted *P*<0.0001)** Calculated 6 mos. crude: -37.6 (95% CI, -49.6 to -25.6) RM 6 mos.: -37.8 (*P*<0.0001) 1 yr.: -27.6 (*P*<0.0001) 2 yrs.: -34 (*P*<0.001)	ODI, mean (SD or 95% CI) I: Baseline: 57.5 (14.4) 3 mos.: 35.1 (18.3) Change: -*22.4* 6 mos.: 32.0 (18.4) Change: 25.5 (NR) (*P*<0.0001) 1 yr.: 32.1 (19.9) Change: -25.4 2 yrs.: NR Change: -26 (95% CI, 21 to 32) C (LOCF used for crossovers for timepoints > 6 mos.):Baseline: 55.6 (13.7) 3 mos.: 50.6 (15.5) Calculated change: -5.0 6 mos.: 50.2 (17.2) Change: -5.6 (NR) (*P*=0.0114) 1 yr.: 46.9 (20.8) Calculated change: -8.7 2 yrs.: NR Change: -8 Between-group differences (I-C) 6 mos.: -19.8 (*P*<0.0001) Calculated 1 yr.: -20.1 (*P*<0.0001) 2 yrs.: NR (*P*<0.001) At least 15-point improvement: I: 6 mos.: 37 (71.2%) 1 yr.: NR (65%) 2 yrs.: 30/47 (64%)	Overall level of satisfaction I: 6 mos.: Very satisfied: 28 (54.9) Somewhat satisfied: 19 (37.3) Somewhat dissatisfied: 2 (3.9) Very dissatisfied: 2 (3.9) 1 yr.: Very satisfied: 25 (52.1) Somewhat satisfied: 18 (37.5) Somewhat dissatisfied: 5 (10.4) Very dissatisfied: 0 (0) C: 6 mos.: Very satisfied: 9 (18.4) Somewhat satisfied: 15 (30.6) Somewhat dissatisfied: 23 (46.9) Very dissatisfied: 2 (4.1) 1 yr.: NR Between-group differences 3 mos.: *P*<0.0001 6 mos.: *P*<0.0001	EQ-5D, mean (SD) I: Baseline: 0.35 (0.24) 3 mos.: 0.69 (0.25) Change: 0.34 6 mos.: 0.73 (0.24) Change: 0.37 (NR) (*P*<0.0001) 1 yr.: 0.74 (0.25) Change: 0.39 2 yrs.: NR Change: 0.39 C (LOCF used for crossovers for timepoints > 6 mos.): Baseline: 0.37 (0.27) 3 mos.: 0.46 (0.29) Change: 0.09 6 mos.: 0.48 (0.30) Change: 0.11 (NR) (*P*=0.0189) 1 yr.: 0.54 (0.33) Change: 0.17 2 yrs.: NR Change: 0.15 Between-group differences (I-C) 6 mos.: 0.21 (*P*<0.0001) 1 yr.: Calculated 0.22 (*P*=0.0009) 2 yrs.: Calculated 0.24 (*P*<0.001)

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	Subgroup analyses at 6 mos.: Similar between-group results in subgroups based on pregnancy-related pain, prior lumbar fusion, and unilateral vs. bilateral SI joint pain At least 20-mm improvement on VAS LBP: I: 6 mos. 41/52 (79%) 1 yr. NR (69%) 2 yrs. 37/47 (79%) C (LOCF used for crossovers for timepoints > 6 mos. unless otherwise specified): 6 mos. 11/49 (22%) 1 yr.(crossovers): NR 1 yr. (no crossovers): 14/28 (27% of those originally assigned to C) (*P*<0.0001 for both 6 mos. and 1 yr. comparisons) 2 yrs. 11/46 (24%) Between-group difference (I-C) 6 mos.: NR (*P*<0.001) Calculated RR 3.51 (95% CI, 2.05 to 6.02) Calculated ARD 56.4% (95% CI, 40.3% to 72.5%) 2 yrs.: NR (*P*<0.001) Calculated RR 3.29 (95% CI, 1.92 to 5.63) Calculated ARD 54.8% (95% CI, 37.8% to 71.8%)	C(LOCF used for crossovers for timepoints > 6 mos. unless otherwise specified): 6 mos.: 12 (24.5%) 1 yr.: (crossovers): NR 1 yr.: (no crossovers): 13 (25%) (*P*<0.0001 for both 6 mos. and 1 yr. comparison) 2 yrs.: 11/46 (24%) Between-group difference (I vs. C) Calculated 6 mos.: NR (*P*<0.001) Calculated RR 2.91 (95% CI, 1.73 to 4.89) Calculated ARD 46.7% (95% CI, 29.4% to 63.9%) 2 yrs.: NR (*P*<0.001) Calculated RR 2.67 (95% CI, 1.53 to 4.67) Calculated ARD 39.9% (95% CI, 21.5% to 58.4%) Self-reported walking distance, N (%) able to walk each distance I: Baseline: NR 6 mos.: <100 m: 6 (11.8) 100-500 m: 12 (23.5) 0.5-1 km: 13 (25.5) >1 km: 20 (39.2) 1 yr.: <100 m: 4 (8.3) 100-500 m: 8 (16.7) 0.5-1 km: 15 (31.2) >1 km: 21 (43.8)		

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	VAS RLP in mm, mean (SD) I: Baseline: 52.7 (31.5) 1 mo.: 20.0 (23.4) Calculated change: -32.7 3 mos.: 19.0 (22.2) Calculated change: -33.7 6 mos.: 22.6 (25.1) Change: -30 1 yr.: 24.0 (27.8)[a] Calculated change: -28.7 2 yrs.: NR Change: -32 C(LOCF used for crossovers for timepoints > 6 mos.): Baseline: 47.1 (31.1) 1 mo.: 50.0 (30.5) Calculated change: 2.9 3 mos.: 45.6 (32.5) Calculated change: -1.5 6 mos.: 46.5 (31.4) Change: -1.4 1 yr.: 41.7 (32.4)[a] Calculated change: -5.4 2 yrs.: NR Change: -7.7 Between-group differences (I-C) Calculated 1 mo.: -35.6 Calculated 3 mos.: -32.2 Calculated 6 mos.: -29.5 (P<0.001) Calculated 1 yr.: -23.3 (P=0.0002)[a] 2 yrs.: NR (P<0.001)	C (LOCF used for crossovers for timepoints > 6 mos.): Baseline: NR 6 mos.: <100 m: 12 (24.5) 100-500 m: 17 (34.7) 0.5-1 km: 10 (20.4) >1 km: 10 (20.4) 1 yr.: NR At 2 yrs., walking distance was superior after sacroiliac joint arthrodesis compared to conservative management (actual values NR, only dipicted on a figure) Between-group differences 6 mos.: P=0.17721		
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	VAS SI joint pain in mm, mean (SD) I: Baseline: 82.3 (11.9) 1 mo.: 33.3 (27.3)	ODI, mean (SD) I: Baseline: 62.2 (14.5) 1 mo.: 44.8 (22.1)	Self-reported treatment satisfaction as “very satisfied” 6 mos.: I: NR (77.2%)	SF-36 Physical Health Component Score I: Baseline: 30.2 (6.2)

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	Change: -49.2 (26.4) 3 mos.: 25.5 (25.0) Change: -56.5 (27.0) 6 mos.: 29.8 (29.3) Change: -52.6 (29.2) 1 yr.: 28.3 (29.3) Change -54.2 (28.5) 2 yrs.: 26.7 (NR) Change -55.4 (NR) C: Baseline: 82.2 (9.9) 1 mo.: 69.2 (18.2) Change: -13.0 (14.3) 3 mos.: 63.5 (26.2) Change: -18.7 (23.7)-12.1 6 mos.: 70.4 (25.9) Change -12.1 (22.7) 1 yr. (crossovers): 35.8 (30.3) Change -48.5 (30.2) 1 yr. (no crossover): 55.5 (25.7) Change -21.6 (31.9) 2 yrs.: Actual value NR, only reported on a figure Between group difference RM 6 mos. 38.2 (*P*<0.001) Calculated between-group differences (I-C) 1 mo.: -36.2 (95% CI, -42.9 to -29.5; *P*<0.0001) 3 mos.: -37.9 (95% CI, -47.3 to -28.5; *P*<0.0001) 6 mos.: -40.5 (95% CI, -50.1 to -30.9; *P*<0.0001) 1 yr. (crossovers): -5.7 (95% CI, -17.1 to 5.7; *P*=0.32)	Change: -17.4 (22.2) 3 mos.: 32.3 (21.2) Change: -29.5 (21.3) 6 mos.: 31.9 (22.7) Change: -30.3 (21.9) 1 yr. 28.1 (20.8) Change -29.3 (19.9) C: Baseline: 61.1 (15.3) 1 mo.: 57.1 (17.5) Change: -3.7 (11.6) 3 mos.: 51.1 (21.5) Change: -10.3 (16.4) 6 mos.: -56.4 (20.8) Change: -4.9 (16.4) 1 yr. (crossovers): 30.2 (30.3) Change -28.2 (20.5) 1 yr. (no crossover): 34.0 (16.9) Change -28.9 (20.0) Calculated between-group differences 1 mo.: -13.7 (95% CI, -19.3 to -8.1; *P*<0.0001) 3 mos.: -19.2 (95% CI, -26.4 to -12.0; *P*<0.0001) 6 mos.: -25.4 (95% CI, -32.5 to -18.3; *P*<0.0001) 1 yr. (crossovers): -1.1 (95% CI, -8.9 to 6.7; *P*=0.78) 1 yr. (no crossover): -0.4 (95% CI, -18.5 to 17.7; *P*=0.97) 2 yrs.: Unable to determine At least 15-point improvement: I: 1 mo.: 49/100 (49.0%)	C: NR (27.3%) (*P*<0.001) 1 yr.: I: NR (77.6%) C (crossovers): NR (71.0%) C (no crossovers): NR 2 yrs.: I: NR (73.3%) C: NR	6 mos.: 42.8 (10.0) Change: 12.7 (10.3) 1 yr.: 43.1 (10.3) Change: 13.0 (9.9) 2 yrs.: NR Change 11.2 (NR) C: Baseline: 30.8 (6.1) 6 mos.: 32.0 (7.5) Change: 1.2 (8.0) 1 yr. (crossovers): 42.4 (10.6) Change: 11.9 (11.6) 1 yr. (no crossovers): 37.8 (9.5) Change 5.3 (8.2) 2 yrs.: actual value NR (only depicted on a figure) Calculated between-group difference 6 mos.: 11.5 (95% CI, 8.1 to 14.9; *P*<0.0001) 1 yr. (crossovers): 1.1 1 yr. (no crossovers): 7.7 SF-36 Mental Health Component Score I: Baseline: 43.0 (11.5) 6 mos.: 49.3 (11.5) Change: 6.2 (11.4) 1 yr.: 50.4 (11.0) Change: 7.2 (12.4) 2 yrs.: NR C: Baseline: 43.3 (12.1) 6 mos.: 44.0 (12.5) Change: 0.6 (9.7) 1 yr. (crossovers): 50.7 (9.4)

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	1 yr. (no crossovers): -32.6 (95% CI, -58.7 to -6.6; *P*=0.01) 2 yrs.: Unable to determine At least 20 mm improvement: I: 1 mo.: 85/100 (85%) 3 mos.: 87/100 (87%) 6 mos.: 83/101 (82.2%) 1 yr. 80/98 (81.6%) 2 yrs.: 74/89 (83.1%) C: 1 mo.: 13/45 (28.9%) 3 mos.: 17/44 (38.6%) 6 mos.: 12/44 (27.3%) 1 yr.: 5/40 (12.5%)[a] 2 yrs.: 4/40 (10%)[a] Calculated between-group difference 6 mos.: ARD 54.9% (95% CI, 39.8% to 70.0%) RR 3.01 (95% CI, 1.84 to 4.92) 1 yr.: ARD 69.1% (95% CI, 56.3% to 81.9%) RR 6.53 (95% CI, 2.86 to 14.91) 2 yrs.: ARD 73.2% (95% CI, 61.0% to 85.3%) RR 8.32 (95% CI, 3.27 to 21.16)	3 mos.: 72/100 (72.0%) 6 mos.: 74/101 (73.3%) 1 yr.: 72/100 (72.0%) 2 yrs.: 60/88 (68.2%) C: 1 mo.: 6/45 (13.3%) 3 mos.: 13/43 (30.2%) 6 mos.: 6/44 (13.6%) 1 yr.: 3/40 (7.5%)[a] 2 yrs.: 3/40 (7.5%)[a] Calculated between-group difference 6 mos.: ARD 59.6% (95% CI, 46.3% to 73.0%) RR 5.37 (95% CI, 2.53 to 11.41) 1 yr.: ARD 64.5% (95% CI, 52.5% to 76.5%) RR 9.6 (95% CI, 3.21 to 28.7) 2 yrs.: ARD 60.7% (95% CI, 48.0% to 73.4%) RR 9.09 (95% CI, 3.03 to 27.24)		Change: 7.8 (12.0) 1 yr. (no crossover): 46.2 (9.8) Change 2.3 (7.2) Calculated between-group difference 6 mos.: 5.6 (95% CI, 1.8 to 9.4; *P*=0.0054) 1 yr.: NR EQ-5D I: Baseline: 0.44 (0.18) 6 mos.: 0.72 (0.21) Change: 0.29 (0.22) 1 yr.: 0.74 (0.20) Change: 0.31 (0.22) 2 yrs.: NR Change: 0.28 (NR) C: Baseline: 0.47 (0.19) 6 mos.: 0.52 (0.22) Change: 0.05 (0.27) 1 yr. (crossovers): 0.73 (0.22) Change: 0.30 (0.26) 1 yr. (no crossover): 0.74 (0.12) Change: 0.20 (0.17) 2 yrs.: actual value NR (only depicted on a figure) Calculated between-group difference 6 mos.: 0.24 (95% CI, 0.16 to 0.32); *P*<0.0001) 1 yr (crossovers): 0.01 (P NR) 1 yr (no crossover: 0.11 (P NR)

Notes: Values in **bold type** are the primary study endpoints designated by study authors.
a. Crossovers were considered "failures" for analyses evaluating the percentage of participants achieving a specific threshold on the outcome (i.e., VAS improvement greater than or equal to 20 points, ODI improvement greater than or equal to 15 points).

Abbreviations: ARD = absolute risk difference; C = control group; CI = confidence interval; EQ-5D = EuroQOL 5 item measure of general health status; I = intervention group; iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; km = kilometer(s); LB*P*=low back pain; m = meters; mo(s). = month(s); mm = millimeters; NR = not reported; ODI = Oswestry Disability Index; RL*P*=referred leg pain; RM = repeated measures; RR = risk ratio; SD = standard deviation; SF-36 = Short form survey (36 item); SI = sacroiliac; VAS = visual analog scale; vs. = versus; yr(s). = year(s).

Table C-3. Efficacy outcomes from randomized controlled trials evaluating sacroiliac joint fusion—Part II

Author (Year) Study Name	Opioid Use	Return to Work	Nonunion	Length of Stay	Global Recovery or "Success"
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	N (%) using opioids I: Baseline: 29/52 (56%) 2 yrs.: 16/47 (33%) Change: -23% (*P*=0.009) C: Baseline: 24/51 (47.1%) 2 yrs.: 21/46 (45.7%) Change: -1.4% (*P*=1.0) Calculated between-group difference at 2 yrs.: RR 0.75 (95% CI, 0.45 to 1.24) ARD 11.6% (95% CI, -31.4% to 8.2%)	Work status, N (%) I: Baseline: Not working due to LBP: 23 (44.2) Not working due to other reason: 1 (1.9) Retired: 10 (19.2) Working with limitations: 13 (25.0) Working normal hours/type: 5 (9.6) 6 mos.: Not working due to LBP: 20 (39.2) Not working due to other reason: 2 (3.9) Retired: 11 (21.6) Working with limitations: 6 (11.8) Working normal hours/type: 12 (23.5) 1 yr.: Not working due to LBP: 15 (31.2) Not working due to other reason: 4 (8.3) Retired: 10 (20.8) Working with limitations: 11 (22.9) Working normal hours/type: 8 (16.7) C: Baseline: Not working due to LBP: 27 (52.9) Not working due to other reason: 2 (3.9) Retired: 7 (13.7) Working with limitations: 12 (23.5) Working normal hours/type: 3 (5.9) 6 mos.: Not working due to LBP: 28 (57.1) Not working due to other reason: 0 (0) Retired: 5 (10.2)	NR	Hospital length of stay, days I: Median (range) 3 (1 to 28)	Global comparison to baseline, N (%) I: 6 mos.: Worse: 3 (5.9) Same: 6 (11.8) Better: 22 (43.1) Much better: 20 (39.2) 1 yr.: Worse: 3 (6.2) Same: 6 (12.5) Better: 21 (43.8) Much better: 18 (37.5) C: 6 mos.: Worse: 16 (32.7) Same: 17 (34.7) Better: 12 (24.5) Much better: 4 (8.2) 1 yr.: NR Between-group differences 6 mos.: *P*<0.0001 2 yrs.: Global comparison with baseline and overall satisfaction were superior after sacroiliac joint arthrodesis compared to conservative management (actual values NR)

Author (Year) Study Name	Opioid Use	Return to Work	Nonunion	Length of Stay	Global Recovery or "Success"
		Working with limitations: 10 (20.4) Working normal hours/type: 6 (12.2) 1 yr.: NR Between-group differences 6 mos.: *P*=0.0711 2 yrs.: Work status: Improved significantly over time (*P*=0.001) in the SI joint fusion group			
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	N (%) using opioid analgesics for SI joint pain I: Baseline: 70 (68.6%) 6 mos.: 58 (58.4%) Change: -9.0% 1 yr.: 51 (52.0%) Calculated change: -16.6% 2 yrs.: 43 (48.3%) Calculated change: -20.3% C: Baseline: 29 (63.0%) 6 mos.: 31 (70.5%) Change: 7.5% 1 yr.: 55% but unclear whether specific to cross over participants, those who did not cross over, or both 2 yr.: NR Between-group difference	NR	NR	Hospital length of stay, days I: Mean (SD, range) 0.78 (0.97, 0 to 7)	**Binary success/failure outcome** with success defined as reduction from baseline VAS by at least 20 mm, absence of device-related serious adverse events, absence of neurological worsening related to sacral spine, absence of surgical reintervention for SI joint pain. Success at 6 mos.: I: 83/102 (81.4% [95% Credible Interval, 72.4% to 88.4%]) C: 11/46 (23.9% [95% Credible Interval, 12.6% to 38.8%]) Difference: 56.6% (95% Credible Interval, 41.4% to 70.0%) Posterior probability that the success rate was higher in the SI joint fusion group was >0.999. Prespecified subgroup analyses: Underlying condition I: Degenerative sacroiliitis: 70/86 (81.4% [95% Credible Interval, 71.6% to 89.0%])

Author (Year) Study Name	Opioid Use	Return to Work	Nonunion	Length of Stay	Global Recovery or "Success"
	6 mos.: calculated difference -16.5% (*P*=0.08) 1 yr.: calculated difference -8.6% (P=0.61) but unclear whether includes both crossover participants and those who did not crossover 2 yr: unable to calculate because NR for CM group; authors do report that 55.9% of participants who crossed over were using opioids by 12 months after crossover				SI joint disruption: 13/14 (92.9% [95% Credible Interval, 66.1% to 99.8%]) C: Degenerative sacroiliitis: 10/38 (26.3% [95% Credible Interval, 13.4% to 43.1%]) SI joint disruption: 1/6 (16.7% [95% Credible Interval, 0.4% to 64.1%]) Difference Degenerative sacroiliitis: 54.1% (95% Credible Interval 37.2% to 69.0%) SI joint disruption: 68.6% (95% Credible Interval 31.2% to 93.1%) Prior lumbar fusion I: Yes: 33/39 (84.6% [95% Credible Interval, 69.5% to 94.1%]) No: 50/61 (82.0% [95% Credible Interval 70.0% to 90.6%]) C: Yes: 2/17 (11.8% [95% Credible Interval, 1.5% to 36.4%]) No: 9/27 (33.3% [95% Credible Interval, 16.5% to 54.0%]) Difference Prior fusion-yes: 69.9% (95% Credible Interval, 48.0% to 86.0%) Prior fusion-no: 47.5% (95% Credible Interval, 26.9% to 66.1%) Bilateral procedure I: Yes: 25/33 (75.8% [95% Credible Interval, 57.7% to 88.9%])

Author (Year) Study Name	Opioid Use	Return to Work	Nonunion	Length of Stay	Global Recovery or "Success"
					No: 58/67 (86.6% [95% Credible Interval, 76.0% to 93.7%]) C: Yes: 2/11 (18.2% [95% Credible Interval, 2.3% to 51.8%]) No: 9/33 (27.3% [95% Credible Interval, 13.3% to 45.5%]) Difference Bilateral-yes: 54.2% (95% Credible Interval, 24.7% to 76.8%) Bilateral-no: 58.1% (95% Credible Interval, 40.1% to 73.8%)

Abbreviations: ARD = absolute risk difference; C = control group; CI = confidence interval; I = intervention group; iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; LB*P*=low back pain; mm = millimeters; mo(s). = months; N = number of participants; NR = not reported; NS = not significant; RR = risk ratio; SD = standard deviation; SI = sacroiliac joint; VAS = visual analog scale; yr(s). = year(s).

Table C-4. Safety outcomes from randomized controlled trials evaluating sacroiliac joint fusion—Part I

Author (Year) Study Name	Adverse Events	Revision Surgery
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA N analyzed=101	Total adverse events I: 6 mos.: 20 (among 16 participants) 2 yrs.: 54 (participants NR) C: 6 mos.: 17 (among 15 participants) 2 yrs.: 47 (participants NR) Mean number of events per subject at 6 mos. I: 0.33 C: 0.38 *P*=0.6644 All adverse events by severity at 2 yrs. I: Mild: 6 Moderate: 9 Severe: 39 C: Mild: 6 Moderate: 14 Severe: 27 Mild adverse events at 2 yrs. I: Probably or definitely related to study device or procedure 6 mos.: 0 >6 to 2 yrs.: 0 Not related to study device or procedure 6 mos.: 2 >6 to 2 yrs.: 4 C:	6 mos. I: 1 (1.9%) (1 due to postoperative nerve impingement) C: 0 At 2 yrs. I: 2/52 (3.8%) (1 due to radicular pain from implant nerve root impingement, 1 postoperative hematoma evacuation) C: 1/21 (4.8% among 21 who crossed over to surgery)

Author (Year) Study Name	Adverse Events	Revision Surgery
	Probably or definitely related to study device or procedure 6 mos.: 0 >6 to 2 yrs.: 1 Not related to study device or procedure 6 mos.: 3 >6 to 2 yrs.: 2 Moderate adverse events at 2 yrs. I: Probably or definitely related to study device or procedure 6 mos.: 0 >6 to 2 yrs.: 0 Not related to study device or procedure 6 mos.: 2 >6 to 2 yrs.: 7 C: Probably or definitely related to study device or procedure 6 mos.: 0 >6 to 2 yrs.: 1 Not related to study device or procedure 6 mos.: 3 >6 to 2 yrs.: 10 Severe adverse events at 2 yrs. I: Probably or definitely related to study device or procedure 6 mos.: 4 >6 to 2 yrs.: 0 (2 increased SI joint pain, 1 gluteal hematoma, 1 implant-related nerve root impingement causing radicular pain) Not related to study device or procedure 6 mos.: 12 >6 to 2 yrs.: 23	

Author (Year) Study Name	Adverse Events	Revision Surgery
	(14 in the low back [e.g., disc herniation, lumbar facet pain], 3 in the hip [e.g., trochanteric bursitis], 10 in the pelvis [primarily SI joint or contralateral SI joint pain], 8 unrelated to the pelvis, spine, or hip) C: Probably or definitely related to study device or procedure 6 mos.: 0 >6 to 2 yrs.: 1 (1 gluteal and leg pain after crossover SI joint fusion due to implant loosening) Not related to study device or procedure 6 mos.: 11 >6 to 2 yrs.: 15	
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE N analyzed=148	Total adverse events I: 6 mos.:129 1 yr.: 179 C: 6 mos.: 49 1 yr.: 89 (includes subjects who underwent crossover SI fusion surgery) Adverse event rate, mean I: 6 mos.: 1.5 1 yr.: 1.8 C: 6 mos.: 1.3 1 yr.: 1.9 Between-group differences (I-C) 6 mos.: *P*=0.2253 1 yr.: *P*=0.45 Severe adverse events I: 6 mos.: 22 (2 were device related and 4 were procedure related) 2 yrs.: 55 (5 were procedure or device related) Postoperative atrial fibrillation, neuropathic pain due to implant malposition, wound hematoma, and ilial fracture related to an implant, SI joint pain related to physical activity and loosening C (including all patients originally assigned to conservative management):	6 mos. I: 1/102 (0.98%) for implant malposition and persistent pain 1 yr. I: 1/102 (0.98%) for implant malposition and persistent pain 2 yrs. I: 3/89 (3.4%) for implant malposition and persistent pain, suboptimal device position, buttock pain from hairline fracture of ipsilateral ilium C (crossovers): 1/39 (2.6%) for postoperative radicular pain to reposition implant

Author (Year) Study Name	Adverse Events	Revision Surgery
	6 mos.: 8 (1 was back pain attributed to treatment) 2 yrs.: 23 1 yr.: 42 events, not broken down by treatment group Between-group differences (I-C) 6 mos.: *P*=0.6 2 yrs.: NR N (%) with infection I: 6 mos.: 3 (2.9%) 1 yr.: 5 (4.9) C (including all patients originally assigned to conservative management): 6 mos.: 3 (6.5%) 1 yr.: 3 (6.5) Between-group differences (I-C) 6 mos.: *P*=0.3752 1 yr.: *P*=0.70 N (%) with surgical wound complication I: 6 mos.: 6 (5.9%) 1 yr.: 5 (4.9) C (including all patients originally assigned to conservative management): 6 mos.: 0 (0%) 1 yr.: 2 (4.3) Between-group differences (I-C) 6 mos.: *P*=0.1774 1 yr.: *P*=0.89 Authors also reported total adverse events by body system at 6 mos. and at 1 yr. (not abstracted) N (%) with device-related events at 6 mos.: I: 3 (2.9) Definitely related: 2 (2.0) Probably related: 1 (1.0) Sacral nerve root impingement, hairline fracture of ilium, contralateral SI joint pain	

Author (Year) Study Name	Adverse Events	Revision Surgery
	C: NA N (%) with procedure-related events at 6 mos. I: 16 (15.7) Definitely related: 6 (5.9) Probably related: 10 (9.8) Neuropathic symptoms (2), postoperative medical problems (4), SI joint pain/bursitis (4), surgical wound (4), iliac fracture (1), asymptomatic exam finding (1) C: 4 (8.7) Definitely related: 3 (6.5) Probably related: 1 (2.2) Increased back or joint pain after treatment (3), flushing and shortness of breath after injection (1) N (%) with events related to preexisting conditions at 6 mos. I: 40 (39.2) Definitely related: 23 (22.5) Probably related: 17 (16.7) C: 17 (37.0) Definitely related: 11 (23.9) Probably related: 6 (13.0) Deaths at 2 yrs. 2 unrelated to SI joint fusion (1 from pulmonary fibrosis and chronic obstructive pulmonary disease and 1 from a fatal myocardial infarction)	

Abbreviations: C = control group; CI = confidence interval; I = intervention group; iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; mo(s). = month(s); NA = not applicable; NR = not reported; SI = sacroiliac; yr(s). = year(s).

Table C-5. Safety outcomes from randomized controlled trials evaluating sacroiliac joint fusion—Part II

Author (Year) Study Name	Intraoperative Blood Loss	Duration of Surgery
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	NR	Mean (range): 57 (19 to 107) mins.
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	Estimated blood loss, cc Mean (SD, range): 32.7 (32.8, 0.5 to 250)	Procedure time, mins. Mean (SD, range): 44.9 (22.3, 14 to 140)

Abbreviations: cc = cubic centimeters; iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; mins. = minutes; SD = standard deviation.

Table C-6. Study characteristics of controlled cohort studies evaluating sacroiliac joint fusion

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
Claus (2020)[33] U.S; Funding source NR 1 author receives consulting fees from SI-Bone	N eligible: 156 N analyzed: 156 I: 74 C: 82	Participants who had received SI joint fusion between 2012 and 2018 by 1 of 4 surgeons at a single institution Mean age (range) Rialto: 58.4 (range 23 to 82) iFuse: 55.7 (range 27 to 85) N (%) Female Rialto: 54 (73.0) iFuse: 60 (73.2) Mean (SD) duration of symptoms: NR N (%) with lumbar fusion Rialto: 48 (64.9) iFuse: 51 (61.0) *Key inclusion criteria*: Underwent SI joint fusion between 2012 and 2018 for SI joint dysfunction after failing at least 3 mos. of conservative treatment and had at least 6 mos. of postoperative outpatient follow-up. SI joint dysfunction confirmed with physical exam, provocative tests, imaging studies ruling out other pathology, and 2 consecutive SI joint injections under fluoroscopic guidance with ≥60% improvement in pain scores. *Key exclusion criteria:* Other lumbosacral pathology	Diagnosis based on 1) physical examination, 2) positive provocative tests, 3) imaging studies that ruled out other lumbosacral pathology, and 4) confirmation of diagnosis was established with 2 consecutive injections demonstrating ≥60% improvement in baseline pain scores	I: Rialto (cylindrical threaded implant); minimally invasive posterior oblique approach 0/74 bilateral 74/74 unilateral C: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach NR bilateral NR unilateral

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
Kibsgard (2013)[25] Norway; Norwegian Foundation for Health and Rehabilitation and Sophies Minde Ortopedi AS	I: N eligible: 81 N analyzed: 50 C: N eligible: 48 N analyzed: 28	Participants who had received surgery between 1977 and 1998 at a single institution Mean age (range) I: 58 (56 to 61) C: 52 (49 to 55) N (%) Female I: 47 (94%) C: 28 (100%) Mean (range) duration of symptoms, in years: I: 5 (1 to 21) C: NR N (%) with prior lumbar fusion: NR *Key inclusion criteria:* Pain in the SI joint >1 yr. after pregnancy or after trauma, pain with an idiopathic origin, severe disability, and resistance to conservative treatment. *Key exclusion criteria:* Abnormal rheumatology or blood tests or abnormal neurological or gynecological examinations	Tenderness at the superior and inferior posterior iliac spines; pains with active and passive straight leg raise, Patrick Fabere's test, passive hip rotation, forcible inward rotation and extension of the hip joint; normal spinal X-rays and radiculography	I: Open procedure using a dorsal approach for either a transiliac fusion or an intra/extra-articular fusion between ilium and sacrum. Bilateral: 35 Unilateral: 25 Pubic symphysis: 4 (in addition to bilateral or unilateral SI joint fusion) Patients confined to bedrest for 6 wks. C: Nonsurgery group, no specific details regarding treatment was provided, but this group appeared to have been enrolled from a later time period when open fusion was becoming less commonly used
Ledonio (2014)[32] U.S.; Funding source NR; Authors reported no conflicts of interest	N treated: 63 N analyzed: 44 I: 22 C: 22[a]	Participants who had received surgery between 2006 and 2011 at a single institution Mean age (SD) I: 47.9 (13.1) C: 51.0 (9.4)	Specific provocative physical examination tests and diagnostic/therapeutic image-guided SI joint injections	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach; physical therapy after 3 wks. to restore normal gait

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
		N (%) Female I: 17 (77) C: 13 (59) Mean duration of symptoms: NR N (%) with prior spine surgery: I: 14 (64) C:11 (60) *Key inclusion criteria:* Undergone open or minimally invasive SI joint fusion, confirmed diagnosis of SI joint dysfunction/sacroiliitis, and failed nonoperative treatment, minimum follow-up of 1 yr. *Key exclusion criteria:* NR		C: Open anterior ilioinguinal approach, local bone grafting, and anterior plating; at 6 wks. the participants were treated with pool therapy for 4 wks. with progressive weightbearing followed by 8 wks. of land-based therapy
Ledonio (2014)[31] U.S.; Funding source NR; one author reported a consultancy with SI-BONE, Inc.	N eligible: 49 N analyzed: 39 I: 17 C: 22[a]	Participants who had received surgery between 2006 and 2012 at 2 institutions Mean age (range) I: 66 (39 to 82) C: 51 (34 to 74) *P*<0.0018 N (%) female I: 11 (64.7) C: 13 (59.1) Mean duration of symptoms: NR N (%) with history of spine surgery I: 14 (82) C: 11(50)	Disruption/degenerative sacroiliitis confirmed by specific provocative physical examination tests, diagnostic/therapeutic fluoroscopic image-guided SI joint injections using a local anesthetic and steroid	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach; physical therapy after 8 wks. C: Open anterior ilioinguinal approach, local bone grafting, and anterior plating; at 6 wks. the participants were treated with pool therapy for 4 wks. with progressive weightbearing followed by 8 wks. of land-based therapy

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
		Key inclusion criteria: Confirmed diagnosis of SI joint disruption/degenerative sacroiliitis, diagnostic; failed nonoperative treatment *Key exclusion criteria:* Less than 1 yr. of follow-up information		
Smith (2013)[30] U.S.; Funding source NR; several authors were either employees, paid consultants, or stockholders of SI-BONE, Inc.	N eligible: NR N analyzed 263 I: 114 C: 149	Participants who had received open or minimally invasive SI joint fusion between 1994 and 2012 at 7 institutions Mean age (SD) I: 57.4 (14.0) C: 45.8 (11.3) N (%) female I: 82 (71.9) C: 103 (69.1) Mean duration of symptoms in years: NR N (%) with prior lumbar fusion I: 54 (47.4) C: 35 (23.5) *Key inclusion criteria:* Adults with chronic SI joint pain and undergoing SI joint fusion surgery between 1994 and 2012 after failing 6 mos. of nonsurgical treatment consisting of medication optimization, activity modification, physical therapy, and SI	SI joint pain diagnosis based on a combination of detailed history, clinical exam, imaging, and diagnostic injections, including 1) ≥3 positive findings on pain provocation tests, 2) diagnostic imaging to assess pathology in the lumbopelvic hip complex for differential diagnosis, and 3) image-guided intraarticular SI joint block	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 11/114 bilateral 103/114 unilateral Individualized physical therapy for 4 wks. beginning 7 wks. postoperatively C: Open posterior approach 4/149 bilateral 145/149 unilateral Procedure employed packing morselized bone or rhBMP into cages placed into the SI joint and then fixation

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
		joint injections; both 12 and 24 mos. postoperative pain scales documented in medical chart *Key exclusion criteria:* NR		
Spain (2017)[34] U.S.; SI-BONE, Inc.	N eligible: 312 N treatment received/N analyzed: I: 274/263 C: 38/29	Participants who had received SI joint fixation or fusion at a single spine surgery practice between 2004 to 2011 (fixation) or between 2011 to 2016 (fusion) Mean age (range) I: 54.3 (24.0 to 85.0) C: 46.6 (27.0 to 61.0) N (%) female I: 166 (63.1) C: 16 (55.2) Mean duration of symptoms, in years: NR N (%) with prior lumbar fusion: NR *Key inclusion criteria:* Age ≥19 yrs. *Key exclusion criteria:* NR	NR	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach Bilateral: A "small proportion of patients" Unilateral: NR C: SI joint fixation using cannulated 7.2-mm diameter stainless steel screws (Synthes) and performed percutaneously through small (2 to 5 mm) punctures in the skin Bilateral: NR Unilateral: NR
Vanaclocha (2018)[24] Spain; Funding source NR	N with suspected SI joint pain: 423 N with initial conservative management: 406 N failing initial conservative management: 193 N eligible: 152 (positive response to joint infiltration)	Participants who had received conservative management, radiofrequency ablation, or SI joint fusion between 2007 and 2015 at a single institution Mean age (range) I: 48.0 (range 25 to 69) C1: 48.0 (range 24 to 70) C2: 51.4 (range 29 to 70)	Diagnosis based on 1) positive Fortin Finger Test, 2) ≥3 positive findings on 8 physical exam maneuvers for SI joint pain, 3) ≥50% pain reduction following image-guided intraarticular SI joint block	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach Bilateral: 3/27 Unilateral: 24/27 All procedures performed in inpatient setting.

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
	N received treatment/N analyzed: I: 27/27 C1: 51/47 C2: 74/63	N (%) female I: 19 (70.4) C1: 25 (53.2) C2: 36 (57.1) Mean (SD) duration of pain, years I: 1.6 (NR) C1: 2.9 (NR) C2: 4.6 (NR) % with pain >5 yrs. I: 2 (7.4%) C1: 7 (14.9%) C2: 26 (41.3%) N (%) with prior lumbar fusion I: 2 (7.4) C1: 16 (34.0) C2: 27 (42.9) *Key inclusion criteria:* Aged 21 to 75 yrs. old with pain for ≥3 mos. in lumbosacral area immediately medial and below posterior superior iliac spine with possible radiation into buttocks, posterior thigh, or groin; baseline ODI score ≥30; baseline LBP VAS ≥5 mm with no focal neurological signs. *Key exclusion criteria:* Severe residual pain due to other causes; other SI joint pathology (trauma, fracture, tumor, ankylosing spondylitis, osteitis condensans ilii, arthropathy, Reiter's syndrome, psoriatic arthritis, enteric arthritis);		C1: SI denervation of the posterior sensory rami of L4, L5, S1, S2, and S3 performed using Neurotherm, KC, Cosman 20G 145-mm needle with 10-mm exposed tip. All procedures performed in outpatient setting, and none were hospitalized. C2: Continued conservative management after the initial 6 mos. of conservative management consisting of 1) counseling for smoking cessation and weight control, 2) physiotherapist consultation regarding chronic pain behavior avoidance (stopped after 3 mos. if no improvement seen), 3) use of NSAIDs (indomethacin, naproxen sodium, or ibuprofen), and 4) steroid SI joint injections

Author (Year) Study Name; Country; Funding Source	Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description; Control Description
		recent major trauma; lack of definitive proof that pain originated in SI joint; lumbar spine instability; osteoporosis; other metabolic bone disease. Any patient with <12 mos. of follow-up after SI joint pain diagnosis.		

Note: a. The same participants receiving open fusion were used in the Ledonio et al., 2014[31] and Ledonio et al.[32] studies.

Abbreviations: C = control group; CA = California; I = intervention group; LB*P*=low back pain; mo(s). = month(s); mm = millimeters; N = number of participants; NR = not reported; NSAIDs = nonsteroidal anti-inflammatory drugs; ODI = Oswestry Disability Index; rhBM*P*=recombinant human Bone Morphogenetic Protein-2; SD = standard deviation; SI = sacroiliac; U.S. = United States; VAS = visual analog scale; wk(s). = week(s); yr(s). = year(s).

Table C-7. Efficacy outcomes from controlled cohort studies evaluating sacroiliac joint fusion—Part I

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
Claus (2020)[33]	VAS-back in mm, mean (SD) Rialto: Baseline: 81 (17) 6 mos.: 58 (34) Change: -22 (35) 1 yr.: NR Change: -28 (-33) iFuse: Baseline: 79 (25) 6 mos.: 54 (35) Change: -26 (41) 1 yr.: NR Change: -24 (49) Between-group differences (Rialto-iFuse) 6 mos.: 4.3 (95% CI, -8.7 to 17; *P*=0.53) 1 yr.: -3.7 (95% CI, -23 to 15; *P*=0.70) VAS-leg in mm, mean (SD) Rialto: Baseline: 57 (36) 6 mos.: 39 (36) Change: -18 (49) 1 yr.: NR Change: -17 (44) iFuse: Baseline: 64 (36) 6 mos.: 41 (37) Change: -23 (41) 1 yr.: NR Change: -19 (46) Between-group differences (Rialto-iFuse) 6 mos.: 3.6 (95% CI, -11 to 19; *P*=0.64) 1 yr.: 2.1 (95% CI, -19 to 23; *P*=0.84)	ODI, mean (SD) Rialto: Baseline: 53.6 (13.6) 6 mos.: 47.5 (19.8) Change: -6.6 (14.8) 1 yr.: NR Change: -8.3 (14.9) iFuse: Baseline: 55.7 (11.8) 6 mos.: 46.7 (18.0) Change: -9.6 (16.1) 1 yr.: NR Change: -6.2 (13.3) Between-group differences (Rialto-iFuse) 6 mos.: 3.0 (95% CI, -2.1 to 8.1; *P*=0.25) 1 yr.: -2.1 (95% CI, -9.2 to 4.9; *P*=0.55)	NR	SF-12 (PCS), mean (SD) Rialto: Baseline: 27.0 (5.9) 6 mos.: 30.6 (8.8) Change: 3.3 (9.3) 1 yr.: NR Change: 2.5 (5.7) iFuse: Baseline: 28.3 (6.5) 6 mos.: 29.7 (10.1) Change: 1.6 (10.1) 1 yr.: NR Change: -0.5 (9.9) Between-group differences (Rialto-iFuse) 6 mos.: 1.7 (95% CI, -1.5 to 4.9; *P*=0.28) 1 yr.: 3.0 (95% CI, -0.48 to 6.5; *P*=0.09)

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
Kibsgard (2013)[25]	Morning VAS score in mm, adjusted mean (95% CI) at 11 to 32 yrs. I: 44 (31 to 57) C: 50 (41 to 59) Calculated between-group difference (I-C): -6 (95% CI, -13.0 to 25.0) *P*=0.54 Evening VAS score in mm, adjusted mean (95% CI) at 11 to 32 yrs. I: 54 (46 to 63) C: 60 (46 to 74) Calculated between-group difference (I-C): -6 (95% CI, -10.2 to 22.2) *P*=0.50 Adjusted for BMI, age, and time at follow-up Subgroup analyses: Participants with "successful" outcomes at 1 yr. had significantly lower scores on VAS at 11 to 32 yrs. follow-up compared to participants who had 'unsuccessful' outcomes at 1 yr.	ODI, adjusted mean (95% CI) at 11 to 32 yrs. I: 33 (24 to 42) C: 37 (31 to 43) Calculated between-group difference (I-C): -4 (95% CI, -9.1 to 17.1) *P*=0.54 Adjusted for BMI, age, and time at follow-up Subgroup analyses: Participants with "successful" outcomes at 1 yr. had significantly lower scores on ODI at 11 to 32 yrs. follow-up compared to participants who had "unsuccessful" outcomes at 1 yr.	NR	SF-36 subscales, adjusted mean (95% CI) at 11 to 32 yrs. (all differences reported as nonsignificant) Physical functioning I: 45 (36 to 54) C: 48 (34 to 62) Between-group difference (I-C): -3 Role physical I: 25 (12 to 37) C: 19 (1 to 39) Between-group difference (I-C): 6 Bodily pain I: 39 (32 to 47) C: 39 (28 to 51) Between-group difference (I-C): 0 General health I: 55 (48 to 63) C: 48 (37 to 59) Between-group difference (I-C): 7 Vitality I: 46 (40 to 53) C: 36 (26 to 45) Between-group difference (I-C): 10 Social functioning I: 62 (54 to 71) C: 59 (47 to 72) Between-group difference (I-C): 3 Role emotional I: 63 (49 to 76) C: 61 (49 to 76) Between-group difference (I-C): 2

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
				Mental health I: 73 (67 to 79) C: 71 (62 to 80) Between-group difference (I-C): 2 Adjusted for BMI, age, and time at follow-up Subgroup analyses: Participants with "successful" outcomes at 1 yr. had SF-36 scores at 11 to 32 yrs. follow-up that were not significantly different from participants who had "unsuccessful" outcomes at 1 yr., except for physical functioning, which was significantly better in the group that had "success" at 1 yr.
Ledonio (2014)[32]	NR	ODI, mean (SD) I: Baseline: 61.5 (12.5) Postoperative (mean follow-up 15 mos.): 52.0 (16.9) Change: -9.5 C: Baseline: 61.8 (10.8) Postoperatively (mean follow-up 13 mos.): 47.4 (21.7) Change: -14.4 Calculated between-group differences (I-C) 4.9 (*P*=0.272)	NR	NR
Ledonio (2014)[31]	NR	ODI, median (range) I: Baseline: 53 (14 to 84) ~15 mos.: 13 (0 to 38)	NR	NR

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
		Change: -42 (0 to 80) *P<0*.0002 C: Baseline: 64 (44 to 78) ~ 15 mos.: 46 (10 to 80) Change: -9 (-56 to 8)[a] *P*<0.0005 Calculated between-group difference (I-C) -33 (*P*<0.0008) N (%) meeting MCID threshold (≥12.8 points) at follow-up I: 14 (82%) C: 10 (45%) *P*=0.0204		
Smith (2013)[30]	VAS pain score in mm, mean (SD) I: Baseline: 83 (16) (based on N=113) 1 yr.: 23 (26) (based on N=94) Adjusted change: -62 (31) 2 yrs.: 17 (29) (based on N=38) Adjusted change: -56 (35) C: Baseline: 71 (1.9) (based on N=139) 1 yr.: 46 (30) (based on N=114) Adjusted change: -27 (32) 2 yrs.: 56 (29) (based on N=58) Adjusted change: -20 (33) Between-group differences (I-C) 1 yr.: -36 2 yrs.: -37 RM adjusted: -30.2 (95% CI, -20.7 to -39.9) (adjusting for age and sex and history of prior lumbar fusion)	NR	NR	NR

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	Improvement in VAS ≥ 20 mm, N/denominator (%) I: 1 yr.: 80/94 (86.0) 2 yrs.: 31/38 (81.6) C: 1 yr.: 69/114 (61.1) 2 yrs.: 29/58 (50.0) Between-group differences: NR Substantial clinical benefit (defined as ≥25 mm decrease or raw score <35 mm), N/denominator (%) I: 1 yr.: 81/94 (86.2) 2 yrs.: 31/38 (81.6) C: 1 yr.: 66/114 (57.9) 2 yrs.: 27/58 (46.6) Between-group differences: NR Subgroup analyses at 1 or 2 yrs.: Decreases in pain scores were larger in the I arm vs. C arm among patients either with or without a history of prior lumbar fusion.			
Spain (2017)[34]	NR	NR	NR	NR
Vanaclocha (2018)[24]	VAS LBP in mm, mean Baseline and follow-up datapoints only reported in Figure 3, actual values NR. 6 mos. to ~3.5 yrs.: RM mean difference (I-C1): -45 (*P*<0.001) RM mean difference (I-C2): -60 (*P*<0.001)	ODI, mean Baseline and follow-up data points only reported in Figure 4, actual values NR. 6 mos. to ~3.5 yrs.: RM mean difference (I-C1): -17 (*P*<0.001) RM mean difference (I-C2): -24 (*P*<0.001)	NR	NR

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
		ODI, N/denominator with improvement of at least 15 points at 4 yrs. I: 15/15 (100%) C1: 0/23 (0%) C2: 0/34 (0%) (*P*<0.001)		

Note: a. Author query sent to clarify change data reported by study; author did not respond.

Abbreviations: BMI = body mass index; C = control group; CI = confidence interval; I = intervention group; LB*P*=low back pain; MCID = minimal clinically important difference; mo(s). = months; mm = millimeters; N = number of participants; NR = not reported; ODI = Oswestry Disability Index; PCS = Physical Component Score; RM = repeated measures; SD = standard deviation; SF-12 = Short form survey (12 item); SF-36 = Short form survey (36 item); VAS = visual analog scale; vs. = versus; yr(s). = year(s).

Table C-8. Efficacy outcomes from controlled cohort studies evaluating sacroiliac joint fusion—Part II

Author (Year)	Opioid Use	Return to Work	Global Recovery or 'Success'	Nonunion	Length of Stay
Claus (2020)[33]	NR	NR	NR	NR	Length of stay (days), mean (SD) Rialto: 1.7 (0.93) iFuse: 1.8 (0.93) *P*=0.42
Kibsgard (2013)[25]	NR	NR	N (%) with success at 1 yr. I: Successful: 24 (48) Partly successful: 12 (24) Unsuccessful: 14 (28) Successful surgery defined as negative SI joint tests and no or minor pain that did not interfere with the patient's work; "partly successful" defined as obvious improvement but pain that interfered with activities; "unsuccessful" defined as no relief from pain or if joint deteriorated after surgery N (%) self-reported effect of surgery at 11 to 32 yrs. I: 65% report a positive effect (of these 74% report a good or excellent result); 18% report no effect, and 8% were uncertain	NR	NR
Ledonio (2014)[32]	NR	NR	NR	NR	Hospital length of stay in days, mean (SD) I: 2 (1.5)

Author (Year)	Opioid Use	Return to Work	Global Recovery or 'Success'	Nonunion	Length of Stay
					C: 3.3 (1.1) *P*=0.002
Ledonio (2014)[31]	NR	NR	NR	NR	Hospital length of stay in days, median (range) I: 1 (1 to 2) C: 3 (2 to 6) *P*<0.0001
Smith (2013)[30]	NR	NR	NR	NR	Hospital length of stay in days, mean (SD) I: 1.3 (0.5) (based on 30 of 114 patients) C: 5.1 (1.9) (based on 137 of 149 patients) (*P*<0.0001)
Spain (2017)[34]	NR	NR	NR	NR	NR
Vanaclocha (2018)[24]	N (%) taking opioids I: Baseline: 17 (63.0) 1 mo: 4 (14.8) Change: -13 (-48.2) 6 mos.: 2 (7.4) Calculated change: -15 (-55.6) Last follow-up: 2 (7.4) Calculated change: -15 (-55.6) (*P*=0.0003, baseline vs. last follow-up) C1: Baseline: 26 (55.3) 1 mo.: 8 (17.0) Change: -18 (-38.3) 6 mos.: 8 (17.0) Calculated change: -18 (-38.3) Last follow-up: 40 (85.1) Calculated change: 14 (29.8)	N (%) working at last follow-up I: 19 (70.4%) C1: 16 (34.0%) C2: 12 (19.0%) Between-group difference: *P*<0.001	NR	NR	All SI joint fusion patients were discharged the day following surgery.

Author (Year)	Opioid Use	Return to Work	Global Recovery or 'Success'	Nonunion	Length of Stay
	(*P*=0.0012, baseline vs. last follow-up) C2: Baseline: 31 (49.2) 1 mo.: 27 (42.9) Calculated change: -4 (-6.3) 6 mos.: 28 (44.4) Calculated change: -3 (-4.8) Last follow-up: 53 (84.1) Calculated change: 22 (34.9) (*P*<0.0001, baseline vs. last follow-up) Calculated difference in use (I-C1) 6 mos.: -9.6% (95% CI, -24.21% to 5.0%; *P*=0.25) Last follow-up: -77.7% (95% CI, -91.9% to -63.5%, *P*<0.001) Calculated change in use (I-C1) 1 mo.: -9.9% 6 mos.: -17.3% Last follow-up: -85.4% Calculated difference in use (I-C2): 6 mos.: -37.04% (95% CI, -52.79% to -21.29%; *P*<0.001) Last follow-up: -76.72% (95% CI, -90.10% to 63.34%; *P*<0.001) Calculated change in use (I-C2) 1 mo.: -41.9% 6 mos.: -50.8% Last follow-up: -90.5%				

Author (Year)	Opioid Use	Return to Work	Global Recovery or 'Success'	Nonunion	Length of Stay
	Oral morphine equivalents in mg/day, mean (range) Last follow-up I: 3.1 (0 to 60) C1: 32.2 (0 to 133) C2: 38.5 (0 to 98) Between-group difference *P*<0.001				

Abbreviations: ARD = absolute risk difference; C = control group; CI = confidence interval; I = intervention group; mg = milligrams; mo(s). = month(s); N = number of participants; NR = not reported; SD = standard deviation; SI = sacroiliac; vs. = versus; yr(s). = year(s).

Table C-9. Safety outcomes from controlled cohort studies evaluating sacroiliac joint fusion—Part I

Author (Year)	Adverse Events	Revision
Claus (2020)[33]	Total N analyzed: 156 N (%) with postoperative complications at 1 yr. Rialto: 6 (6.1) due to persistent SI joint pain resulting in revision surgery iFuse: 2 (2.4) with symptoms (unspecified) resulting in revision surgery	Revision rate, N (%) Rialto: 6 (6.1) (due to persistent SI joint pain with radiographic evidence of lucency or nonunion) iFuse: 2 (2.4) *P*=0.11 Calculated ARD -5.7% (95% CI, -12.7% to 1.4%) Calculated RR 0.30 (95% CI, 0.06 to 1.44) Time to revision (months), mean (SD) Rialto: 13 (11.4) iFuse: 42 (33) *P*=0.55
Kibsgard (2013)[25] N analyzed=78	Postoperative complications I: 3 (6%) 1 icterus of unknown etiology 1 pulmonary embolism 1 pin tract infection after the use of a Hoffman frame C: NR Postoperative complications not related to the fusion surgery I: 2 (4%) 1 acute appendicitis 1 surgery for a small bowel obstruction C: NR	Revisions (time frame unspecified) I: 7 of 83 joints (8.4% of joints) (4 due to pseudoarthrosis, 3 due to unspecified symptoms) C: NR
Ledonio (2014)[32] N analyzed=44	Postoperative complications I: 3 (13.6%) 1 pulmonary embolism 2 recurring SI joint pain with halo formation on the sacral side resulting in revision surgery C: 3 (13.6%) 1 pulmonary embolism 2 nerve root irritation resulting in revision surgery	Revisions I: 2 (9.1%) (due to halo formation on the sacral side with recurring sacroiliac joint pain) C: 2 (9.1%) (for failed implant and nerve root irritation) *P*=1.00 Calculated ARD 0.0% (95% CI, -51.5% to 51.4%) Calculated RR 1.0 (95% CI, 0.36 to 2.79)
Ledonio (2014)[31] N analyzed=39	Intraoperative complications I: 0 C: NR Postoperative complications	Revision surgery I: 1 (5.9%) (removal of device due to malposition) C: 2 (9.1%) (failed implant and nerve root irritation) *P*=0.77 Calculated ARD -3.2% (95% CI, -19.6% to 13.2%)

Author (Year)	Adverse Events	Revision
	I: 6 (35.3%) 1 hematoma at operative site 3 transient trochanteric bursitis 1 transient toe numbness 1 malpositioned implant resulting in revision surgery C: 3 (13.6%) 1 pulmonary embolism 2 nerve root irritation resulting in revision surgery *P*=0.08 Calculated ARD 32.3% (95% CI, -0.03% to 67.20%) Calculated RR 1.93 (95% CI, 0.997 to 3.770)	Calculated RR 0.65 (0.06 to 6.55)
Smith (2013)[30] N analyzed=263	Intraoperative complications I: 0 C: 0 Postoperative adverse events I: 20 (18%) C: 34 (reported as 21%, 22.8%) *P*=0.294 Calculated ARD -7.9% (95% CI, -22.5% to 6.6%) Calculated RR 0.82 (0.56 to 1.20) Specific postoperative adverse events Device issues (screw loosening, screw replacement misplacement) I: 0 C: 2 (1.3%) Wound infection I: 1 (0.9%) C: 3 (2.0%) Cellulitis I: 3 (2.6%) C: 1 (0.7%) Wound-related issues (dehiscence, seroma, lipoma on wound scar requiring surgical removal) I: 0 C: 4 (2.7%) Various types of pain (low back, facet, buttock, iliotibial band, piriformis, neuropathy, etc.) I: 10 (8.8%) C: 18 (12.1%)	Removal or repositioning of spinal implants I: 4 (3.5%) C: 66 (44.3%) *P*<0.001 Calculated ARD -40.8% (95% CI, -49.51% to -32.1%) Calculated RR 0.08 (95% CI, 0.03 to 0.21) In the I arm, patients underwent postoperative repositioning of implants either because of nerve root impingement (n=3) or based on the surgeon's discretion based on radiographic findings (n=1). In the C arm, implants were removed mostly because of pain at the iliac or sacral screw from pseudoarthrosis, screw loosening, and spinal implant irritation.

Author (Year)	Adverse Events	Revision
	Falls I: 4 (3.5%) C: 2 (1.3%) Deep vein thrombosis or pulmonary embolism I: 0 C: 3 (2.0%) Buttock hematoma I: 2 (1.8%) C: 0 Pneumothorax I: 0 C: 1 (0.7%)	
Spain (2017)[34] N analyzed=292	Postoperative complications I: 12 (4.6%) resulting in revision surgery (1 trauma from fall and NR cases with pain and other symptoms [unspecified] from malposition and loosening of the implant) C: 19 (65.5%) with pain and other symptoms (unspecified) resulting in revision surgery	Revision surgery I: 12 (4.6%) (mean follow-up time 2.8 yrs., [SD 3.2], primarily due to trauma from fall [1 case] or malposition and loosening of the implant (number of cases NR). C: 19 (65.5%) (mean follow-up time 4.6 yrs. [SD 4.9]), primarily due to loosening and recurrence of pain *P*<0.001 Calculated ARD -61.0% (95% CI, -78.4% to -43.5%) Calculated RR 0.07 (95% CI, 0.04 to 0.13) Cumulative probability of revision (out to 10 yrs.): I: NR C: 79.8% (*P*<0.0001) Cumulative probability of revision (out to 4 yrs.): I: 5.7% C: 30.8% *P* value NR ***Subgroup analysis*** No predictors of revision other than type of initial surgery used.
Vanaclocha (2018)[24] N analyzed=137	Serious adverse events I: NR C1: 0 C2: 0	Revision surgery I: 0

Author (Year)	Adverse Events	Revision
	Temporary postoperative sciatic pain due to advancement of Steinman pin into sacral foramen I: 2 (*7.4%*)	

Abbreviations: ARD = absolute risk difference; C = control group; CI = confidence interval; I = intervention group; N = number of patients; NR = not reported; RR = risk ratio; SD = standard deviation; yr(s). = year(s).

Table C-10. Safety outcomes from controlled cohort studies evaluating sacroiliac joint fusion—Part II

Author (Year)	Intraoperative Blood Loss	Duration of Surgery
Claus (2020)[33] N analyzed=156	Estimated blood loss in mL, mean (SD) Rialto: 39.6 (26.3) iFuse: 50.9 (44.1) Calculated between-group difference (Rialto-iFuse): 11.3 (*P*=0.054)	Surgery length in minutes, mean (SD) Rialto: 60.0 (18.8) iFuse: 41.2 (12.5) Calculated between-group difference (Rialto-iFuse): 18.8 (*P*<0.0005)
Kibsgard (2013)[25] N analyzed=78	NR	NR
Ledonio (2014)[32] N analyzed=44	Estimated blood loss in mL, mean (SD) I: 40.5 (31.4) C: 681.8 (479.0) *P*<0.001	Length of surgery in minutes, mean (SD) I: 68.3 (26.8) C: 128.0 (27.9) *P*<0.001
Ledonio (2014)[31] N analyzed=39	NR	Surgical time in minutes, mean (range) I: 27 (18 to 72) C: 128 (73 to 180 mins) *P*<0.0001
Smith (2013)[30] N analyzed=263	Estimated blood loss in mL, mean (SD) I: 33 (27) (based on 66 of 114 patients) C: 288 (182) (based on 138 of 149 patients) *P*<0.0001	Operating room time in minutes, mean (SD) I: 70 (24) (based on 63 of 114 patients) C: 163 (25) (based on 100 of 149 patients) *P*<0.0001
Spain (2017)[34] N analyzed=292	NR	NR
Vanaclocha (2018)[24] N analyzed=137	Mean (range): 58 (40-70) mL	Unilateral: 48 mins Bilateral (n=3): Similar time per side, but procedures were about 15 mins. longer because of need to rearrange X-ray arches

Abbreviations: C = control group; I = intervention group; mins. = minutes; mL = millimeters; NR = not reported; SD = standard deviation.

Table C-11. Study characteristics of uncontrolled studies evaluating sacroiliac fusion

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Al-Khayer (2008)[113] U.K.; Funding source NR	Retrospective, uncontrolled cohort N treated: 9	Single site, 2000 to 2006 Mean age (SD) (range): 42.4 (6.5) (35-56) N (%) female: 9 (100) Mean duration of pain (SD) (range), months: 30 (21) (12-84) N (%) with prior lumbar fusion: NR *Key inclusion criteria*: Chronic SI joint pain; failure of rigorous conservative treatment; minimum of 24 mos.' follow-up *Key exclusion criteria:* Other pain sources, including lumbar disc prolapse and degenerative spinal disease	Use of Patrick (Faber) test (positive in 8/9 patients). Plain radiographs of pelvis and lumbosacral region, with occasional use of other radiologic investigations to exclude other pain sources. Diagnosis confirmed based on temporary pain relief with SI joint block	Percutaneous SI joint fusion using a Hollow Modular Anchorage (HMA) screw (hollow cylindrical titanium implant with surface roughness and a spiral thread design to promote stability, combined with autologous bone graft made from bone reaming and demineralized bone matrix); minimally invasive lateral approach 3 bilateral 6 unilateral
Araghi (2017)[109] EVSI; NCT02074761 U.S.; Zyga Technology, Inc. (Minnetonka, MN)	Uncontrolled trial N eligible: NR N analyzed: 50 (this report is for the first 50 patients; target enrollment is 250 patients)	13 sites in U.S., 2014 to ongoing Mean age (SD) (range): 61.5 (13.7) (21.7 to 85.1) N (%) female: 29 (58.0) Mean duration of pain, N (%): 6 mos. to 1 yr.: 13 (26) 1 yr. to 2 yrs.: 10 (20.0) >2 yrs.: 27 (54.0) N (%) with prior lumbar fusion: 14 (28.0) *Key inclusion criteria*: Age ≥18 yrs.; at least 6 mos. of nonoperative management; VAS SI joint pain score ≥60; ODI score at least 40 *Key exclusion criteria:* Pelvic soft tissue or bony tumors, trauma causing fracture or leading to neurological deficit, central nervous system disorders, painful hip or knee arthrosis, awaiting other spine surgery, pregnancy; receiving worker's compensation or disability or involved in litigation related to low back or SI joint pain	3 positive provocative tests; at least 1 positive diagnostic SI joint injection	SImmetry System (titanium cannulated and antirotational implants with surface roughness to promote bony growth combined with autologous bone with or without allograft or demineralized bone matrix); minimally invasive lateral approach 1 bilateral 49 unilateral

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Beck (2015)[114] U.S.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 20	Single site, study dates NR Mean age (range): 57.7 (33 to 84) N (%) female: 17 (85) Mean duration of symptoms/pain: NR N (%) with prior lumbar fusion: NR *Key inclusion criteria:* Patients testing positive for SI joint pain and who underwent SI joint fusion surgery *Key exclusion criteria:* NR	Subjective reports of SI joint pain, positive point provocation, and localized pain in SI joint; diagnostic/therapeutic intraarticular SI injections, with patients who reported substantial pain relief lasting 1 day or more being deemed positive; CT or MRI imaging used to exclude lumbar and hip pathology as sources of pain	INTERFIX system (single-threaded titanium cage filled with INFUSE [rhBMP-2]; minimally invasive posterior approach using 1 of 2 techniques: a posterior medial oblique procedure (n=first 6) or a modified posterior lateral procedure (n=remaining 14) 13 bilateral 7 unilateral
Belanger (2001)[47] U.S.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 4	Single site, 10-yr. period prior to 2000 Mean age (range): NR (38 to 73) N (%) female: 3 (75) Mean duration of symptoms/pain: NR N (%) with prior lumbar fusion: 3 (75) *Key inclusion criteria:* Patients with chronic SI disease over a 10-yr. period (1989-1999); failure of prolonged conservative treatment (range: 6-18 mos.) *Key exclusion criteria:* NR	Low back and buttock pain, SI joint tenderness and irritability with a positive Faber's test, pelvic rocking, or Gaenslen's maneuver; radiographic evidence of SI arthrosis; a 2-wk. trial of pantaloon casting; immobilization and diagnostic/therapeutic intra-articular joint injections	Posterior open SI joint fusion using a low, midline posterior incision, pedicle screws, and ipsilateral iliac bone graft N bilateral vs. unilateral: NR
Bornemann (2017)[58] Germany; Funding source NR	Study design unclear N analyzed: 24	Single site, study dates NR Mean age (SD): 54.9 (14.5) N (%) female: 22 (91.6) Mean duration of symptoms/pain: NR N (%) with prior lumbar fusion: 0 *Key inclusion criteria:* Adults with chronic, severe, limiting SI joint syndrome who failed conservative treatment (no time period specified)	Distraction test, compression test, Gaenslen's maneuver, Patrick's test (unclear whether 1 or more than 1 exam finding was required for diagnosis)	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach N bilateral vs. unilateral: NR

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key exclusion criteria: <18 years old, allergies/intolerances to titanium, pregnancy, local infections		
Buchowski (2005)[53] U.S.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 20	Single site, 1994 to 2001 Mean age (SD): 45.1 (12.7) N (%) female: 17 (85) Mean duration of symptoms/pain, years (SD): 2.6 (1.9) N (%) with prior lumbar fusion: 12 (60) *Key inclusion criteria*: Adults with SI joint disorders and treated surgically between December 1994-December 2001 and who had ≥24 mos. follow-up *Key exclusion criteria:* Concomitant other procedures at the time of SI joint fusion; fewer than 24 mos. follow-up	Complaints of low back, buttock, or leg pain; failed traditional conservative treatment; palpation tests, Patrick's test, Gaenslen's maneuver, compression test, and hip abduction test; surgical treatment was recommended only after subsequent radiographic and interventional testing, including multiple intra-articular SI joint injections (mean: 2.7; range: 2 to 4)	Modified Smith-Petersen technique using an open posterior approach and stabilization with a T- or L-plate and screws N bilateral vs. unilateral NR
Cher (2018)[42] U.S. and Canada; SI-BONE, Inc.	Retrospective, single group cohort (or registry) N analyzed: 14,210	Postmarketing surveillance data of device reports and internal company inventory management database, 2015 to 2018 Mean age (SD): NR N (%) female: NR Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: NR *Key inclusion criteria*: Cases of minimally invasive SI joint fusion with iFuse Implant System in U.S. and Canada and tracked in manufacturer's database *Key exclusion criteria:* Cases of unapproved use of device or cases where use was to address the failure of another SI joint fusion device; cases occurring outside of U.S. or Canada	NR	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach. 11,070 cases using original (machined) implants; 3,140 cases using 3D-printed implants (available starting in Q2 of 2017) 10% were planned bilateral procedures

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Cher (2015)[68] U.S.; SI-BONE, Inc.	Retrospective uncontrolled cohort N analyzed: 11,388	Postmarket surveillance reports and internal company inventory management database, 2009 to 2014 Mean age: 55.8 N (%) female: 6,709 (59) Mean duration of symptoms/pain: NR N (%) with prior lumbar fusion: NR *Key inclusion criteria*: Cases of minimally invasive SI joint fusion performed with iFuse Implant System in U.S. and tracked in manufacturer's database *Key exclusion criteria*: Index cases that were inconsistent with the device's labeled instructions for use (of 11,416 cases in the database, 28 were excluded from the analysis for this reason)	NR	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 432 (3.8%) bilateral 10,956 (96.2%) unilateral
Cleveland (2019)[39] U.S.; Funding source NR	Retrospective, single group cohort (or registry) N eligible: 50 N analyzed: 50 (57 procedures)	Single site and two surgeons, 2011 to 2016 Mean age (SD): 51 (13.4) N (%) female: 38 (76.0) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: NR *Key inclusion criteria*: Age ≥18 yrs. at time of surgery, underwent primary SI fusion using the authors' technique, and had at least one postoperative follow-up visit at 6 wks. *Key exclusion criteria:* Having revision SI procedures, having SI arthrodesis by any other technique, or undergoing concomitant spine procedures	Extensive preoperative workup; steroidal injection relieve patients SI joint pain temporarily	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 7 bilateral 43 unilateral
Cross (2018)[119] NCT02425631; U.S.; Zyga Technology, Inc.	Uncontrolled cohort N eligible: NR N treated: 19	3 sites, 2014 to 2016 Mean age (SD) (range): 60.1 (13.7) (30.8 to 84.4) N (%) female: 15 (79) Mean duration of symptoms/pain: NR N (%) with prior lumbar fusion: NR	NR	SImmetry System (titanium cannulated and antirotational im plants with surface roughness to promote bony growth combined with autologous bone or demineralized bone matrix;

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key inclusion criteria: Minimally invasive SI joint fusion within prior 1 yr. *Key exclusion criteria*: None		minimally invasive lateral approach 0 bilateral 19 unilateral
Cummings (2013)[59] U.S.; Funding source NR	Retrospective uncontrolled cohort N eligible and analyzed: 18	Single center, 2011 to 2012 Mean age (SD) (range): 64 (12.2) (39-81) N (%) female: 12 (67) Mean duration of symptoms/pain (SD or range): NR N (%) with prior lumbar fusion: 15 (83) *Key inclusion criteria:* Minimally invasive SI joint fusion more than 1 yr. ago; unilateral surgery *Key exclusion criteria:* Concomitant spine procedures; bilateral SI joint fusion; lack of preoperative or follow-up outcome reporting	Detailed history, clinical exam (positive results on ≥3 pain provocation tests), imaging, and positive diagnostic injections (positive results defined as 75% reduction in pain immediately following injection); failure of conservative treatment for ≥6 mos.	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 0 bilateral 18 unilateral
Darr (2018);[56] Darr (2018);[57] Whang (2019)[120] LOIS (Long Term outcomes from INSITE and SIFI); NCT02270203; U.S.; SI-BONE, Inc.	Prospective uncontrolled cohort N eligible: 127 N enrolled: 103 N analyzed: 97 at 3 yrs.; 94 at 4 yrs.; 93 at 5 yrs.	12 sites, 2012 to ongoing Mean age (SD): 50.8 (10.8) N (%) female: 75 (72.8) Mean duration of symptoms/pain, years (SD): 5.7 (6.8) N (%) with prior lumbar fusion: 46 (44.7) Key inclusion criteria: Participants from 12 of the 39 sites that conducted the INSITE and SIFI trials and who agreed to participate in long-term follow-up; all participants underwent SI joint fusion with iFuse Implant system and as part of the INSITE or SIFI trials and satisfied those studies' criteria Key exclusion criteria: None specific to LOIS; exclusion from SIFI and INSITE included severe low back or hip pain due to other conditions; SI joint dysfunction due to autoimmune or inflammatory conditions and osteoporosis	Same as reported in INSITE and SIFI trials: clinical history; positive Fortin finger test; ≥3 of 5 positive physical exam signs suggesting SI joint dysfunction; positive diagnostic SI joint block, defined as 50% decrease in pain	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 10 bilateral 93 unilateral
Duhon (2013);[55] Duhon (2016);[124]	Uncontrolled trial	26 sites, 2012 to 2015 Mean age (range): 50.9 (23.5 to 71.6)	Clinical history of pain at or near SI joint; ≥3 of 5	iFuse Implant System (triangular titanium implant coated with

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Duhon (2016)[125] Sacroiliac Joint Fusion with iFuse Implant System (SIFI); NCT01640353; U.S.; SI-BONE, Inc.	N eligible: 194 N treated: 184 N analyzed: 172 at 1 yr.; 169 at 2 yrs.	N (%) female: 120 (69.8) Mean duration of pain, years (range): 5.1 (0.43 to 41.08) N (%) with prior lumbar fusion: 76 (44.2) *Key inclusion criteria:* Adults aged 21 to 70 yrs. with low back pain for ≥6 mos.; inadequate response to conservative treatment; baseline VAS SI joint pain score of ≥50 mm; ODI score of ≥ 30; diagnosed SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption *Key exclusion criteria:* Severe low back due to other conditions; diagnosed sacral pathology of other origin; recent (<1 yr.) major pelvic trauma; metabolic bone disease; chronic rheumatologic condition or chondropathy; titanium allergy; use of medications that impair bone quality or soft-tissue healing; neurologic conditions that would interfere with physical therapy; infection; pregnancy; drug abuse; psychiatric conditions that could interfere with study participation; currently a prisoner or ward of state; participation in another investigational study; involvement in litigation; on disability leave; receiving workers' compensation related to back or SI joint pain	positive physical exam signs suggesting SI joint dysfunction; positive diagnostic SI joint block, defined as ≥50% decrease in pain	porous titanium plasma spray); minimally invasive lateral transiliac approach 14 bilateral 158 unilateral
Fuchs (2018)[54] Germany; SIGNUS medizintechnik GmbH	Uncontrolled trial N enrolled: 171 N analyzed: 137 at 1 yr. and 132 at 2 yrs.	20 sites, 2011 to 2012 Mean age (range): (combining data for males and females) 53-54 (21-82) N (%) female: 115 (67) Mean duration of pain, years: 4.5 N (%) with prior lumbar operation: 77 (45) *Key inclusion criteria:* Chronic SI joint pain persisting for ≥6 mos.; failed conservative treatment lasting ≥6 mos.	Diagnosis and decision to pursue surgery based on conclusive combination of medical history, clinical tests, SI joint injections, and imaging. Not necessary for all criteria to be fulfilled. More specifically, combination of provocation tests; peri- or intra-articular	DIANA (distraction interference arthrodesis) implant system (insertion of an interference screw in SI joint recess between sacrum and ilium at the S2 level to bring about distraction near the joint and cause a repositioning of joint surfaces, combined with use of allograft material); open posterior approach

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key exclusion criteria: Multiple prior SI joint surgical procedures; sacral insufficiency fractures; bony defects in recess of ilium and sacrum following bone graft harvesting; bacterial infections; tumors; patients with ongoing pension claims or on disability	SI joint injections performed additionally, with positive results defined as pain reduction of 50% or more; X-ray and CT scans of both SI joints	7 bilateral 164 unilateral
Gaetani (2013)[60] Italy; Funding source NR	Retrospective uncontrolled cohort N analyzed: 10	Single center, 2012 to 2013 Mean age (range): 53.2 (36-71) N (%) female: 10 (100) Mean duration of pain: NR N (%) with prior treatment for lumbar instability: 1 (10) Key inclusion criteria: Diagnosis of SI joint instability/disruption Key exclusion criteria: NR	Combination of clinical symptoms, provocative SI joint pain maneuvers, radiographic imaging, and positive diagnostic SI joint blocks; failure of conservative treatment (i.e., intensive physical therapy) lasting ≥4 mos.	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 1 bilateral 9 unilateral
Kancherla (2017)[115] U.S.; Funding source NR	Retrospective uncontrolled cohort N eligible: 57 patients (61 cases) N analyzed: 41 patients (45 cases)	Single center, 2012 to 2014 Mean age (SD, range): 52.7 (12.1, 33.3 to 84.5) N (%) female: 31 (68.9) Mean duration of pain: NR N (%) with prior thoracolumbar surgery: 16 (35.6) *Key inclusion criteria*: Patients who underwent SI joint fusion *Key exclusion criteria*: Age <18; infection; previous SI joint surgery; alternative etiology for back pain besides SI joint pain	Clinical history, ≥3 positive on 3 or more physical provocative maneuvers, single SI joint diagnostic injection with improvement in pain (minimum required reduction in pain NR); failure of conservative, nonsurgical treatment (minimum duration NR)	2 different implants were used. • iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach (N=36 cases, but N patients was NR) • SAMBA Screw System (fenestrated screw used in combination with bone autograft or allograft); minimally invasive lateral transiliac approach (N=9 cases, but N patients was NR) 4 patients (8 cases) bilateral 37 patients (37 cases) unilateral

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Khurana (2009)[116] U.K.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 15	Single site, 2004 to 2007 Mean age (range): 48.7 (37.3 to 62.6) N (%) female: 11 (73) Mean duration of pain: NR N (%) with prior lumbar fusion: NR N (%) with prior spine surgery: 6 (40) *Key inclusion criteria*: Consecutive patients who underwent SI joint fusion for a chronic nontraumatic condition *Key exclusion criteria:* Additional pelvic pathology; required further surgery; history of operations for SI joint injuries	Positive physical provocative maneuvers (i.e., Patrick's test, Gaenslen's maneuver, and confirmed tenderness over posterior SI joint), diagnostic imaging, and SI joint diagnostic injections with positive subjective result (minimum required reduction in pain NR)	Percutaneous technique using Hollow Modular Anchorage screws (Aescalup Ltd., Tuttlingen, Germany) packed with demineralized bone substitute (DBX, Synthes Inc.) 4 bilateral 11 unilateral
Kibsgard (2014)[51] NCT00900601; Norway; Industry (Sophies Minde Ortopedi AS) and nonprofit (Norwegian Foundation for Health) funding	Uncontrolled trial N eligible: 9 N analyzed: 8	Single site, 2007 to 2010 Mean age (range): 40 (33-47) N (%) female: 8 (100) Mean duration of pain (range) in years: 11 (2-25) N (%) with prior lumbar fusion: NR *Key inclusion criteria*: Patients with severe pelvic girdle pain located at 1 or more pelvic joints; minimum ≥2 of 5 positive pain provocation tests; high pain and disability score (ODI >40 or VAS >50); adequate physiotherapy over time without positive effect *Key exclusion criteria:* Known psychiatric diagnosis; another spine pathology; CT-verified ankylosis; BMI >30	Three clinical exams with positive physical provocative maneuvers, diagnostic imaging, and SI joint diagnostic injections with positive subjective result (no minimum required reduction in pain, since 3/8 patients reported no pain relief)	Unilateral fusion of most painful SI joint and symphysiodesis using 2 AO-DC plates (Synthes, Synthes GmbH, Switzerland) in combination with bone graft and a Matta plate (Stryker, U.S.); open, anterior approach
Kleck (2016)[61] U.S.; Funding source NR (all but 2 authors disclosed financial relationships with multiple drug and/or medical device manufacturers)	Retrospective uncontrolled cohort N analyzed: 47	Single site, time period NR Mean age (range): 51 (25 to 82) N (%) female: 33 (70%) Mean duration of pain, years: NR N (%) with prior lumbar fusion: NR	Positive provocative physical examination maneuvers, with greater than 80% pain relief from SI joint injection	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach with O-arm and StealthStation navigation

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key inclusion criteria: Aged 18 to 85 yrs.; failed at least 6 mos. of nonoperative management		41 unilateral 6 bilateral
Kube (2016)[117] U.S.; Funding source NR	Retrospective uncontrolled cohort N treated: 18 patients/20 procedures N analyzed: 15 patients/17 procedures	Single site, 2011 to 2014 Mean age (SD): 47.2 (14.2) N (%) female: 10 (56) Mean duration of pain, years: NR N (%) with prior lumbar fusion: 4 (22) *Key inclusion criteria:* Underwent SI joint fusion at the institution *Key exclusion criteria:* NR	Physical examination of the SI joint; 2 diagnostic injections with a minimum of 75% pain relief prior to being deemed a candidate for surgery	SImmetry System (titanium cannulated and antirotational implants with surface roughness to promote bony growth combined bone graft; minimally invasive lateral approach 16 unilateral 2 bilateral
Mao (2018)[43] U.S.; Funding source NR	Retrospective, single group cohort (or registry) N eligible: 24 N analyzed: 24	Single surgeon, 2012 to 2014 Mean age (SD) (range): 57.3 (11.7) (35 to 80 yrs.) N (%) female: 19 (79.2) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: 13 (54.2) *Key inclusion criteria*: Underwent minimally invasive SI fusion between 2012 and 2014 with at least 12 mos. of follow-up after surgery. Clinical diagnosis of SI joint pain and failed at least 6-8 wks. of conservative management *Key exclusion criteria:* NR	Localized SI joint pain with positive Fortin finger test or pain over posterior superior iliac spine; five exam maneuvers (distraction, compression, FABER test [Patrick's test], thigh thrust, and Gaenslen's maneuver; threshold number of tests required to be positive NR); >50% improvement of symptoms after fluoroscopically guided intra-articular injection	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray) N bilateral vs. unilateral NR
Mason (2013)[112] U.K.; Funding source NR	Prospective uncontrolled cohort N treated: 73 N analyzed: 55	Single center, 2004 to 2011 Mean age (range): 57.0 (30 to 86) N (%) female: 46 (84) Mean duration of pain, years: NR N (%) with prior lumbar fusion: 22 (40) *Key inclusion criteria:* Exhausted conservative management, including SI joint specific rehabilitation	A corroborative history and physical assessment including the use of provocative tests, X-rays to exclude other pathology, diagnostic SI joint injection with significant improvement	Percutaneous iliosacral screw fixation with hollow modular anchorage screws (Aescalup Ltd, Tuttlingen, Germany), which is a plasma-sprayed titanium cage that is filled with a bone substitute (DBX, Demineralised Bone Matrix, Synthes Inc., West

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key exclusion criteria: NR		Chester, PA, USA) prior to insertion N bilateral vs. unilateral NR
McGuire (2012)[118] U.S.; Funding source NR	Retrospective uncontrolled cohort N treated: 37 patients/38 procedures N analyzed: 34 at 1 yr., 30 at 2 yrs.	Single site, 1985 to 2006 Mean age (range): 42.5 (23 to 63) N (%) female: 34 (92) Mean duration of pain, years: NR N (%) with prior lumbar fusion: NR *Key inclusion criteria:* SI joint pain unrelieved with conservative treatment but substantial pain relief with diagnostic SI joint injections using 2 separate computed tomographic (CT)-directed injections with long- and short-duration anesthetic *Key exclusion criteria:* Patients not obtaining relief from diagnostic blocks	NR	Minimally invasive fusion using dual fibular dowel allografts 36 unilateral 1 bilateral
Miller (2013)[62] U.S. and Europe; SI-BONE, Inc.	Retrospective uncontrolled cohort N treated: 5,319 (n=4,962 in U.S.) (n=357 in Europe)	Postmarketing surveillance database, 2009 to 2013 Mean age: NR N (%) female: NR Mean duration of pain, years: NR N (%) with prior lumbar fusion: NR	NR	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach N bilateral vs. unilateral NR
Mohit (2020)[46] U.S.; Musculoskeletal Education and Research Center (MERC), a Division of Globus Medical, Inc. (GMI)	Retrospective, single group cohort (or registry) N eligible: 47 N analyzed: 44 at 1 yr., 33 at 2 yrs.	Setting NR, 2013 to 2017 Mean age (SD) (range): 68.8 (9.4) (44 to 84) N (%) female: 29 (61.7) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: 41 (87.2) *Key inclusion criteria*: Patients with sacroiliitis or SI joint dysfunction; failed conservative treatment; underwent SI joint fusion using hydroxyapatite-coated screws from November 2013 to December 2017	Diagnosis based on North American Spine Society guidelines for the diagnosis of SI joint dysfunction (3 of 5 positive provocative physical exam maneuvers and 50 to 75% pain relief after anesthetic intra-articular SI joint injection)	SI-LOK (hydroxyapatite-coated SI joint screws) 9 bilateral 35 unilateral

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key exclusion criteria: NR		
Montenegro (2021)[45] U.S.; Funding: None	Retrospective, single group cohort (or registry) N eligible: 96 N analyzed: 96 N analyzed (I): 96	Single site and surgeon, 2014 to 2020 Mean age (SD): 54.2 (13.12) N (%) female: 66 (68.7) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: 51 (53.12) *Key inclusion criteria*: Age ≥18 with SI joint dysfunction; underwent a minimally invasive SI joint fusion; had ≥3 mos. follow-up *Key exclusion criteria:* NR	Fulfilled the North American Spine Society (NASS) coverage guidelines for minimally invasive SI fusion	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach guided by fluoroscopy or stereotactic navigation 0 bilateral 96 unilateral
Murakami (2018)[37] Japan; Funding source NR	Prospective, single group cohort (or registry) N eligible: 45 N analyzed: 27	Setting NR (surgeries performed by study authors), 2001 to 2015 Mean age (range): 49 (24 to 86) N (%) female: 16 (59) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: 3 (11) *Key inclusion criteria*: Underwent SI joint surgery between 2001 and 2015. SI joint pain with inadequate response to conservative treatments including stabilization by pelvic belt, manipulation, or SI joint injections for ≥6 mos. and marked restrictions in daily living. *Key exclusion criteria:* Inflammatory findings in blood tests or on radiological examination.	Radiographs and CT scans to examine preoperative joint changes and inflammatory disease for all patients; MRI for patients with suspected lumbar spine diseases (disc herniation and canal stenosis Diagnosis of SI joint pain was based on pain over the SI joint, at least 3 positive provocative physical exam maneuvers (Gaenslen's maneuver, Patrick's test, or SI joint shear test), and reproduction of pain when an injection needle inserted into the SI joint and improvement of at least 70% after local anesthetic block placed under imaging guidance	Open SI joint fusion using either anterior approach along the iliac crest (n=14, done in earlier period) or anterior approach along the pararectals (n=13, current process). Authors switched to pararectal approach based on early problems with iliac muscle detachment and lateral femoral cutaneous nerve injury from initial anterior approach.

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Nystrom (2017)[49] Sweden; Funding source NR	Uncontrolled trial N treated: 55 N analyzed: 50	Single site, 2000 to 2006 Mean age (range): 45 (28 to 65) N (%) female: 55 (100) Mean duration of pain (range), years: 9.1 (2 to 30) N (%) with prior lumbar fusion: NR N (%) with prior lumbar surgery: 15 (27) *Key inclusion criteria:* Long-term pelvic pain suspected to emanate from the SI joint or ligamentous structures; failed multiple conservative therapies including manipulation, pelvic belt, massage, chiropractic, and physical therapy *Key exclusion criteria*: NR	Normal neurological exam, at least 3 of 7 physical provocative tests, percutaneous mechanical provocation, positive response to extra-articular SI injections	Open fusion using anterior approach N bilateral vs. unilateral NR
Patel (2019);[35] Patel (2020)[36] SALLY (Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants); NCT03122899; U.S.; SI-BONE, Inc.	Uncontrolled (single arm) trial N eligible: 51 N analyzed: 46 at 12 mos.	11 sites in U.S., 2017 to ongoing Mean age (SD): 53.2 (15) N (%) female: 39 (76.5) Mean duration of pain (SD): 8.1 (8.9) yrs. N (%) with lumbar fusion: 16 (31.4) *Key inclusion criteria*: Underwent SI joint fusion surgery between October 2017 and January 2019. Adults aged 21 to 70 yrs. with SI joint pain due to degeneration or disruption of the joint for ≥6 mos. inadequately responsive to conservative care; ODI score of ≥30; VAS SI joint pain score ≥50 *Key exclusion criteria:* Bilateral SI joint symptoms with pain scores >50 but refusal to undergo bilateral treatment within the study; pregnant or attempting pregnancy; severe back or hip pain due to other causes; SI joint dysfunction due to inflammatory condition, tumor, infection or unstable/acute fracture; recent major trauma to the pelvis; body habitus that could prevent implant placement; diagnosed osteoporosis or osteomalacia; pathologic fracture;	Localized SI joint pain with positive Fortin finger test or pain over posterior superior iliac spine with possible radiation into buttocks, posterior thigh or groin; ≥3 provocative physical exam maneuvers; >50% or more decrease in pain after image guided SI joint block with local anesthetic	iFuse-3D Implant System (triangular titanium implant coated with porous titanium plasma spray; manufactured via 3D printing) with optional use of FDA-cleared allograft (including demineralized bone matrix) or autograft; minimally invasive lateral transiliac approach 5 bilateral 46 unilateral

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		rheumatologic diagnosis; allergy to titanium; any condition that contraindicates surgery or could prevent long-term follow-up; uncontrolled psychiatric disease; unwillingness to sign opioid contract; or involvement in litigation related to low back/SI joint pain		
Rainov (2019)[40] Germany; Funding source NR	Retrospective, single group cohort (or registry) N eligible: 160 N analyzed: 151 at 3 mos., 135 at 6 mos., 114 at 9 mos., 90 at 1 yr.	Single site in Germany, 2015 to 2017 Mean age (range): 58 (20 to 91) N (%) female: 108 (67.5) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: 102 (63.8) *Key inclusion criteria*: Patients with chronic low back pain and leg pain and underwent SI joint fusion between 2015 and 2017. All patients had a prior conservative treatment for their pain, and SI joint or lumbar facet joint injections with local anesthetic or steroid drugs that failed to produce long-term pain relief. *Key exclusion criteria:* NR	Diagnosis based on history, ≥3 of 5 positive provocative physical exam maneuvers (compression test, Gaenslen's maneuver, thigh thrust, Patrick's test, and distraction test), and one or more confirmatory diagnostic SI joint injections under imaging guidance with ≥50% pain relief; CT scan to rule out other sources of pain	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 48 bilateral 112 unilateral
Rajpal (2018)[41] U.S.; Funding source NR	Retrospective, single group cohort (or registry) N analyzed: 24	Single site and surgeon, 2015 to 2017 Mean age (range): 62.2 (33 to 79) N (%) female: 21 (87.5) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: 15 (62.5) *Key inclusion criteria*: Underwent minimally invasive SI joint fusion between May 2015 and October 2017; diagnosed with SI joint disruption or sacroiliitis; underwent at least 6 mos. of conservative treatment *Key exclusion criteria:* NR	Diagnosis based on physical examination, provocative SI joint pain tests, imaging studies, and diagnostic SI joint injections under guidance	Rialto SI Fusion System (cylindrical threaded implants) with intraoperative stereotactic navigation; posterior oblique approach 2 bilateral 22 unilateral
Rappoport (2017)[110] U.S.; Globus Medical Inc. and the Musculoskeletal Education	Uncontrolled trial N treated and analyzed: 32	Single site, time period NR Mean age (SD): 55.2 (10.7) N (%) female: 20 (62.5) Mean duration of pain: NR	Diagnosis was based on clinical presentation of SI joint dysfunction supported by medical history, physical	SI-LOK Sacroiliac Joint Fusion System; minimally invasive, lateral approach that uses

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
and research Center (a division of Globus Medical, Inc.)		N (%) with prior lumbar fusion: NR *Key inclusion criteria:* Ages between 21 and 70 yrs., diagnosis of SI joint dysfunction *Key exclusion criteria:* Osteopenia or osteomalacia, metabolic bone disease, condition that required postoperative medication(s) that may interfere with bone/soft tissue healing, presence of a condition that precludes the possibility of bone fusion	examination, and lumbar MRI showing absence of disease that would correlate with clinical presentation, diagnostic injections only used in patients who failed to respond to nonoperative treatment	hydroxyapatite coated screws with graft slot option 0 bilateral 32 unilateral
Rudolf (2012)[63] U.S.; Funding source NR; author is consultant to SI-BONE, Inc., and acknowledged assistance with writing from 2 SI-BONE, Inc. employees	Retrospective uncontrolled cohort N analyzed: 50	Single community-based spine practice, 2007 to 2010 Mean age (range or SD) 54 (24 to 85); N (%) female: 34 (68) Mean duration of pain: NR N (%) with prior lumbar fusion: 22 (44) *Key inclusion criteria*: First 50 consecutive patients diagnosed with degenerative sacroiliitis or SI joint disruption and treated with minimally invasive SI joint fusion by single surgeon between October 2007 and July 2010 *Key exclusion criteria:* NR	Clinical history of pain at or near SI joint; ≥3 of 5 provocative physical exam maneuvers; suggesting SI joint dysfunction; X-ray, CT, or MRI imaging; when clinical, physical, and radiographic exams were concordant, diagnostic SI joint blocks were used, with positive results defined as ≥75% decrease in pain	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 5 bilateral 45 unilateral
Sachs (2013)[64] U.S.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 40 patients/41 procedures[a]	Single site, 2011 to 2012 Mean age (range): 58 (30-81) N (%) female: 30 (75) Mean duration of pain: NR N (%) with prior lumbar fusion: 12 (30%) *Key inclusion criteria*: Underwent minimally invasive SI joint fusion for SI joint disruption or degenerative sacroiliitis; failed 6 mos. of conservative therapy must have had 12-mo. follow-up data available *Key exclusion criteria*: NR	Detailed clinical history, ≥3 positive physical provocative maneuvers, diagnostic imaging, and, when clinical, physical, and imaging findings were concordant, SI joint diagnostic injections with positive result (i.e., 75% reduction in pain immediately after injection)	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 1 bilateral 39 unilateral

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Sachs (2014)[65] U.S.; SI-BONE, Inc.	Retrospective uncontrolled cohort N analyzed: 144[b]	6 sites, time period NR Mean age (range): 57.7 (30-89) N (%) female: 102 (71) Mean duration of pain: NR N (%) with prior lumbar fusion: 89 (62) *Key inclusion criteria*: Underwent minimally invasive SI joint fusion using iFuse; must have had preoperative and minimum 12-mo. follow-up data available; failure of 6 mos. of conservative treatment *Key exclusion criteria*: NR	Detailed clinical history, ≥3 positive physical provocative maneuvers, diagnostic imaging, and, when clinical, physical, and imaging findings were concordant, SI joint diagnostic injections with positive result (i.e., 75% reduction in pain immediately after injection)	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 26 bilateral 118 unilateral
Sachs (2016)[66] U.S.; SI-BONE, Inc. (San Jose, California)	Retrospective uncontrolled cohort N: 107[c]	7 sites, surgery prior to 2012 Mean age (range): 57.5 (18.6 to 87) N (%) female: NR Mean duration of pain in years, N (range): 5.9 (0.3 to 46) N (%) with prior lumbar fusion: 39 (36.4) *Key inclusion criteria*: Age ≥21 who underwent SI joint fusion using iFuse; must have had preoperative pain scores reported in medical charts *Key exclusion criteria*: NR	Unified diagnostic criteria not used across included sites, but diagnosis was always made using history (buttocks pain with optional radiation into groin or upper leg), ≥3 positive provocative physical exam maneuvers, and positive diagnostic SI joint block	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive, lateral transiliac approach 3 bilateral 104 unilateral
Schoell (2016)[67] U.S.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 469	Insurance claims database, 2007 to 2014 Mean age (SD): NR N (%) female: 305 (65) Mean duration of pain, N (%): NR N (%) with prior lumbar fusion: NR *Key inclusion criteria*: Received minimally invasive SI joint fusion based on CPT codes and diagnosed with ≥1 of the 6 ICD-9 codes listed in ISASS policy statement as medical indications for SI joint fusion	NR	Minimally invasive SI joint fusion based on CPT codes 27280, 27299, or 22899 N bilateral vs. unilateral NR

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key exclusion criteria: Previous diagnoses of pelvic ring fracture or pelvic neoplasms; procedures performed as revision surgery		
Schmidt (2020)[44] U.S.; Allegheny Health Network Research Institute	Retrospective, single group cohort (or registry) N analyzed: 19	Single site and surgeon, 2013 to 2015 Median age (IQR): 50 (44 to 52) N (%) female: 4 (21.0) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: NR *Key inclusion criteria*: Aged 18 to 80 yrs.; diagnosis of sacroiliitis or SI dysfunction; short-term resolution of symptoms (≥80% relief) with image-guided diagnostic intra-articular SI joint injection *Key exclusion criteria:* NR	Diagnosis based on ≥3 positive provocative physical exam maneuvers (thigh thrust test, compression test, Gaenslen's maneuver, distraction test, Patrick's sign, posterior provocation test)	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive, lateral transiliac approach 5 bilateral 14 unilateral
Schutz (2006)[52] Switzerland; Funding source NR	Retrospective uncontrolled cohort N treated: 17	Single site, 1990 to 1995 Mean age (range): 43.2 (22 to 76) N (%) female: 12 (71) Mean duration of pain (range), years: 6.6 (1 to 20) N (%) with prior lumbar surgery: 59% *Key inclusion criteria*: Pain of more than 1 yr. positive Mennell sign, degenerative changes on X-rays or CT, positive SI joint infiltration test or positive temporary external fixation, or positive bone scan (note only 30% of included patients met these criteria) *Key exclusion criteria*: NR	Varied approaches to diagnosis used, including diagnostic injections (14 of 17) patients, temporary selective external immobilization of joint (3 of 17 patients) and various physical and radiologic exams	Bilateral, open fusion using dorsal interlocking technique described by Verral and Pitkin
Slinkard (2013)[50] U.S.; Funding source NR	Uncontrolled cohort N treated: 25 N analyzed: 19	Single site, 2006 to 2008 Mean age (range): 51 (34 to 77) N (%) female: 14 (76) Mean duration of pain, N (%): NR N (%) with prior lumbar fusion: 12 (63%)	History congruent with SI joint dysfunction, positive Patrick test, X-ray and CT imaging, diagnostic intraarticular with local anesthetic	Open SI joint fusion using anterior ilioinguinal approach N bilateral vs. unilateral NR

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		Key inclusion criteria: Patients with history of SI joint dysfunction at least 1 yr.; 6 to 12 wks. of physical therapy and nonsteroidal medications without improvement; relief of 50% of symptoms from diagnostic intraarticular SI joint injection *Key exclusion criteria*: NR		
Waisbrod (1987)[48] Germany; Funding source NR	Retrospective uncontrolled cohort N analyzed: 22 procedures/21 patients	Single site, 1981 to 1985 Mean age (range): 42 (20 to 58) N (%) female: 18 (86) Duration of symptoms: >2 yrs. N (%) with prior lumbar fusion: 5 (23) *Key inclusion criteria*: Physical examination of pain; positive Patrick and Gaenslen's maneuver; injections to relieve SI joint pain *Key exclusion criteria:* Psychological disturbances as assessed by 3 psychological instruments	Pain in the SI area, local tenderness in joint area, positive Patrick and Gaenslen's maneuver, abnormal X-rays, CT, and bone scan, reproducible pain with intraarticular saline injection, relief of pain with local anesthetic injection	Open SI joint fusion using a posterior approach N bilateral vs. unilateral NR
Wales (2021)[38] U.K.; Funding source NR	Prospective, single group cohort (or registry) N eligible: 40 N analyzed: 33	Single site and surgeon, 2013 to 2015 Mean age (range): 55.4 (33 to 84) N (%) female: 32 (80) Mean duration of symptoms/pain (SD): NR N (%) with lumbar fusion: NR *Key inclusion criteria*: Diagnosis of SI joint pain; exhausted nonoperative methods for pain relief; showed pain relief following CT-guided SI joint injection followed by recurrence of symptoms *Key exclusion criteria:* Concomitant lumbar spine pathology	Clinical evaluation including palpitation over the SI joint for tenderness, physical exam of spine and hip to rule out other sources of pain, SI joint physical exam provocation tests, plain radiographs of pelvis, MRI of lumbosacral spine, an image-guided block of the SI joint injection with local anesthetic and steroid performed by a radiologist	SI-LOK Fixation System (hydroxyapatite-coated screws) N bilateral vs. unilateral NR
Wise (2008)[111] U.S.; Funding source NR	Uncontrolled trial N treated: 13	Single site, 2004 Mean age (range): 53 (45 to 62) N (%) female: 12 (92) Mean duration of symptoms: NR	Positive history and physical exam, intraarticular injections of local anesthetic and	Minimally invasive SI joint fusion with threaded fusion cages (Medtronic Sofamor Danek,

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		N (%) with prior lumbar fusion: 8 (62) *Key inclusion criteria:* Failed conservative therapy for at least 6 mos., physical examination, pain referral patterns, and a positive diagnostic injection followed later by recurrence of pain *Key exclusion criteria:* Other lumbar spine pathology as a source of pain	corticosteroid with at least 75% reduction in pain within 30 mins. and lasting at least 2 hrs.	Memphis, TN) filled with INFUSE/rhBMP-2 6 bilateral 7 unilateral

Notes: a. We are unable to determine the overlap in study population between this study and Sachs (2014).[65] The study author was contacted for clarification but did not reply.
b. Includes patients that were reported in Sachs (2016)[66] We are unable to determine the overlap in study population between this study and Sachs (2013).[64] The study author was contacted for clarification but did not reply.
c. Included patients that were also reported in Sachs (2014).[65]

Abbreviations: BMI = body mass index; CPT = Current Procedural Terminology; CT = computed tomography; DIANA = distraction interference arthrodesis; FDA = Food and Drug Administration; HMA = Hollow Modular Anchorage; hr(s). = hour(s); ICD = International Classification of Disease; IQR = interquartile ratio; ISASS = International Society for the Advancement of Spine Surgery; LOIS = Long Term Outcomes from INSITE and SIFI; MRI = magnetic resonance imaging; mins. = minutes; mm = millimeters; mo(s). = month(s); N = number of participants; NR = not reported; ODI = Oswestry Disability Index; rhBMP-2 = recombinant human bone morphogenetic protein-2; SD = standard deviation; SI = sacroiliac; U.K. = United Kingdom; U.S. = United States; VAS = visual analog scale; vs. = versus; wk(s). = weeks(s); yr(s). = year(s).

Table C-12. Safety outcomes from uncontrolled studies evaluating sacroiliac joint fusion

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
Al-Khayer (2008)[113] N analyzed=9	N events 1 deep wound infection 0 loosening, screw failure, or breakage events	NR
Araghi (2017)[109] EVSI; NCT02074761; N analyzed=50	N (%) serious adverse events (procedure related) resulting in hospitalization: 2 (4) 1 radiculopathy post-surgery due to nerve impingement 1 ongoing low back pain requiring hospitalization for management N surgical related events neither deemed serious in nature nor required intervention: 8	At 6 mos.: 1 (2%) to change implant to a shorter device to relieve nerve impingement causing radiculopathy
Beck (2015)[114] N analyzed=20	N events 1 device malposition, but unclear whether this resulted in a symptomatic adverse event 0 bleeding events, infections, or medical complications	At mean 27 mos. (range 17 to 45 mos.) 0 revisions
Belanger (2001)[47] N analyzed=4	N events 1 (25%) local pain and tenderness resulting in hardware removal Death: 1 due to myocardial infarction nearly 10 yrs. after surgery	Time frame unspecified: 1 (25%) to remove hardware and allow exploration of patient's fusion and alleviate postoperative local pain and tenderness
Bornemann (2017)[58] N analyzed=24	N events 0 during surgery 0 device or surgery-related events during 2 yrs. follow-up	At 2 yrs.: 0 revisions
Buchowski (2005)[53] N analyzed=20	N (%) participants/N events: 4 (20%)/6 events 3 pseudarthrosis 2 deep wound infection 1 device-related event (painful hardware)	Time frame unspecified: 3 (15%) participants with 5 revision surgeries 3 revisions to resolve nonunions 2 to resolve pseudarthrosis
Cher (2018)[42] N analyzed=14,210	*N (%) total product complaints (including revision surgery) 837 (4.9) % of complaints related to instrument sets (same set used for both implant types) 1.3% (mean over years analyzed with no time trends noted) Days from index surgery to instrument set complaint, mean (SD; range) iFuse (N=31): 126.5 (362; 0 to 1,529) iFuse-3D (N=0): NA *N (%) complaints related to pain (including transient pain after surgery, wound infection, persistent pain, and pain recurrence; none resulted in a surgical revision) 173 (1.2) total	*Surgical revision defined as an additional surgical procedure on an SI joint treated with the company's device (iFuse or iFuse-3D) N (%) with revision as of June 30, 2018 409 (3.7) iFuse 26 (0.8) iFuse-3D 1-yr. product-limit estimate of the cumulative rate of revision surgery iFuse: 1.5% iFuse-3D: 1.0% *P*=0.0408

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	170 (1.5) iFuse 3 (<0.1) iFuse-3D Number of pain complaints by year 2015: 69 2016: 56 2017: 33 2018: 15 Probability of pain complaint event (Kaplan-Meier): 1-yr. rate <0.5%; no difference between devices (log rank *P*=0.138) Days from index surgery to pain complaint, mean (SD; range) iFuse (N=151): 520.3 (533.6; 3 to 1,651) iFuse-3D (N=3): 41 (52; 2 to 100) *N with other complaints (all less than 0.1% incidence); days from index surgery to complaint, mean (SD; range) 11 hematoma/seroma/bleeding; n=8 for iFuse; 12 (25.6; 0 to 73); n=1 iFuse-3D; 15 (NA; NA) 6 other medical procedures; 609 (177.8; 413 to 819) 6 off-label use, data not available 5 iFuse implant product problem; based on n=2; 4.5 (6.4; 0 to 9) 3 embolism/aneurysm/DVT; 24 (16.1; 11 to 42) 3 cardiac incident; 20.7 (35.8; 0 to 62) 2 iFuse use problem; data not available 2 metal allergy (not confirmed by MELIA or LTT) 151.5 (204.4; 7 to 296) 2 bone fracture; 270.5 (301.9; 57 to 484) 2 intraoperative issues; 0.3 (0.6; 0 to 1) 2 infection; based on n=1; 8 2 others; based on n=1; 965 1 instrument use problems, data not available	Days from index surgery to revision surgery complaint (surgery/complaint date not available for some), mean (SD; range) iFuse (N= 406): 497.4 (495.1; 0 to 2,626) iFuse-3D (N=26): 72.1 (100.9; 2 to 408) Suspected cause of surgery revision (U.S. data only; N=278 with suspected causes) N, % of revision surgeries, median days after index surgery Insufficient fixation iFuse: 51, 20.2%, 408 iFuse-3D: 1, 3.8%, 63 Total: 52, 18.7%, 400.5 Lucency/halos iFuse: 26, 10.3%, 477.5 iFuse-3D: 0 Total: 26, 9.4%, 477.5 Malpositioned implant with nerve impingement iFuse: 127, 50.4%, 29 iFuse-3D: 24, 94.3%, 41 Total: 151, 54.3%, 29 Malpositioned implant not nerve related iFuse: 19, 7.5%, 402 iFuse-3D: 1, 3.8%, 182 Total: 20, 7.2%, 367.5 Removed because of no pain relief (possible misdiagnosis) iFuse: 15, 6%, 456 iFuse-3D: 0 Total: 15, 5.4%, 456 Other reasons iFuse: 14, 5.6%, 414 iFuse-3D: 0 Total: 14, 5%, 414

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
Cher (2015)[68] N analyzed=11,388	NR (this study was only focused on reporting revision surgeries)	N with any revision: 320 (2.8%); including 5 that could not be linked to an index surgery 24% occurred within first month 63% occurred within first year 4-yr. survival rate free from revision surgery: 96.5% with revision rates decreasing significantly over time (*P*<0.0001); 4-yr. cumulative revision rate: 3.5%; year: revision rate for cases in that year 2009: 9.7% 2010: 4.9% 2011: 2.0% 2012: 1.8% 2013: 1.5% 2014: 1.4% **Reasons for revision surgeries, N (%)** Symptomatic malposition: 121 (38.4) Most cases (86.8%) occurred within first 6 mos.; 4-yr. probability: 1.0%; 2-yr. risk of revision: 0.9% Recurrence of symptoms: 150 (47.6) Most cases (87.9%) occurred after first 6 mos.; 4-yr. probability: 1.9%; 2-yr. risk of revision: 1.07% Never improved: 29 (9.2) Iliac fracture: 3 (1.0) Early revision for asymptomatic implant malposition: 12 (3.8) **Variation by index surgeon** 34.8% of all revisions associated with 22 surgeons who performed only 5.4% of index surgeries (*P*<0.0001) Among surgeons performing >100 cases: 12-mo. all-cause revision rates (*P*=0.0041) Cases 1 to 20: 1.6%

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
		Cases 21 to 50: 1.1% Cases 51 to 100: 0.8% Cases >100: 0.7% Among surgeons performing >20 surgeries: 12-mo. all-cause revision rates (*P*=0.0952) 2009: 6.0% 2010: 2.5% 2011: 1.5% 2012: 1.8% 2013: 0.7%
Cleveland (2019)[39] N analyzed=50 (57 procedures)	At 6 mos. N (%) with adverse events: 2 (4) 1 intraoperative injury to a branch of the inferior gluteal artery following placement of the distal SI implant 1 postoperative buttock wound drainage	6 mos. and beyond (mean follow-up of 8.6 [SD: 7.8] mos.) 0 revisions
Cross (2018)[119] NCT02425631; N analyzed=19	N events 0 procedural complications 0 serious adverse events N (%) with device-related adverse events (nonserious) 1 yr.: 4 (21) 2 yrs.: 2 (11) Unspecified as to specific events	NR
Cummings (2013)[59] N analyzed=18	N intraoperative complications: 0 N (%) with postoperative adverse events (major) at 1 yr. 1 (5.6, reported as 5) radicular pain due to implant malposition N (%) with postoperative adverse events Trochanteric bursitis: 3 (16.7) Hematoma: 1 (5.6) Fluid retention: 1 (5.6) Toe numbness: 1 (5.6) Implant malposition: 1 (5.6)	Time frame unspecified: 1 *(5.6%)* for radicular pain at 3 mos. resolved with implant removal
Darr (2018);[56] Darr (2018);[57] Whang (2019)[120]	At 3 yrs. N (%) with adverse events: 75 (78%, 168 events) 0 were severe device or procedure related	By 4 yrs.:

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
LOIS (Long Term outcomes from INSITE and SIFI); NCT02270203; N analyzed=97 at 3 yrs.; 94 at 4 yrs.; 93 at 5 yrs.	146 not related to the pelvis 22 pelvis related 1 bilateral SI joint pain 1 potentially ipsilateral SI joint pain 5 ipsilateral SI joint pain 15 contralateral SI joint pain (of these 5 underwent SI joint fusion of contralateral joint) N adverse events between years 3 and 4: 114 0 probably or definitely related to study devices or index surgical procedure "Many" due to underlying degenerative disease associated with age and osteoarthritis At 5 yrs. N (%) with adverse events: 95 (92%, 328 events) N (%) with pelvis related events/N events: 42 (40.8)/48 16 SI joint pain 18 contralateral SI joint pain 1 buttock pain and thigh numbness/tingling 3 hip and leg pain, radicular hip pain 7 trochanteric bursitis 1 hip gluteus minimum tear 1 pelvic floor nerve impingement after lumbar fusion unrelated to index SI joint fusion 1 pelvic organ prolapse N (%) with definitely or probably device-related events: 1 (2); 0 severe Hip and gluteal pain, likely trochanteric bursitis: 1 N (%) with definitely or probably procedure-related events: 2 (1.9); 1 severe SI joint pain: 1 (patient underwent placement of an additional titanium triangular implant due to prior with partial resolution of SI joint pain) Implant malposition: 1 (patient underwent revision surgery) N severe adverse events: 43 (most were unrelated to the pelvis; 0 device related) N (%) reported exacerbations of their SI joint pain related to falls: 3 (2.9)	1 (*1%*) at patient's request by nonstudy physician for pain relief; believed to originate from progressive lumbar scoliosis By 5 yrs.: N (%) revisions: 3/103 (2.9%) 1 due to poor implant placement (early; probably procedure related) 1 at patient's request by nonstudy physician for pain relief; believed to originate from progressive lumbar scoliosis 1 during the SIFI study

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	N (%) underwent an unplanned contralateral SI joint fusion between years 1 and 5: 12 (11.7; the lack of further clinical information about indications for the contralateral surgery make it challenging to categorize these events as adverse events related to the index surgery) Death: 2 (both unrelated to the SI joint [lung cancer and myocardial infarction])	
Duhon (2013);[55] Duhon (2016);[124] Duhon (2016)[125] SIFI; NCT01640353; N analyzed=94 at 6 mos; 172 at 1 yr.; 169 at 2 yrs.	At 6 mos. N with adverse events: 34 patients (36.2%, 53 events) Number of events within various time frames Within 30 days: 23 Between 31 days and 6-mo. follow-up: 29 Unknown: 1 N severe adverse events: 6 events (2 were probably or definitely procedure related) Bowel obstruction: 1 Deep venous thrombosis: 1 Pneumonia requiring hospitalization: 1 Immediate postoperative nausea and vomiting prolonging hospitalization: 1 Wound infection: 1 Acute cholecystitis: 1 N adverse events possibly device related: 2 events; 0 severe Buttocks pain: 2 N adverse events probably or definitely procedure related: 6 events; 2 severe Postoperative nausea: 2 Wound infections: 2 Cellulitis: 1 Exacerbation of buttock pain with initiation of postoperative physical therapy: 1 At 1 yr. N nonsevere adverse events unrelated to the procedure or device: 257 events 83 (32.3%) probably or definitely related to preexisting conditions N (%) adverse events definitely or probably device related: 5 (2.9)	At 6 mos. 0 implant revisions or implant removal At 1 yr. N (%) revisions: 4 (2.3) 2 for new onset leg pain that resolved when implants were repositioned 2 for minimal improvement in symptoms thought to be due to suboptimal implant placement Cumulative revision rate: 2.8% (95% CI, 0 to 5.5) At 2 yrs. N (%) revisions: 8 (4.7) 2 for new onset leg pain that resolved when implants were repositioned 4 for minimal improvement in symptoms thought to be due to suboptimal implant placement 1 for pain recurrence 6 mos. postoperatively, found to have bilateral labral tears and possible femoral acetabular impingement, underwent open fusion and placement of 1 additional implant in each joint bilaterally resulting in improved pain 1 for recurrent pain that developed several months after an L4-S1 fusion that took place 13 mos. after SI joint fusion. The S1 screw was found to be touching 1 of the implants, revision to remove the implant and replace with a non-iFuse device.

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	Neuropathy related to device malposition: 2 (1.2) SI joint pain after fall associated with inadequate device placement: 1 (0.6) Hip pain related to periosteal bone growth and implant: 1 (0.6) Mild SI joint pain: 1 (0.6) N (%) adverse events definitely or probably procedure related: 21 (12.2) Wound infection or drainage: 5 (2.9) Buttock or SI joint pain: 5 (2.9) Postoperative nausea/vomiting: 3 (1.7) Neuropathy related to malposition: 2 (1.1; also captured in device-related event) Staple irritation: 1 (0.6) Numbness around surgical wound: 1 (0.6) Gluteal artery bleeding: 1 (0.6) Urinary retention: 1 (0.6) Fall causing SI joint pain: 1 (0.6) N severe adverse events: 29 (5 were device or procedure related) 1 was device related: Nerve irritation due to implant malposition (already captured above) 4 were probably or definitely procedure related: Implant radiculopathy: 1 Postoperative surgical pain requiring brief hospitalization: 1 Postoperative nausea/vomiting requiring prolonged hospitalization: 1 Deep wound infection requiring surgical wound debridement: 1 All remaining events were unassociated with the SI joint surgery At 2 yrs: N total adverse events: 153 patients (90.5%, 454 events) N (%) adverse events definitely or probably device related: 7 (1.5); 1 severe Neuropathic pain related to device malposition: 3 (1.8) SI joint or buttock pain: 2 (1.2) SI joint pain after fall associated with inadequate device placement: 1 (0.6) Hip pain related to periosteal bone growth around implant: 1 (0.6) N (%) adverse events definitely or probably procedure related: 26 (15.4); 6 severe	

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	Buttock pain: 2 (1.2%) Foot weakness related to anesthesia: 1 (0.6) iFuse impingement: 3 (1.7) Nausea/vomiting: 3 (1.7) SI joint pain: 5 (2.9) SI joint pain (inadequate stabilization): 3 (1.7) Urinary retention: 1 (0.6) Vascular injury: 1 (0.6) Wound drainage/irritation/infection: 6 (3.5) Wound numbness: 1 (0.6) N severe adverse events: 73 (7 were device or procedure related) 1 was probably or definitely device related: Neuropathic pain related to suboptimal implant placement (already captured above) 6 were probably or definitely procedure related: Serious neuropathic pain: 1 Recurrent/persistent pain because of suboptimal implant position: 2 Postoperative surgical pain: 1 Postoperative nausea/vomiting: 1 Deep wound infection: 1	
Fuchs (2018)[54] N analyzed=137 at 1 yr.; 132 at 2 yrs.	N (%) with postoperative complications: 7 (5.3) 6 (4.5) persistent pain or implant misplacement resulting in revision surgery 1 (0.8) radiculitis from bone substitute that was applied too liberally	By 2 yrs.: 7 (5.3%) total 6 due to misplacements or persistent pain 1 due to radiculitis from bone substitute that was applied too liberally
Gaetani (2013)[60] N analyzed=10	N (%) with postoperative complications: 3 (30.0) 2 local hematoma 1 intense low back pain treated successfully with facet joint injections 0 mechanical complications	NR
Kancherla (2017)[115] N analyzed=41 patients (45 cases)	N (%) with postoperative complications: 3 (6.7) All were neurologic deficits or injuries caused by device malposition	Mean time to revision in mos. (SD, range): 2.2 (2.1, 0 to 4.2) N (%) revisions: 3 (6.7) iFuse: 1 (removal of superior implant) SAMBA: 2 (1 repositioning screw; 1 removal of screw)
Khurana (2009)[116]	N events	Mean (range) of follow-up, months: 17 (9 to 39)

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
N analyzed=15	0 postoperative neurological or wound complications 0 screw placement problems 0 implant failures	0 revisions
Kibsgard (2014)[51] NCT00900601; N analyzed=8	N (%) with complications: 6 (75); 3 major 1 complex regional pain syndrome with drop-foot 1 loss of bladder sensation 1 infection 3 transient sensitivity loss to lateral femoral cutaneous nerve	NR
Kleck (2016)[61] N analyzed=47	N (%) with intraoperative complications: 2 (4.3) Both involved a guide pin breaking in situ	0 for patients at least 1-yr. postoperative (though mean follow-up of the group was only 35.6 wks.)
Kube (2016)[117] N analyzed=15 patients/17 procedures	N procedures with minor procedure-related complications: 4 1 small portion of metal cutting tool broke and lodged within joint 1 uncontrolled pain related to undisclosed history of narcotic dependence 2 prolonged surgery (1 due to dysplastic pelvis and other due to high BMI)	At 1 yr. 0 revisions
Mao (2018)[43] N analyzed=24	N postoperative events (number of participants NR) 2 lucency 1 same side pain 2 contralateral side pain (1 participant required a contralateral SI joint fusion) 4 LBP +/- LEP 3 hip pain 1 trauma 3 wound healing issues	At 12 mos. 0 revisions
Mason (2013)[112] N analyzed=55	N (%) with postoperative complications: 2 (3.6) 2 nerve pain immediately postoperatively resulting in revision surgery 0 wound infections 0 bleeding or vascular injury 0 deep vein thrombosis 0 pulmonary embolism 0 late failure	At mean of 36.18 mos. (range 12 to 84 mos.) 2 (3.6%) due to nerve pain resulting in 1 screw repositioning and 1 attempted screw removal
McGuire (2012)[118] N analyzed=34 at 1 yr.; 30 at 2 yrs.	N (%) with postoperative complications 4 (10.5) with symptoms (unspecified) resulting in revision surgery 0 infections	Mean (range) of follow-up, months: 39.6 (8 to 62) 4 (10.5%) for nonunion, successfully treated by secondary bone grafting and iliosacral compression screw fixation
Miller (2013)[62] N analyzed=5,319 patients (487 different surgeons)	N (%) with reported complaints: 204 (3.8) Median (range) time from index surgery to complaint: 5 mos. (intraoperative to 37 mos.)	Revision surgeries by year, N (%) of revisions/N iFuse cases in that year 2009: 0 (0)/31

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	% complaints reported within various time frames Within 90 days: 43% Between 90 days and 1 yr.: 30% Between 1 and 2 yrs.: 21% Beyond 2 yrs.: 6% Rate of complaints by year, N (%) of complaints/N iFuse cases in that year 2009: 0 (0)/31 2010: 15 (5.6)/273 2011: 56 (4.0)/1,397 2012: 126 (3.5)/3,611 N (%) with pain complaints/N complaints Overall: 119 (2.2)/157: 48 nerve impingement 43 recurrent sacroiliac joint pain 18 unknown cause 13 neuropathic pain 12 inadequate pain relief 11 malalignment 7 piriformis syndrome 5 local soft tissue pain N (%) with postoperative complications Hematoma/excessive bleeding: 11 (0.2) Iliac fracture: 4 (<0.1) Superficial wound infection: 3 (<0.1) Deep vein thrombosis: 2 (<0.1) Deep wound infection: 1 (<0.1) Pulmonary embolism: 0 Vascular injury: 0 Gastrointestinal injury: 0 Genitourinary injury: 0 Sacral fracture: 0 Death: 0	2010: 0 (0)/273 2011: 8 (0.6)/1,397 2012: 86 (2.4)/3,611 Over all years: 94 patients (1.8%) with 96 revisions Median (range) time to revision: 4 mos. (0 to 30) 56 (58% of revisions) were early (median 19 days postoperatively, 10 to correct an improperly sized implant, 46 to correct a symptomatic malpositioned implant) 40 (42% of revisions) were late (median 279 days postoperatively, 34 to treat symptom recurrence, 6 for unknown etiology, adjunctive procedures used in 34 revision cases including supplemental fixation in 20 cases and bone grafting in 25 cases)

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	N (%) with device-related events 43 (0.8) pin bind/bend/break 14 (0.3) pin advancement 13 (0.2) radiographic halo 4 (<0.1) migration N (%) with procedure-related events 72 (1.4) improper device placement (medial, anterior, dorsal, cephalad, proud, inferior, or other malposition) 36 (0.7) improper device size	
Mohit (2020)[46] N analyzed=44 at 1 yr., 33 at 2 yrs.	N (%) with complications at 2 yrs.: 3 (9.1) 1 (3.0) postoperative gluteal hematoma 2 (6.1) asymptomatic sacral side lucency Deaths: 3 due to cardiopulmonary issues at least 1 yr. postoperative	NR
Montenegro (2021)[45] N analyzed=96	N (%) with complications: 9 (9.4) 2 (2.1) neurological complications 4 (4.2) pseudoarthrosis 2 (2.1) wound-related issues 1 (1.04) hematoma	At 3 mos. 5 (5.2%) with early revisions 3 implant position related 2 wound-related issues
Murakami (2018)[37] N analyzed=27	N (%) with complications 3 (11.1) dislocation of screw 7 (25.9) lateral femoral cutaneous neuralgia 1 (3.7) hematoma 14 (51.9) pain in the unaffected side (12 coped with pain, 2 had a pelvic ring fusion) 1 (3.7) continued lumbar radiculopathy requiring nerve root decompression 4 (14.8) continued lumbar radiculopathy that was present prior to the SI joint fusion but did not require nerve root decompression	By 5 yrs. 6 (22.2%) for inadequate pain relief postoperatively (open fusion using posterior approach, 4; pelvic ring fusion, 2)
Nystrom (2017)[49] N analyzed=50	N (%) with postoperative complications: 6 (12.0) 3 decreased sensation in distribution of the lateral femoral cutaneous nerve postoperatively 1 weakness of muscles innervated by femoral nerve 2 persistent symptoms and defective bone healing Death: 1 (unrelated to SI joint fusion)	At mean of 2 yrs. (range: 1 to 3 yrs.) 2 (4.0%) for persistent symptoms and defective bone healing based on CT scan

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
Patel (2019);[35] Patel (2020)[36] SALLY (Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants) NCT03122899; N analyzed=46	At 12 mos. N (%) with adverse events/N events: 43 (93)/112 N adverse events definitely device related: 1 (postoperative pain in the L5 distribution leading to revision) N adverse events definitely or probably procedure related: 6; 0 severe 1 skin rash related to bandages placed in the OR 1 muscular dysfunction of the hip related to L3/4 disc herniation 1 anemia 1 temporary surgical site pain 1 trochanteric bursitis 1 small wound dehiscence N (%) with serious adverse events/N events: 4 (8.7)/5 3 contralateral SI joint pain (1 related to the motor vehicle accident) 1 ipsilateral SI pain (also related to the motor vehicle accident) 1 aspiration pneumonitis N (%) with serious adverse events/N events: 4 (8.7)/5 3 contralateral SI joint pain (1 related to the motor vehicle accident) 1 ipsilateral SI pain (also related to the motor vehicle accident) 1 aspiration pneumonitis	At 6 mos. 0 revisions At 12 mos. 2 (4.3%) revisions 1 due to postoperative pain from implant malposition 1 late revision related to a motor vehicle accident
Rainov (2019)[40] N analyzed=151 at 3 mos., 135 at 6 mos., 114 at 9 mos., 90 at 12 mos.	N (%) with complications 0 intraoperative complications "small number" among first 25 patients had hematomas in the surgical path of approach 0 postoperative wound infections 0 displacements or pullouts of SI joint implant	At 12 mos. 0 revisions due to implant malposition, recurrent pain, or radiolucencies
Rajpal (2018)[41] N analyzed=24	N (%) with complications: 5 (20.8) 2 (8.3) symptomatic subcutaneous hematomas 2 (8.3) superficial wound infections treated with antibiotics 1 (4.2) osteophyte on the lateral aspect of the implant 0 hardware failures	At mean of 19 mos. (range 12 to 34) 1 osteophytectomy due to localized pain symptoms, performed 1 yr. after index surgery
Rappoport (2017)[110] N analyzed=32	N (%) with postoperative complications at 1 yr. 2 (6.3) with symptoms (unspecified) resulting in revision surgery	At 1 yr. 2 (6.3%) with revision surgery

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
		1 for screw loosening at 11 mos. with pain/symptoms 1 for removal of cephalad screw and placement of a caudal screw at 3 mos. due to bony deficiency/dysplasia with pain/symptoms
Rudolf (2012)[63] N analyzed=50	N (%) with perioperative complications: 10 (20) 3 superficial cellulitis at wound closure 1 deep soft tissue wound infection 2 large buttock hematoma 2 implant penetration into sacral neural foramen with radicular pain 1 implant placed too cephalad in patient with unrecognized hemi-sacralized L5 transitional vertebrae with pain 1 nondisplaced fracture at edge of ilium N (%) with late complications: 1 (2) loosened implants causing persistent, gradually increasing SI joint pain 3 yrs. Post-surgery	At 2 yrs. 4 (8%) revision surgeries 3 for initial implant malposition and pain symptoms 1 for late implant loosening and pain symptoms
Sachs (2013)[64] N analyzed=40 patients/41 procedures[a]	N intraoperative events: 0 At 1 yr. N postoperative events thought to be related to index surgery: 4 2 trochanteric bursitis 1 piriformis syndrome 1 new low back pain N postoperative events thought to be unrelated to index surgery as conditions were present preoperatively 8 facet joint pain 1 discectomy at L4/5 2 lumbar spine fusions	At 1 yr. 0 revisions
Sachs (2014)[65] N analyzed=144[b]	N intraoperative events: 0 Mean follow-up of 16 mos. (range: 12 to 26 mos.) N postoperative events: 28 Specific events, N (% of all events) Fall: 5 (3.5%) Trochanteric bursitis: 4 (2.8%) Piriformis syndrome: 3 (2.1%)	At 1 yr. 1 (0.7%) revision to correct an improperly sized implant resulting in nerve root impingement

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	Facet pain: 3 (2.1%) Contralateral SI joint pain: 2 (1.4%) Recurrent pain: 2 (1.4%) Leg pain: 1 (0.7%) Numbness in left foot: 1 (0.7%) Toe numbness: 1 (0.7%) Burning and numbness in upper thigh: 1 (0.7%) Bladder incontinence: 1 (0.7%) Hematoma: 1 (0.7%) Increased pain: 1 (0.7%) New lower-back pain: 1 (0.7%) Nerve root impingement: 1 (0.7%)	
Sachs (2016)[66] N analyzed=107[c]	N (%) with complications: 8 (7.5) 1 mild ileus 1 suture material extending from wound 1 adhesive tape allergic reaction 4 pain symptoms resulting in revision surgery 1 injury sustained in motor vehicle accident resulting in revision surgery Note: It is unclear over what duration adverse events were monitored as the events reported all seem limited to an early postoperative period.	At mean of 3.7 yrs. (range 3.0 to 4.7 yrs.): 5 (4.7%) revisions 1 for early postoperative neuropathic pain due to implant malposition 1 pain recurrence at 18 mos. and CT evidence of nonunion and possible loosening of 1 implant and inadequate placement of another 1 for recurrent pain at 6 mos. possibly due to malposition 1 for inadequate pain relief possibly due to implant malposition but also had L5/S3 decompression with interbody fusion and pedicle screw instrumentation for lumbar pain 1 for injury sustained in motor vehicle accident requiring replacement of implants and also contralateral SI joint fusion, T9 laminotomy, and placement of spinal cord stimulator
Schmidt (2020)[44] N analyzed=19	NR	At mean (SD) of 58 (8.4) mos. 0 revisions
Schoell (2016)[67] N analyzed=469	N (%) with complications 90 days: 62 (13.2) 6 mos.: 77 (16.4) N (%) neuralgia, neuritis, sciatica, or radiculitis	NR

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	90 days: 20 (4.3) 6 mos.: 29 (6.2) N (%) novel lumbar pathology 90 days: 17 (3.5) 6 mos.: 25 (5.2) N (%) any infection 30 days: 14 (3.0) 90 days: 17 (3.6) 6 mos.: 19 (4.1) N (%) any pain 90 days: 12 (2.6) 6 mos.: 19 (4.1) N (%) urinary tract infection 90 days: 18 (3.8) 6 mos.: 23 (4.9) N (%) osteomyelitis 90 days: ≤11 (no other data reported) 6 mos.: ≤11 (no other data reported) N (%) joint derangement 90 days: ≤11 (no other data reported) 6 mos.: ≤11 (no other data reported)	
Schutz (2006)[52] N analyzed=17	N (%) with intraoperative complications: 1 (5.8) 1 dorsal iliac crest fracture N (%) with postoperative complications: 11 (64.7) 10 persistent local pain resulting in revision surgery 1 spondylosis and discopathy L4/5 resulting in revision surgery	N (%) with revisions: 11 (64.7) 10 within 2 yrs. to remove hardware for persistent local pain 1 performed at 42 mos. after initial fusion
Slinkard (2013)[50] N analyzed=19	N (%) with postoperative complications: 4 (21.1) 1 wound hematoma 1 nonunion	At mean 1.1 yrs. (range: 10-33 mos.) 3 (15.7%) re-operations to resolve surgical complications; unclear whether these were actually revision surgeries

Author (Year) Study Name; Registry Number; N Analyzed	Adverse Events	Revision Surgery
	1 posterior superior iliac spine irritation from long screw 1 nonfatal pulmonary embolism related to pelvic deep vein thrombosis	
Waisbrod (1987)[48] N analyzed=21 patients/22 procedures	N (%) with complications: 3 (14) 2 nonunions 1 infection	NR
Wales (2021)[38] N analyzed=33	N (%) with complications at 1 yr. 4 (12.1%) persistent and deteriorating symptoms leading to revision surgery 2 (6.1) with superficial wound-healing problems 0 with deep infections 0 with other surgical complications 0 with nerve root injury	After at least 1 yr. follow-up (possibly longer for some patients) 4 (12.1%) for persistent and deteriorating symptoms with relief following SI joint block and evidence of lysis on radiographs. Screws could not be removed in 3 patients and were managed expectantly; in the 4th patient 1 of 2 screws removed and 2 titanium triangular SI joint stabilizing devices were added.
Wise (2008)[111] N analyzed=13	N (%) with complications 1 persistent pain resulting in revision surgery 0 infections 0 neurovascular complications	Time frame unspecified: 1 (8%) revision to address nonunion and persistent pain

Notes: a. We are unable to determine the overlap in study population between this study and Sachs (2014).[65] The study author was contacted for clarification but did not reply.
b. Includes patients that were reported in Sachs (2016).[66] We are unable to determine the overlap in study population between this study and Sachs (2013).[64] The study author was contacted for clarification but did not reply.
c. Included patients that were also reported in Sachs (2014).[65]

Abbreviations: BMI = body mass index; CI = confidence interval; CT = computed tomography; DVT = deep vein thrombosis; LB*P*=low back pain; LE*P*=lower extremity pain; LOIS = Long Term outcomes from INSITE and SIFI; LTT = lymphocyte transformation testing; mo(s). = month(s); N = number of participants; NA = not available; NR = not reported; OR = odds ratio; SD = standard deviation; SI = sacroiliac; yr(s). = year(s).

Table C-13. Study characteristics and findings related to cost outcomes for sacroiliac joint fusion

Author (Year); Country; Sponsor	Intervention (I); Comparator (C)	Study Methods	Results
Ackerman (2014)[69] United States; SI Bone, Inc.	Minimally invasive SI joint fusion (unilateral); Nonoperative care	Study design: Comparative cost analysis based on an economic model Year/unit of currency reported: 2012 USD Discount rate: 3% Perspective: Payer Time horizon: 3 yrs. Costs included: Direct medical costs (inpatient, outpatient, medication, diagnostic services, including follow-up care services) based on commercial insurance payments Sensitivity analysis: Yes Key assumptions: Estimates based on population with mean age of 45.2 (SD 12.6) and 64% female and most common diagnoses SI subluxation (33.9%), sacroiliitis (25.7%), and disorders of sacrum (25.0%) 84% of procedures performed in inpatient setting 82% treatment success after initial procedure (based on studies using the iFuse implant system) 10% receive a repeat procedure 50% receiving nonoperative care experience chronic pain 35% of failures are managed with lumbar spinal fusion	Per-patient 3-yr. costs (5-yr. costs) Overall: I: $30,884 ($31,810) C: $16,339 ($25,673) Difference (C-I): -$14,545 (-$6,137) Patients with lumbar spinal fusion: I: $37,653 ($42,674) C: $92,470 ($143,166) Difference (C-I): $54,817 ($100,493) Patients without lumbar spinal fusion: I: $30,846 ($31,749) C: $15,916 ($25,019) Difference (C-I): -$14,931 (-$6,730)
Ackerman (2013)[70] United States; SI Bone, Inc.	Minimally invasive SI joint fusion (unilateral); Nonoperative care	Study design: Comparative cost analysis based on an economic model Year/unit of currency reported: 2012 USD Discount rate: 3% Perspective: Payer Time horizon: Lifetime costs (extrapolated from actual 5-yr. costs) Costs included: Direct medical costs (inpatient, outpatient, medication,[a] diagnostic services, including follow-up care services) based on Medicare payments. Sensitivity analysis: Yes Key assumptions: Patients are age 70 in year 1 and have a life expectancy of 84 yrs. and suffer from chronic low back pain due to SI joint disruption or degenerative sacroiliitis and who are eligible for minimally invasive surgery; 100% of procedures performed in inpatient setting	Per-patient lifetime costs Overall: I: $48,185 C: $51,543 Difference (C-I): $3,358 Patients with lumbar spinal fusion: I: $85,772 C: $149,477 Difference (C-I): $63,705 Patients without lumbar spinal fusion: I: $46,726 C: $47,759 Difference (C-I): $1,033

Author (Year); Country; Sponsor	Intervention (I); Comparator (C)	Study Methods	Results
		82% treatment success after initial procedure (based on studies using the iFuse implant system) 75% receiving nonoperative care experience chronic pain 10% receive a repeat procedure 35% of failures are managed with lumbar spinal fusion	
Blissett (2020)[72] U.K.; SI-Bone, Inc.	Minimally invasive SI joint fusion with titanium triangular implants (iFuse) Nonsurgical management (medications, PT, intra- and peri-articular joint injections, RFA) Strategy 1: Stepped care PT/injections first, failures proceed to RFA Strategy 2: Half of patients receive PT/injections and half receive RFA Strategy 3: All patients receive RFA	Study design: Cost-effectiveness based on Markov decision model Year/unit of currency reported: 2018 GBP Discount rate: 3.5% Perspective: Payer Time horizon: 5 yrs. Costs included: Direct medical costs including hospital stay, procedure costs, surgical training hours, follow-up consultations, consumables costed using NHS reference cost schedule Effectiveness/utility measures: MID response based on ODI transformed to EQ-5D scores Sensitivity analysis: Deterministic analysis varying each input individually to 20% of the base case Key assumptions: Model population were adults with chronic, disabling SI joint pain unrelated to acute trauma or inflammatory disease who failed conservative therapy with mean age of 50 yrs. and baseline ODI of 56.1; patients transition from highly symptomatic to much less symptomatic within 1 to 2 mos. of surgery; patients treated with injections temporarily improve but then worsen quickly, patients treated with RFA show some response over time but then worsen over time. Treatment of all interventions occurred within a 3-mo. time period. Various assumptions about timing of pain relief with respect to interventions and proportions of patients entering the various health states in the model; surgical response rate 65.4%, PT and steroid joint injection response rate 25%, RFA response rate 26%; ODI change for response -33.3 (surgery and PT and joint injections) and -33.0 (RFA); ODI change for no response -1.64 (RFA) and -1.9 (surgery and PT and joint injections); duration of treatment effect varies (RFA 7.9 mos., PT and joint injections 3 mos., surgery durable to 5 yrs.) and treatment responders in NSM received continued treatments at intervals consistent with duration of effect; risk of early revision surgery 0.81%, risk of late revision 0.17%; mortality	Base case at 5-yr. follow-up Costs GBP (2015 USD) Surgery: 8,358 GBP ($10,415) Stepped care NSM: 6,880 GBP ($8,573) Half PT/injections and half RFA: 6,564 GBP ($8,179) RFA: 6,580 GBP ($8,199) QALYs Surgery: 2.98 Stepped care NSM: 2.30 Half PT/injections and half RFA: 2.26 RFA: 2.28 ICER surgery vs. stepped care NSM: 2,164 GBP ($2,697) /QALY gained ICER surgery vs. half PT/injections and half RFA: 2,468 GBP ($3,075)/QALY gained ICER surgery vs. RFA: 2,518 GBP ($3,138)/QALY gained Sensitivity analyses: At a threshold of 20,000 GBP (24,922 2015 USD) surgery has a probability of being cost-effective of 96%, 97%, and 91% versus the three NSM strategies. Base case was most sensitive to the input related to response to treatment with surgery, but varying this input by 20% in either direction still resulted in an ICER that would be considered cost-effective.

Author (Year); Country; Sponsor	Intervention (I); Comparator (C)	Study Methods	Results
		modeled as per the general population and no hazard for SI joint fusion was applied.	Authors also modeled lifetime costs, but these not abstracted because of limitation in extrapolating costs and utilities beyond 5 yrs.
Buysman (2018)[122] U.S.; SI-Bone, Inc., Optum	SI joint fusion procedure coded using CPT codes 27279, 27280, or 0034T; specific device or approach NR None	Study design: Retrospective observational analysis of low back pain-related costs before and after SI joint fusion and cumulative cost model Year/unit of currency reported: 2016 USD Discount rate: NA Perspective: Primarily payer (some patient-paid direct medical costs included) Time horizon: 1 yr. prior and 1 yr. post-surgery Costs included: Physician and facility claims that had diagnosis or procedure codes for low back pain or its treatment, including patient-paid and health-plan paid amounts; outpatient pharmacy costs for patient and health-plan-paid pain medication fills occurring within 7 days of a claim related to low back pain. Costs occurring in the quarter immediately prior to the index procedure and in the quarter immediately after the index procedure were excluded from the analysis. Sensitivity analysis: None Key assumptions: Costs in the last quarter prior to SI joint fusion are likely to reflect different utilization patterns once a decision to proceed and prepare for surgery occurs. Cost in the first quarter after SI joint fusion is excluded because the cost of the surgery is included in this quarter. For the cumulative cost model, assumed ongoing postoperative low back pain costs as the average of the three postsurgical quarterly costs, assumed that costs for the nonsurgical counterfactual would be the average of the quarterly costs incurred in the three presurgical quarters, and assumed the cost of SI joint fusion was the cost of the first postsurgical quarter minus the average of the three presurgical quarterly costs.	Mean (SD) low back pain costs Before surgery: $16,803 ($32,144) After surgery: $13,297 ($28,122) *P*=0.095 Median (IQR) low back pain costs Before surgery: $5,849 ($2,423 to $14,287) After surgery: $2,269 ($606 to $8,855) *P*<0.001 Cost results stratified by setting were consistent with overall results. Cumulative cost model result: Break-even costs for SI joint fusion and nonsurgical treatment was at 7.25 yrs. (range 2.5 yrs. to 11.75 yrs. across the different settings)
Cher (2016)[71] United States; SI Bone, Inc.	Minimally invasive SI joint fusion; Nonoperative care	Study design: Cost-effectiveness analysis based on economic model Year/unit of currency reported: 2015[b] USD Discount rate: 3% Perspective: Payer Time horizon: 5 yrs.	Base Case: Cost I: $22,468 C: $12,635 Difference (C-I): -$9,833

Author (Year); Country; Sponsor	Intervention (I); Comparator (C)	Study Methods	Results
		Costs included: Direct health care utilization costs based on inputs from the INSITE and SIFI trials Utility measurements: EQ-5D time trade-off Sensitivity analysis: Yes Key assumptions: Age of patient at start is 50 yrs. 82% treatment success after initial surgical procedure (based on studies using the iFuse implant system) 27% treatment success from nonoperative care and 50% reduction in utilization after 6 mos. 25% received bilateral fusion Utilities: 0.77 mild pain (good response), 0.45 severe pain (poor response) 1% yearly rate of revision	QALYs I: 3.20 C: 2.46 Difference (C-I): -0.74 Incremental cost-effectiveness ratio (ICER): $13,313/QALY gained Sensitivity analyses: All simulations found ICERs <$45,000/QALY 10-yr. horizon ICER ~$2,300/QALY Break-even costs at approximately 13 yrs.

Notes: a. Medicare prescription claims were not available, so authors estimated pharmacy costs based on a similar study they performed using commercial claims.
b. Year not reported in published paper but verified through author query.

Abbreviations: C = control group; CPT = Current Procedural Terminology; EQ-5D = Euroqol 5-item utility measure; I = intervention group; GB*P*=British Pound Sterling ; ICER = incremental cost effectiveness ratio; IQR = interquartile range; MID = minimally important difference; mo(s). = month(s); NA = not applicable; NHS = National Health Service; NR = not reported; NSM = Non-surgical management; ODI = Oswestry Disability Index; PT = physical therapy; QALY = quality-adjusted life-year; RFA = radiofrequency ablation; SD = standard deviation; SI = sacroiliac; USD = United States dollars; vs. = versus; yr(s). = year(s).

Appendix D. Excluded Articles

List of Exclusion Codes

X1: Ineligible study design
X2: Ineligible population
X3: Ineligible intervention
X4: Ineligible comparator
X5: Ineligible outcomes
X6: Ineligible setting
X7: Ineligible country
X8: Systematic review for handsearch
X9: Ineligible publication type
X10: Duplicate or superseded
X11: Study protocol or study in progress
X12: Abstract only
X13: Non-English full text
X14. Data missing or uninterpretable

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Appendix E. Individual Study Risk of Bias Assessments

Table E-1. Risk of bias ratings for randomized controlled trials—Randomization process

Main Study Author (Year); Follow-up Studies Author (Year)	Was the allocation sequence random?	Was allocation sequence concealed until participants were recruited and assigned to interventions?	Were there baseline imbalances that suggest a problem with the randomization process?	Bias arising from randomization or selection?	Comments
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	Yes	No information	No	Low	None
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	Yes	Probably yes	Probably no Higher prevalence of current smoking and lower prevalence of never smoking among SI joint fusion group. Compared to the nonsurgical group, the SI joint fusion group was slightly younger (50 vs. 54 yrs.) and had a higher proportion of women (74% vs. 61%).	Low	None

Abbreviations: iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; SI = sacroiliac; vs. = versus.

Table E-2. Risk of bias for randomized controlled trials—Deviations from intended interventions

Main Study Author (Year); Follow-up Studies Author (Year)	Were the participants aware of their assigned intervention during the trial?	Were carers and trial personnel aware of participants' assigned intervention during the trials?	Were there deviations from the intended intervention beyond what would be expected in usual practice?	Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	Were any participants analyzed in a group different from the one to which they were assigned?	Was there potential for a substantial impact of analyzing participants in the wrong group?	Bias arising from deviations from intended interventions?	Comments
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	Yes	Yes	No No crossovers through 6 mos. After 6 mos., 21 of the 49 participants in the conservative management group that were still participating crossed over to surgery.	NA	No Not at the 6-mo. follow-up, LOCF was used for 12-mo. data for participants who crossed over after 6 mos.	NA	Low to some concerns	Low for outcomes up to 6 mos. Some concerns for outcomes later than 6 mos. because of crossovers
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	Yes	Yes	No No crossovers occurred at 6 mos. or earlier. After 6 mos., 35 of the 44 participants in nonsurgical management group that were still participating crossed over to surgery.	NA	No Not at the 6-mo. follow-up time point	NA	Low to some concerns	Low for outcomes up to 6 mos. Some concerns for outcomes later than 6 mos. because of crossovers

Abbreviations: iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; LOCF = last observation carried forward; mo(s). = month(s); NA = not applicable.

Table E-3. Risk of bias for randomized controlled trials—Missing outcome data

Main Study Author (Year); Follow-up Studies Author (Year)	Were outcome data available for all, or nearly all, participants randomized?	Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?	Is there evidence that results were robust to the presence of missing outcome data?	Bias arising from missing outcome data?	Comments
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	Yes 109 enrolled, 103 received treatment, 6-mo. follow-up available for 101/109=93%. 12-mo. follow-up data available for 94; 24-mo. follow-up data available for 93.	NA	NA	Low	None
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	Yes 159 enrolled, 148 received treatment, 6-mo. follow-up available for 144; after 6 mos. there are extensive crossovers. 12-mo. follow-up data available for 138; 24-mo. follow-up data available for 89 of 102 assigned to fusion; follow-up still ongoing in nonsurgical management group since most crossed over.	NA	NA	Low	None

Abbreviations: iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; mo. = month; NA = not applicable.

Table E-4. Risk of bias for randomized controlled trials—Measurement of the outcome

Main Study Author (Year); Follow-up Studies Author (Year)	Were outcome assessors aware of the intervention received by study participants?	Was the assessment of the outcome likely to be influenced by knowledge of intervention received?	Were the outcomes measured in the same manner for all individuals (equal), in a way that accurately reflects the outcome (valid), and in reproducible manner (reliable)?	Bias arising from measurement of the outcome?	Comments
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	Yes	Probably yes	Yes	Some concerns	Some concerns for bias because patient-reported outcomes were used, but treatment assignment could not be blinded.
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	Yes	Probably yes	Yes	Some concerns	No information about whether outcome assessors were blinded, given that many of the outcomes are self-reported pain and symptoms, these outcomes are susceptible to bias given that study was not blinded. The specified primary endpoint (binary success/failure) was a composite of at least 20 mm reduction in VAS, absence of device-related serious adverse events, absence of neurological worsening related to the sacral spine, and absence of surgical reintervention (removal, revision, reoperation, or supplemental fixation). The Polly et al. (2015)[27] says that no participants assigned to nonsurgical management were classified as a failure for reasons other than inadequate pain reduction.

Abbreviations: iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; VAS = visual analog scale.

Table E-5. Risk of bias for randomized controlled trials—Selection of the reported result and overall risk of bias rating

Main Study Author (Year); Follow-up Studies Author (Year)	Are the reported outcome data likely to have been selected on the basis of results from multiple outcome measurements within the outcome domain?	Are the reported outcome data likely to have been selected on the basis of results from multiple analyses of the data?	Bias arising from selection of reported results?	Comments	Overall Rating	Rationale/Comments
Dengler (2019);[29] Dengler (2017);[26] Dengler (2016);[107] Sturesson (2016)[22] iMIA	Yes	Probably yes	Some concerns	Multiple measures of general health-related quality of life and function reported, outcomes measured at 1, 3, 6, 12, and 24 mos. post-intervention; inconsistency in safety data presented for the same trial across multiple publications; authors acknowledged but did not send updated data to clarify.	Some concerns	Some concerns for bias because treatment not masked to participants or researchers, including outcome assessors and multiple outcomes reported. This rating does not apply to outcomes reported after 6 mos. as extensive crossovers occurred after 6 mos.

Main Study Author (Year); Follow-up Studies Author (Year)	Are the reported outcome data likely to have been selected on the basis of results from multiple outcome measurements within the outcome domain?	Are the reported outcome data likely to have been selected on the basis of results from multiple analyses of the data?	Bias arising from selection of reported results?	Comments	Overall Rating	Rationale/Comments
Whang (2015);[23] Polly (2015);[27] Polly (2016)[28] INSITE	Yes	Yes	Some concerns	Multiple measures of general health-related quality of life and function (EQ-5D time trade-off index, SF-36, ODI) measured at 1,3, 6, 12, and 24 mos. post-intervention; inconsistency in safety data presented for the same trial across multiple publications; authors acknowledged but did not send updated data to clarify.	Some concerns	Some concerns for bias because treatment not blinded to participants or researchers, including outcome assessors, and multiple outcomes reported, including a composite outcome. This risk of bias rating does not apply to outcomes later than 6 mos. as extensive crossovers occurred after 6 mos.

Abbreviations: EQ-5D = EuroQOL 5 item measure of general health status; iMIA = iFuse Implant System Minimally Invasive Arthrodesis; INSITE = Investigation of Sacroiliac Fusion Treatment; mo(s). = month(s); ODI = Oswestry Disability Index; SF-36 = Short Form 36-item survey.

Table E-6. Risk of bias for controlled cohort studies—Confounding, Part I

Main Study Author (Year); Study Design	Outcomes Assessed	Is there potential for confounding of the effect of intervention in this study?	Was the analysis based on splitting participants' follow-up time according to intervention received?	Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome?	Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?
Claus, 2020[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	Yes	No	NA	Probably no	NA
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	Yes	No	NA	Probably no	NA
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	No	NA	Probably no	NA
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	No	NA	Probably no	NA
Smith (2013)[30] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Yes	No	NA	Probably no	NA
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	Yes	No	NA	Probably no	NA

Main Study Author (Year); Study Design	Outcomes Assessed	Is there potential for confounding of the effect of intervention in this study?	Was the analysis based on splitting participants' follow-up time according to intervention received?	Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome?	Did the authors use an appropriate analysis method that controlled for all the important confounding domains?	Were confounding domains that were controlled for measured validly and reliably by the variables available in this study?
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	Yes	No	NA	Probably no	NA

Abbreviations: NA = not applicable; ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale.

Table E-6. Risk of bias for controlled cohort studies—Confounding, Part II

Main Study Author (Year); Study Design	Outcomes Assessed	Did the authors control for any post-intervention variables that could have been affected by the intervention?	Did the authors use an appropriate analysis method that adjusted for all the important confounding domains and for time varying confounding?	Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?	Overall Bias due to Confounding	Comments
Claus, 2020[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	No	NA	NA	High	The devices were evenly distributed among the 4 surgeons but unclear how patients were assigned to treatment by surgical technique and if relevant variables were considered. No adjustment for baseline differences in analyses.
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	No	Probably no	Probably no	High	Analysis only adjusted for basic demographics such as BMI and age. Nonsurgery group consisted of patients that surgeons were reluctant to perform SI joint fusion due to their own experiences with surgery failures.
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	NA	NA	High	Assignment to treatment based on surgeon, and did not consider all relevant variables such as duration of pain and difference in patient selection and diagnosis among surgeons. No adjustment for important confounders.
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	NA	NA	High	Used propensity matching to adjust for underlying differences between groups, but did not consider all relevant variables such as duration of pain and differences in patient selection among the 2 treating surgeons.
Smith (2013)[30] Retrospective controlled cohort	VAS Pain	No	NA	NA	Some concerns	Assignment to treatment was based on which surgeon a patient saw, patients seeing 3 of the 7 participating surgeons received

Main Study Author (Year); Study Design	Outcomes Assessed	Did the authors control for any post-intervention variables that could have been affected by the intervention?	Did the authors use an appropriate analysis method that adjusted for all the important confounding domains and for time varying confounding?	Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?	Overall Bias due to Confounding	Comments
study with concurrent comparator						open procedure and the patients seeing the other 4 received MIS; differences in patient selection and diagnosis by treating surgeon are potential confounders.
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	No	Probably no	NA	High	Assignment to treatment based on time period during which surgery received. Other factors (advances in anesthesia, surgeon or surgical team skill, imaging guidance used) may have varied between these time periods and this was not adjusted for. Few demographic/ clinical characteristics shown; no description of adjusted analysis other than noting that subgroup analyses showed no predictors of revision (other than intervention).
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	No	NA	NA	High	Assignment to treatment was not entirely based on patient/provider selection; it was somewhat determined by whether the patient's insurance would cover the fusion procedure. No adjustment for baseline differences in analyses. Authors note that some outcomes were assessed via subgroup analyses based on certain clinical factors, which did not change results.

Abbreviations: BMI = body mass index; MIS = minimally invasive surgery; NA = not applicable; ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); SI = sacroiliac; VAS = visual analog scale.

Table E-7. Risk of bias for controlled cohort studies—Selection of participants into the study

Main Study Author (Year); Study Design	Outcomes Assessed	Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention?	Were the post-intervention variables that influenced selection likely to be associated with intervention?	Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?	Do start of follow-up and start of intervention coincide for most participants?	Were adjustment techniques used that are likely to correct for the presence of selection biases?	Overall Bias in Selection of Participants into the Study	Comments
Claus, 2020[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	Yes	Yes	No	Yes	No	High	Participants had to have at least 6 mos. of postoperative outpatient follow-up.
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	Probably no	NA	NA	Yes	No	Some concerns	Assignment to treatment was based on time period evaluated, subjects were only assigned to control group in the 1990s after surgeons experienced poor outcomes from surgery.
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Yes	No	High	Participants had to have at least 1 yr. of follow-up available.
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Yes	No	High	Participants had to have at least 1 yr. of follow-up available.
Smith (2013)[30] Retrospective controlled cohort	VAS Pain	Yes	Yes	No	Yes	No	High	Participants had to have VAS pain scores recorded in their medical

Main Study Author (Year); Study Design	Outcomes Assessed	Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention?	Were the post-intervention variables that influenced selection likely to be associated with intervention?	Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome?	Do start of follow-up and start of intervention coincide for most participants?	Were adjustment techniques used that are likely to correct for the presence of selection biases?	Overall Bias in Selection of Participants into the Study	Comments
study with concurrent comparator								records at 12 and 24 mos. to be included in the study. Participants who did not return for follow-up or for whom surgeons did not document a pain score would not be eligible for selection into the study.
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	No	NA	NA	Yes	NA	Low	None
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	Yes	Yes	No	Yes	No	High	Only participants that had at least 12 mos. of follow-up were included in study.

Abbreviations: mo(s). = month(s); NA = not applicable; ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale; yr. = year.

Table E-8. Risk of bias for controlled cohort studies—Classification of intervention

Main Study Author (Year); Study Design	Outcomes Assessed	Were intervention groups clearly defined?	Was the information used to define intervention groups recorded at the start of the intervention?	Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome?	Overall Bias in Classification of Intervention	Comments
Claus, 2020[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	Yes	Yes	No	Low	None
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	Yes	Yes	No	Low	None
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Low	None
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Low	None
Smith (2013)[30] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Yes	Yes	No	Low	None
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	Yes	Yes	No	Low	None
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	Yes	Yes	No	Some concerns	Details of what constituted conservative management over time is not clear.

Abbreviations: ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale.

Table E-9. Risk of bias for controlled cohort studies—Deviation from intended intervention

Main Study Author (Year); Study Design	Outcomes Assessed	Were there deviations from the intended intervention beyond what would be expected in usual practice?	Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	Overall Bias due to Deviation from Intended Intervention	Comments
Claus (2020)[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	No	NA	Low	None
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	No	NA	Low	None
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	NA	Low	None
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	NA	Low	None
Smith (2013)[30] Retrospective controlled cohort study with concurrent comparator	VAS Pain	No	NA	Low	None
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	No	NA	Low	None
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	No	NA	Low	None

Abbreviations: NA = not applicable; ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale.

Table E-10. Risk of bias for controlled cohort studies—Missing data

Main Study Author (Year); Study Design	Outcomes Assessed	Were outcome data available for all, or nearly all, participants?	Were participants excluded due to missing data on intervention status?	Were participants excluded due to missing data on other variables needed for the analysis?	Are the proportion of participants and reasons for missing data similar across interventions?	Is there evidence that results were robust to the presence of missing data?	Overall Bias due to Missing Data	Comments
Claus (2020)[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	Probably yes	No	No information	No information	No information	No information	No information is reported about missing data or the potential for data to be missing.
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	No	No	Yes	Yes	No information	High	I: 50/81=61.7% C: 28/48=58.3%
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	No	Yes	No	No information	High	Only 79.6% of participants were included in the analysis and all of the missing data is from the open surgical group, thus high risk of bias from differential attrition.
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	No	No	No	No information	High	Only 70% of patients were included in the analysis. In the open surgery group, 10 participants were excluded for incomplete records; an additional 9 participants (4 in the open group and 5 in the MIS group) were excluded for presumably poor propensity score matching.

Main Study Author (Year); Study Design	Outcomes Assessed	Were outcome data available for all, or nearly all, participants?	Were participants excluded due to missing data on intervention status?	Were participants excluded due to missing data on other variables needed for the analysis?	Are the proportion of participants and reasons for missing data similar across interventions?	Is there evidence that results were robust to the presence of missing data?	Overall Bias due to Missing Data	Comments
Smith (2013)[30] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Depends on time point	No	Yes	Probably yes	No information	High	Missing data for 21% of participants at 1 yr., and 63% of participants at 2 yrs.
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	Depends on group	No	No	No	No information	Some concerns	I: 263/274 (96.0%) C: 29/38 (76.3%) Differential attrition by group. Unclear whether available records used to identify cases were complete.
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	Depends on time point (see comments)	No	Yes	No information	Probably no	High	High attrition after the 1 to 2 yrs. follow-up time point. 1 yr.: I: 27/27=100%; C1: 47/51=92.2%; C2: 63/74=85.1% 2 yrs.: I: 24 (88.9%); C1: 41 (80.3%); C2: 52 (70.2%) 3 yrs.: I: 20 (74.1%): C1: 33 (64.7%); C2: 43 (58.1%) 4 yrs.: I: 15 (55.6%); C1: 23 (45.1%); C2: 34 (45.9%) 5 yrs.: I: 6 (22.2%); C1: 6 (11.8%); C2: 23 (31.1%) 6 yrs.: I: 1 (3.7%); C1: 2 (3.9%); C2: 16 (21.6%)

Abbreviations: C = control group; I = intervention group; MIS = minimally invasive surgery; mos. = months; ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale; yr(s). = year(s).

Table E-11. Risk of bias for controlled cohort studies—Measurement of outcome

Main Study Author (Year); Study Design	Outcomes Assessed	Could the outcome measure have been influenced by knowledge of the intervention received?	Were outcome assessors aware of the intervention received by study participants?	Were the methods of outcome assessment comparable across intervention groups?	Were any systematic errors in measurement of the outcome related to intervention received?	Overall Bias in Measurement of Outcomes	Comments
Claus (2020)[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	Probably yes	Yes	Probably yes	Probably no	Some concerns	Outcome assessors (patients in the case of patient-reported outcomes) were not masked, and this could have influenced their outcome assessment to a degree. Relied on clinical records review, and the extent to which outcomes were recorded in a standardized and complete manner across all participants is not known.
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	Probably yes	Yes	Probably yes	Probably no	Some concerns	Outcome assessors (patients in the case of patient-reported outcomes) were not masked and this could have influenced their outcome assessment to a degree. Relied on clinical records review, and the extent to which outcomes were recorded in a standardized and complete manner across all participants is not known.
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Probably yes	Yes	Probably yes	Probably no	Some concerns	Outcome assessors (patients in the case of patient-reported outcomes) were not masked and this could have influenced their outcome assessment to a degree. Relied on clinical records review, and the extent to which outcomes were recorded in a standardized and complete manner across all participants is not known.

Main Study Author (Year); Study Design	Outcomes Assessed	Could the outcome measure have been influenced by knowledge of the intervention received?	Were outcome assessors aware of the intervention received by study participants?	Were the methods of outcome assessment comparable across intervention groups?	Were any systematic errors in measurement of the outcome related to intervention received?	Overall Bias in Measurement of Outcomes	Comments
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Probably yes	Yes	Probably yes	Probably no	Some concerns	Outcome assessors (patients in the case of patient-reported outcomes) were not masked and this could have influenced their outcome assessment to a degree. Relied on clinical records review, and the extent to which outcomes were recorded in a standardized and complete manner across all participants is not known.
Smith (2013)[30] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Probably yes	Yes	Probably yes	Probably no	Some concerns	Outcome assessors (patients in the case of patient-reported outcomes) were not masked and this could have influenced their outcome assessment to a degree. Relied on clinical records review, and the extent to which outcomes were recorded in a standardized and complete manner across all participants is not known.
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	Probably no	Yes	Yes	Probably no	Low	The decision to revise the initial procedure made based on clinical assessment and recorded in the medical record.

Main Study Author (Year); Study Design	Outcomes Assessed	Could the outcome measure have been influenced by knowledge of the intervention received?	Were outcome assessors aware of the intervention received by study participants?	Were the methods of outcome assessment comparable across intervention groups?	Were any systematic errors in measurement of the outcome related to intervention received?	Overall Bias in Measurement of Outcomes	Comments
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	Probably yes	Yes	Probably yes	Probably no	Some concerns	Outcome assessors (patients in the case of patient-reported outcomes) were not masked and this could have influenced their outcome assessment to a degree. Relied on clinical records review, and the extent to which outcomes were recorded in a standardized and complete manner across all participants is not known.

Abbreviations: ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale.

Table E-12. Risk of bias for controlled cohort studies—Selection of reported result and overall rating

Main Study Author (Year); Study Design	Outcomes Assessed	Is the reported effect estimate likely to be selected, on the basis of the results, from multiple outcome measurements within the outcome domain?	Is the reported effect estimate likely to be selected, on the basis of the results, from multiple analyses of the intervention outcome relationship?	Is the reported effect estimate likely to be selected, on the basis of the results, from different subgroups?	Overall Bias in Selection of the Reported Result	Comments	Overall Study Bias	Overall Rating Justification/ Comments
Claus (2020)[33] Retrospective controlled cohort study with concurrent comparator	VAS, ODI, SF-12 (PCS), surgery length, length of stay, safety outcomes	No	No	No	Low	None	High	High or some concerns in multiple domains including confounding, selection (due to how patients were selected for enrollment and unknown attrition), and outcome measurement.
Kibsgard (2013)[25] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success, safety outcomes	No	No	No	Low	None	High	High or some concerns for bias in multiple domains, including confounding, selection bias (both due to enrollment methods and due to attrition), and outcome measurement.
Ledonio (2014)[31] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	No	No	Low	None	High	High or some concerns in multiple domains including confounding, selection (due to how patients were selected for enrollment and differential attrition), and outcome measurement.
Ledonio (2014)[32] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	No	No	Low	None	High	High or some concerns in multiple domains including confounding, selection (due to how patients were selected for enrollment and high attrition), and outcome measurement.

Main Study Author (Year); Study Design	Outcomes Assessed	Is the reported effect estimate likely to be selected, on the basis of the results, from multiple outcome measurements within the outcome domain?	Is the reported effect estimate likely to be selected, on the basis of the results, from multiple analyses of the intervention outcome relationship?	Is the reported effect estimate likely to be selected, on the basis of the results, from different subgroups?	Overall Bias in Selection of the Reported Result	Comments	Overall Study Bias	Overall Rating Justification/ Comments
Smith (2013)[30] Retrospective controlled cohort study with concurrent comparator	VAS Pain	No	No	No	Low	None	High	High or some concerns in multiple domains including confounding, selection (due to how patients were selected for enrollment and high attrition), and outcome measurement.
Spain (2017)[34] Retrospective controlled cohort study with historical comparator	Safety outcomes	No	No	No	Low	None	High	Some concerns for bias due to confounding and differential attrition.
Vanaclocha (2018)[24] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	No	No	No	Low	None	High	High concern for bias because of missing data at time points greater than 1 yr. and use of repeated measures analysis through all time points; some concerns for bias in other domains including selection of participants, confounding, classification of intervention and measurement of outcome.

Abbreviations: ODI = Oswestry Disability Index; SF-12 (PCS) = Short Form-12 health survey (physical health component score); VAS = visual analog scale; yr. = year.

Table E-13. Risk of bias for uncontrolled studies and cohort studies evaluating sacroiliac joint fusion, Part I

Main Study Author (Year)	Were there clear criteria for inclusion in the study?	Did the study have consecutive inclusion of patients?	Did the study analyses have complete inclusion of patients (i.e., loss to follow-up)?	Were included patients comparable?	Was SI joint pain validly diagnosed and in a consistent, reliable way in all included patients?
Al-Khayer (2008)[113]	Yes	Unclear	Unclear as only patients with at least 24 mos. of follow-up were included in the analysis	Unclear	Unclear
Araghi (2017)[109]	Yes	Unclear	Unclear	Yes	Yes
Beck (2015)[114]	No	Yes	Yes	Unclear	Yes
Belanger (2001)[47]	No	Unclear	Unclear	No	No
Bornemann (2017)[58]	No	Unclear	Unclear	Unclear	Unclear
Buchowski (2005)[53]	Yes	Yes	Unclear as only patients with at least 24 mos. follow-up were included in the analysis	Yes	Unclear
Cher (2018)[42]	Probably yes	Probably yes	Unclear	Unclear	No information
Cher (2015)[68]	Yes	Yes	Unclear	Unclear	No information
Cleveland (2019)[39]	Yes	Unclear	probably no	Unclear	Unclear
Cross (2018)[119]	No	Unclear	Yes, 18/19 had follow-up data	Unclear	Unclear
Cummings (2013)[59]	Yes	No, only patients with at least 1 yr. of follow-up were included	No, only patients with at least 1 yr. of follow-up were included.	Unclear	Yes
Darr (2019);[120] Darr (2018);[56] Darr (2018)[57] LOIS	Yes	No	No, only participants at 12 of the 39 original sites were eligible to participate in this long-term follow-up study, and of the 127 eligible participants, only 103 participated.	Yes	Yes
Duhon (2013);[55] Duhon (2016);[124] Duhon (2016)[125] SIFI	Yes	Unclear	Yes, 169/194=87% at 2 yrs.	Yes	Yes
Fuchs (2018)[54]	Yes	Unclear	Yes. (137/171=80.1% at 1 yr. and 132/171=77.2% at 2 yrs.)	Yes	Yes
Gaetani (2013)[60]	Yes	Yes	Yes, as only reports on the first 12 cases at this single institution	Yes	Yes
Kancherla (2017)[115]	Yes	Probably yes	Data available for 41/57 =71.9% of patients	Unclear	Yes

Main Study Author (Year)	Were there clear criteria for inclusion in the study?	Did the study have consecutive inclusion of patients?	Did the study analyses have complete inclusion of patients (i.e., loss to follow-up)?	Were included patients comparable?	Was SI joint pain validly diagnosed and in a consistent, reliable way in all included patients?
Khurana (2009)[116]	Yes	Unclear (study only includes 15 patients who met criteria and describes these patients as consecutive)	Yes, for those who met criteria for inclusion, but this study excluded patients who required further surgery	Unclear	Yes
Kibsgard (2014)[51]	Yes	Yes	Yes, had follow-up data for 8/9= 88.9%	Yes	Yes
Kleck (2016)[68,61]	Yes	Unclear	Unclear, data for intraoperative and postoperative complications was likely complete, but outcomes at 1 yr. likely incomplete	Unclear	Unclear
Kube (2016)[117]	Unclear	Unclear	Yes, follow-up data available for 15/18=83% of patients	Unclear	Unclear
Mao (2018)[43]	Probably yes	Unclear	Unclear	Probably yes	Probably yes
Mason (2013)[112]	Unclear	Yes	No, data available for 55/73=75% of participants	Unclear	Unclear
McGuire (2012)[118]	Unclear	Unclear	Yes, data for 34/37=91.9% at 1 yr. and 30/37=81.8% at 2 yrs.	Unclear	Unclear
Miller (2013)[62]	Yes	Yes	Unclear	Unclear	Unclear
Mohit (2020)[46]	Yes	Yes	Unclear	Probably yes	Yes
Montenegro (2021)[45]	Probably no	Unclear	Unclear	Unclear	Unclear
Murakami (2018)[37]	Yes	Unclear	Probably no	Probably yes	Yes
Nystrom (2017)[49]	Yes	Unclear	Yes, 49/55=89%	Unclear	Yes
Patel (2019)[35]	Yes	Unclear	Yes	Yes	Yes
Rainov (2019)[40]	Yes	Yes	Unclear	Probably yes	Yes
Rajpal (2018)[41]	Yes	Unclear	Unclear	Probably yes	Probably yes
Rappoport (2017)[110]	Yes	Yes	Yes, 100%	Unclear	Unclear, not all patients were required to have a diagnostic block, specific physical exam tests were NR
Rudolf (2012)[63]	Yes	Yes	Unclear	Unclear	Yes
Sachs (2013)[64]	Yes	Unclear (if complete data required for inclusion)	Only patients with 1 yr. follow-up data were included	Unclear	Yes
Sachs (2014)[65]	Yes	Unclear (if complete data required for inclusion)	Only patients with complete preoperative and 1 yr. follow-up data were included	Unclear	Yes

Main Study Author (Year)	Were there clear criteria for inclusion in the study?	Did the study have consecutive inclusion of patients?	Did the study analyses have complete inclusion of patients (i.e., loss to follow-up)?	Were included patients comparable?	Was SI joint pain validly diagnosed and in a consistent, reliable way in all included patients?
Sachs (2016)[66]	Yes	No	Only patients with documented preoperative pain scores and who consented to complete questionnaire were included	Unclear	No
Schmidt (2020)[44]	Probably yes	Probably yes	Unclear	Probably yes	Probably yes
Schoell (2016)[67]	Yes	Yes	Yes	Unclear	Unclear
Schutz (2006)[52]	Yes	Unclear	Yes	No	No
Slinkard (2013)[50]	Unclear	Unclear	No, follow-up data for 19/25=76%	Unclear	Unclear whether abnormal imaging findings in SI joint were required, only 1 provocative physical exam finding required
Waisbrod (1987)[48]	Yes	Unclear	Unclear	Unclear	Unclear, used criteria of the era during which the procedures were performed, but these criteria have evolved
Wales (2021)[38]	Yes	Probably yes	No	Probably yes	Probably yes
Wise (2008)[111]	Yes	Yes	Yes	Unclear	Unclear

Abbreviations: LOIS = Long Term Outcomes from INSITE and SIFI; mo(s). = months; NR = not reported; SI = sacroiliac; SIFI = Sacroiliac Joint Fusion with iFuse Implant System study; yr(s). = years.

Table E-14. Risk of bias for uncontrolled studies and cohort studies evaluating sacroiliac joint fusion, Part II

Main Study Author (Year)	Were SAFETY outcomes assessed using valid measures in a consistent, reliable way for all included patients?	Was the follow-up period long enough for SAFETY outcomes to occur?	If done, were statistical analyses used appropriately?	Was there clear reporting of participants' demographic information?
Al-Khayer (2008)[113]	Unclear	Yes	NA	Yes
Araghi (2017)[109]	Unclear	Yes	NA	Yes
Beck (2015)[114]	Unclear	Yes	NA	Yes
Belanger (2001)[47]	Unclear	Yes	NA	Yes
Bornemann (2017)[58]	No	Yes	NA	Yes
Buchowski (2005)[53]	Unclear	Yes	NA	Yes
Cher (2018)[42]	Probably yes	Unclear	Unclear	No
Cher (2015)[68]	Yes	Yes	Yes	Yes
Cleveland (2019)[39]	Unclear	Yes	NA	Yes
Cross (2018)[119]	Unclear	Yes	NA	Yes
Cummings (2013)[59]	Unclear	Yes	NA	Yes
Darr (2019);[120] Darr (2018);[56] Darr (2018)[57] LOIS	Yes, per the original study protocols	Yes	NA	Yes
Duhon (2013);[55] Duhon (2016);[124] Duhon (2016)[125] SIFI	Yes	Yes	NA	Yes
Fuchs (2018)[54]	Unclear	Yes	NA	Yes
Gaetani (2013)[60]	Unclear	Yes	NA	Yes
Kancherla (2017)[115]	Unclear	Yes	NA	Yes
Khurana (2009)[116]	Unclear	Yes	NA	Yes
Kibsgard (2014)[51]	Yes	Yes	NA	Yes
Kleck (2016)[61]	Unclear	Yes	NA	Yes
Kube (2016)[117]	Unclear	Yes	NA	Yes
Mao (2018)[43]	Unclear	Probably yes	NA	Yes
Mason (2013)[112]	Unclear	Yes	NA	Yes
McGuire (2012)[118]	Unclear	Yes	NA	Yes
Miller (2013)[62]	Unclear	Yes	NA	No
Mohit (2020)[46]	Unclear	Yes	NA	Yes
Montenegro (2021)[45]	Unclear	Yes	NA	Yes

Main Study Author (Year)	Were SAFETY outcomes assessed using valid measures in a consistent, reliable way for all included patients?	Was the follow-up period long enough for SAFETY outcomes to occur?	If done, were statistical analyses used appropriately?	Was there clear reporting of participants' demographic information?
Murakami (2018)[37]	Unclear	Yes	NA	Probably yes
Nystrom (2017)[49]	Unclear	Yes	NA	Yes
Patel (2019)[35]	Yes	Yes	NA	Yes
Rainov (2019)[40]	Unclear	Yes	NA	Yes
Rajpal (2018)[41]	Unclear	Yes	NA	Yes
Rappoport (2017)[110]	Unclear	Yes	NA	Yes
Rudolf (2012)[63]	Unclear	Yes	NA	Yes
Sachs (2013)[64]	Unclear	Yes	NA	Yes
Sachs (2014)[65]	Unclear	Yes	NA	Yes
Sachs (2016)[66]	Unclear	Yes	NA	Yes
Schmidt (2020)[44]	Probably no	Yes	NA	Yes
Schoell (2016)[67]	Unclear	Yes	NA	Yes
Schutz (2006)[52]	Unclear	Yes	NA	Yes
Slinkard (2013)[50]	Unclear	Yes	NA	Yes
Waisbrod (1987)[48]	Unclear	Unclear	NA	Yes
Wales (2021)[38]	Unclear	Unclear	NA	Yes
Wise (2008)[111]	Unclear	Yes	NA	Yes

Abbreviations: LOIS = Long Term Outcomes from INSITE and SIFI; NA = not applicable; SIFI = Sacroiliac Joint Fusion with iFuse Implant System study.

Table E-15. Risk of bias for uncontrolled studies and cohort studies evaluating sacroiliac joint fusion—Part III

Main Study Author (Year)	Was there clear reporting of participants' clinical information?	Overall, were participants described with sufficient details to allow other investigators to replicate the research or allow clinicians to make inferences related to their own practice?	ROB Ratings (Low/Medium/High/ Unclear)	Rationale/Comments
Al-Khayer (2008)[113]	No	No	High	Only included patients who had 24 mos. of follow-up, unstandardized approach to diagnosis used, unclear whether study used standardized protocol for identifying and documenting adverse events.
Araghi (2017)[109]	Yes	Yes	Medium	Unclear whether a consecutive sample was screened for enrollment, authors do not report total adverse events, only those they deemed related to surgery or device, which is more subjective.
Beck (2015)[114]	Unclear	Yes	Medium	Two slightly different approaches were used for the procedure; unclear whether standardized protocol was used for safety events.
Belanger (2001)[47]	Yes	Yes	High	This describes 4 case reports in 1 paper, no standardized protocol for diagnosis of measurement of outcomes.
Bornemann (2017)[58]	No	No	High	Very little information about study population, method of diagnosis, and study inclusion/exclusion criteria, unclear whether study used standardized protocol for identifying and documenting adverse events.
Buchowski (2005)[53]	Yes	Yes	High	Excluded patients that did not have 24 mos. of follow-up; most of the participants had prior spine surgery, including fusion surgery so the applicability to a less selected population is uncertain.
Cher (2018)[42]	No	Probably no	High	No clinical or demographic information about population reported; unclear whether a standardized approach to capturing adverse events and revisions surgery was used across the many settings represented by the manufacturer's database as appears to rely on voluntary reporting of complaints to the manufacturer. Inconsistencies between methods stated and data reported in text and tables; authors contacted for clarification.
Cher (2015)[68]	No	No	High	Very little clinical information about patients in the analysis and no information about diagnosis; unclear whether a standardized approach to capturing adverse events and revisions surgery was used across the many settings represented by the manufacturer's database as appears to rely on voluntary reporting of complaints to the manufacturer. Some concerns about how standardized and consistently cases of revision surgery were reported in the complaints database.

Main Study Author (Year)	Was there clear reporting of participants' clinical information?	Overall, were participants described with sufficient details to allow other investigators to replicate the research or allow clinicians to make inferences related to their own practice?	ROB Ratings (Low/Medium/High/ Unclear)	Rationale/Comments
Cleveland (2019)[39]	Yes	Unclear	High	Unclear whether patients were included consecutively; only patients with a postoperative follow-up visits were included, very little information about the study population and method of diagnosis. Unclear whether standardized protocol was used for safety events. High loss to follow-up and unclear approach to handling missing data.
Cross (2018)[119]	No	No	High	Unclear whether all patients who underwent surgery at these centers were enrolled, unclear whether study used standardized approach for identifying and documenting adverse events.
Cummings (2013)[59]	No	Yes	High	Excluded patients that did not have at least 1 yr. of follow-up or that had bilateral procedures, which was nearly half of all patients; also most patients had undergone prior lumbar spine surgery, so applicability to a less selected population is uncertain.
Darr (2019);[139] Darr (2018);[56] Darr (2018)[57] LOIS	Yes	Yes	Medium	Potential for selection bias as only 12 of the original 39 participating sites qualified to conduct the long-term extension study, participants in the long-term sites had differences in number of implants and had larger improvements in pain and disability compared to subjects who did not participate in this long-term extension study.
Duhon (2013);[55] Duhon (2016);[124] Duhon (2016)[125] SIFI	Unclear	Yes	Low	Clear diagnostic criteria, prospective enrollment and follow-up, on-site monitoring, and systematic approach to measuring safety outcomes. Strengths of the design are that it was a protocol-driven analysis with validated, systematic collection of safety data.
Fuchs (2018)[54]	Unclear	Yes	Medium	Unclear whether consecutive eligible patients were enrolled and diagnostic criteria appear to have some subjectivity.
Gaetani (2013)[60]	No	Unclear	Medium	Though consecutive patients were enrolled, the sample size is only 12 and little clinical information about the patients was reported.
Kancherla (2017)[115]	Unclear	Unclear	Medium	Follow-up on less than 80% of eligible patients.
Khurana (2009)[116]	Unclear	Yes	High	Patients who required further surgery were excluded from the analysis, this introduce a high risk for selection bias.
Kibsgard (2014)[51]	Yes	Yes	Low	Consecutive patients, well-described clinical population, prospective enrollment, and data collection. However, the procedure performed included symphysiodesis in addition to SI joint fusion, so applicability to less selected population is low.

Main Study Author (Year)	Was there clear reporting of participants' clinical information?	Overall, were participants described with sufficient details to allow other investigators to replicate the research or allow clinicians to make inferences related to their own practice?	ROB Ratings (Low/Medium/High/ Unclear)	Rationale/Comments
Kleck (2016)[61]	No	No	High	Unclear diagnostic criteria, concern over completeness of longer-term follow-up data, population not well described.
Kube (2016)[117]	Yes	Yes	Medium	Unclear diagnostic criteria, only modest attrition, unclear approach to assessing safety outcomes.
Mao (2018)[43]	Probably no	Probably yes	High	Retrospective review of patients who underwent SI joint fusion at a single center; high potential for selection bias because only included patients with at least 12 mos. of follow-up data available; unclear how many patients received surgery but were lost to follow-up. Medical records from postoperative clinic used to ascertain adverse events and unclear whether these were evaluated systematically and completely. Unclear the role of a questionnaire administered at 12 mos. (in clinic, by phone, or by mail) in assessing for adverse events.
Mason (2013)[112]	Unclear	Unclear	High	Only 75% of patients had follow-up data, unclear approach to diagnosis, uncertain whether adverse events captured in a systematic way.
McGuire (2012)[118]	No	No	High	Unclear diagnostic criteria, very little clinical information about participants, unclear whether systematic approach to capturing adverse events was used. Only 37 consecutive patients enrolled over a 21-yr. span of time, meaning risk of bias due to growth in surgeon procedural experience or changes in surgical techniques/technology over time.
Miller (2013)[62]	No	Unclear	High	No diagnostic criteria provided and very little clinical information about population; unclear whether a standardized approach to capturing adverse events and revisions surgery was used across the many settings represented by the manufacturer's database as appears to rely on voluntary reporting of complaints to the manufacturer.
Mohit (2020)[46]	Yes	Probably no	High	Of the 47 consecutive patients, only the 44 patients with 12-mo. follow-up included. Unclear whether study used standardized protocol for identifying and documenting adverse events. Two-year outcomes had a 70% follow-up rate.
Montenegro (2021)[45]	Yes	Unclear	High	Few details on the clinical eligibility criteria and diagnosis criteria. Unclear whether a consecutive sample was identified and if there was any loss to follow-up. Authors required that patients have 3 mos. of data to be included in the analysis. Unclear whether a systematic approach to evaluating safety outcomes was used.

Main Study Author (Year)	Was there clear reporting of participants' clinical information?	Overall, were participants described with sufficient details to allow other investigators to replicate the research or allow clinicians to make inferences related to their own practice?	ROB Ratings (Low/Medium/High/ Unclear)	Rationale/Comments
Murakami (2018)[37]	Probably yes	Probably yes	High	High potential for selection bias due to the requirement to have a minimum of 5 yrs. of follow-up and outcomes that could be evaluated. Not clear that all persons who consented to receive surgery were included in the analysis. No information about methods/processes for adverse event outcome ascertainment.
Nystrom (2017)[49]	Unclear	Yes	Medium	Unclear whether systematic approach to measuring safety outcomes used, lack of some detail regarding clinical information about patient population.
Patel (2019)[35]	Yes	Yes	Medium	Unclear whether a consecutive sample was screened for enrollment.
Rainov (2019)[40]	Yes	Probably yes	Medium	Unclear whether study used standardized protocol for identifying and documenting adverse events. Greater than 20% loss to follow-up at 9 and 12 mos. Medium risk of bias for outcomes <9 mos. and high risk of bias for outcomes 9 mos. or later.
Rajpal (2018)[41]	Yes	Unclear	High	Unclear whether all patients who underwent surgery at the center were enrolled. Unclear how authors achieved 100% follow-up at 12 mos., through selection or persistent follow-up methods. Unclear whether study used standardized approach for identifying and documenting adverse events.
Rappoport (2017)[110]	No	No	Medium	Very little clinical information about population, diagnostic criteria do not appear systematically applied.
Rudolf (2012)[63]	Unclear	Yes	Medium	Unclear whether outcomes available for nearly all patients, unclear whether systematic approach to evaluating safety outcomes was used.
Sachs (2013)[64]	Unclear	Yes	High	High potential for bias as 1-yr. follow-up data was required for study inclusion, unclear whether a systematic approach to evaluating safety outcomes was used.
Sachs (2014)[65]	Unclear	Yes	High	High potential for bias as both preoperative and 1-yr. follow-up data was required for study inclusion, unclear whether a systematic approach to evaluating safety outcomes was used.
Sachs (2016)[66]	Unclear	Yes	High	High potential for bias as required patients to have documented preoperative information for inclusion, unclear whether a systematic approach to evaluating safety outcomes was used, nonstandardized approach to diagnosis was used.

Main Study Author (Year)	Was there clear reporting of participants' clinical information?	Overall, were participants described with sufficient details to allow other investigators to replicate the research or allow clinicians to make inferences related to their own practice?	ROB Ratings (Low/Medium/High/ Unclear)	Rationale/Comments
Schmidt (2020)[44]	Probably no	Probably no	High	High potential for selection bias and recall bias. Study was not clear if all eligible patients were included or if only those who received the surgery and could be followed up on were included. Follow-up for efficacy outcomes was done at 2 yrs. via a survey and likely did not include questions about safety. Safety information did not appear to be collected systematically and only the (lack of) revision surgery was reported in the Discussion section.
Schoell (2016)[67]	No	No	High	No information about diagnosis and likely not standardized given the many different sites involved, very little clinical information about patient population, uncertain validity of approach for identifying eligible cases and safety outcomes, (i.e., risk of misclassification bias). Also possible that some patients could have received open SI joint fusion, despite the CPT codes used to code procedures.
Schutz (2006)[52]	Yes	Yes	High	Diagnostic criteria not applied systematically, various approaches used to confirm patients' source of pain was SI joint (e.g., 4/17 [nearly 25%]) patients did not receive diagnostic SI joint blocks). Unclear whether systematic approach to capturing safety outcomes used.
Slinkard (2013)[50]	Unclear	Yes	High	Unclear whether this cohort was assembled prospectively (before surgery) or retrospectively (after surgery); unclear validity of diagnostic approach used, unclear whether safety outcomes were collected systematically and more than 20% with missing data.
Waisbrod (1987)[48]	Unclear	Unclear	High	Unclear patient population, validity of diagnostic approach uncertain, unclear whether systematic approach to measuring safety outcomes was used, unclear whether there was any missing data.
Wales (2021)[38]	Probably yes	Probably yes	Medium	Modest lost to follow-up (7 of 40 patients), unclear whether a standardized and systematic approach to assessing adverse events and revision surgery was used given retrospective nature of evaluation.
Wise (2008)[111]	Yes	Yes	Medium	Unclear validity of diagnostic approach, unclear whether systematic approach to measuring safety outcomes used.

Abbreviations: CPT = Current Procedural Terminology; LOIS = Long Term Outcomes from INSITE and SIFI; mo(s). = months; SI = sacroiliac; SIFI = Sacroiliac Joint Fusion with iFuse Implant System study; yr(s). = years.

Table E-16 Quality of health economic studies—Part I

Author (Year)	Was the study objective presented in a clear, specific, and measurable manner?	Were the perspective of the analysis (societal, third-party payer, and so on) and reasons for its selection stated?	Were variable estimates used in the analysis from the best available source (i.e., randomized control trial-best, expert opinion-worst)?	If estimates came from a subgroup analysis, were the groups pre-specified at the beginning of the study?	Was uncertainty handled by (i) statistical analysis to address random events; (ii) sensitivity analysis to cover a range of assumptions?	Was incremental analysis performed between alternatives for resources and costs?	Was the methodology for data abstraction (including value health states and other benefits) stated?
Ackerman (2014)[69]	Yes	Yes	Yes	NA	Yes	No	NA
Ackerman (2013)[70]	Yes	Yes	Yes	NA	Yes	No	NA
Blissett (2020)[72]	Yes	Yes	Yes	NA	Yes	Yes	Yes
Buysman (2018)[122]	Yes	Yes	Yes	NA	No	NA	Yes
Cher (2016)[71]	Yes	Yes	Yes	NA	Yes	Yes	Yes

Abbreviations: NA = not applicable.

Table E-17. Quality of health economic studies—Part 2

Author (Year)	Did the analytic horizon allow time for all relevant and important outcomes? Were benefits and costs that went beyond 1 yr. discounted (3–5%) and justification given for the discount rate?	Was the measurement of costs appropriate and the methodology for the estimation of quantities and unit costs clearly described?	Was the primary outcome measure(s) for the economic evaluation clearly stated and were the major short-term, long-term, and negative outcomes included?	Were the health outcomes measures/scales valid and reliable? If previously tested valid and reliable measures were not available, was justification given for the measures/scales used?	Were the economic model (including structure), study methods and analysis, and the components of the numerator and denominator displayed in a clear transparent manner?	Were the choice of economic model, main assumptions and limitations of the study stated and justified?
Ackerman (2014)[69]	Yes	Yes	Yes	NA	Yes	Yes
Ackerman (2013)[70]	Yes	Yes	Yes	NA	Yes	Yes
Blissett (2020)[72]	Yes	Yes	Yes	Yes	Yes	Yes
Buysman (2018)[122]	No	No	Yes	NA	No	Yes
Cher (2016)[71]	Yes	Yes	Yes	Yes	Yes	Yes

Abbreviations: NA = not applicable.

Table E-18. Quality of health economics studies—Part 3

Author (Year)	Did the author(s) explicitly discuss direction and magnitude of potential biases?	Were the conclusions/recommendations of the study justified and based on the study results?	Was there a statement disclosing the source of funding for the study?	Total Score[a]
Ackerman (2014)[69]	Yes	Yes	Yes	93
Ackerman (2013)[70]	Yes	Yes	Yes	93
Blissett (2020)[72]	Yes	Yes	Yes	99
Buysman (2018)[122]	Yes	Cannot determine	Yes	60
Cher (2016)[71]	Yes	Yes	Yes	99

Note: a. Based on scale of 0 (worst quality) to 100 (best quality).