Sacroiliac Joint Fusion

Draft Evidence Report

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Health Technology Assessment Program (HTA)

Washington State Health Care Authority

PO Box 42712
Olympia, WA 98504-2712
(360) 725-5126
www.hca.wa.gov/hta
shtap@hca.wa.gov

Prepared by:
RTI International–University of North Carolina Evidence-based Practice Center
Research Triangle Park, NC 27709 www.rti.org

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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The following individuals from the RTI-UNC Evidence-based Practice Center contributed to this report:

Lead Investigator: Leila Kahwati, MD, MPH
Co-Investigator: Cynthia Feltner, MD, MPH
Clinical Advisor: Kenneth Crandall, MD
Project Coordinator/Analyst: Emmanuel Coker-Schwimmer, MPH
Analyst: Ashley Andrews, BA
Scientific Reviewer: Meera Viswanathan, PhD
Library/Document Preparation: Mark Howell, MLS; Loraine Monroe; Laura Small, BA

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List of Abbreviations

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
CPG	Clinical practice guideline
CQ	Cost question
CUA	Cost-utility analysis
EQ	Efficacy question
ES	Executive summary
HTA	Health technology assessment
MID	Minimally important difference
NR	Not reported
NS	Not significant
QALY	Quality-adjusted life year
RCT	Randomized controlled trial
RM	Repeated measures
RR	Risk ratio
SQ	Safety question
SR	Systematic review
U.K.	United Kingdom
U.S.	United States

Executive Summary

Structured Abstract

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

Data Sources: PubMed and Embase from inception through June 20, 2018; 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. We selected relevant CPGs for quality appraisal and synthesis.

Data Extraction: One research team member extracted data and a second checked for accuracy. Two investigators independently assessed risk of bias of included studies and appraised identified CPGs. We rated the quality 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 43 studies in total; 8 were controlled studies (2 RCTs and 6 CCSs), 32 were uncontrolled studies, and 3 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 for pain (between-group differences at 6 months based on the RCTs: -40.5 mm [95% CI, -30.9 to -50.1], -38.1 mm [95% CI not reported; $P < 0.0001$], and at 6 months to 3.5 years based on the CCS: -6 cm [95% CI, not reported; $P < 0.001$]). These studies also observed larger improvements in physical function measured using the Oswestry Disability Index (between-group differences at 6 months: -25.4 points [95% CI, -18.3 to -32.5] and -19.8 points [95% CI, not reported, $P < 0.0001$] based on the RCTs, and at 6 months to 3.5 years: -24 points [95% CI, not reported; $P < 0.001$]) based on the CCS. We graded these outcomes as moderate quality from the RCTs and very low quality from the CCS. No differences in serious adverse events between groups were observed; we graded this outcome as low quality from the RCTs and very low quality from the CCS. The incidence of revision surgery varied by study; the highest incidence reported was 3.4 percent at 2 years. One cost-effectiveness study reported a cost per additional quality-adjusted life year gained of $13,313; we graded this outcome as very low quality. One CCS compared open fusion to no surgery at 11 to 32 years and observed no

difference in pain, physical function, or quality of life; we graded these outcomes as very low quality.

Three CCSs compared minimally invasive fusion with iFuse to open fusion. We graded all outcomes for this comparison as very low quality. One CCS reported larger improvements in pain measured with a visual analog scale (between-group difference over 2 years: -3 cm [95% CI, -2.1 to -4.0]; the other 2 studies did not report pain outcomes but found mixed findings for physical function measured by the Oswestry Disability Index. All 3 studies observed significantly shorter hospital lengths 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 incidence of revision surgery. One of the 3 studies reported significantly fewer revisions among participants that received iFuse (absolute risk difference [ARD] -51.3 percent [95% CI, -60.1% to -42.4%]); the other 2 studies reported infrequent revisions in both the iFuse and the open fusion groups.

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 -57.5% [95% CI, -74.8% to -40.2%]). We graded this outcome as very low quality.

Thirty-two 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 and 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 percent. Another study, which used a post market surveillance database of 11,388 iFuse procedures, reported an incidence of revision surgery of 2.8 percent over the years 2009 to 2014.

Limitations: Most included studies were uncontrolled, which limits a comparative assessment. We did not consider efficacy outcomes from uncontrolled studies. CCSs had critical methodological flaws. The only comparative studies of minimally invasive procedures evaluate the iFuse system, which limits generalizability of findings to other minimally invasive procedures. We did not evaluate unpublished data.

Conclusions: Among patients meeting diagnostic criteria for SI joint pain or dysfunction, minimally invasive SI joint fusion surgery with the iFuse Implant System is more effective than conservative management for reducing pain, improving function, improving quality of life, and is likely cost-effective. Minimally invasive SI joint fusion surgery with iFuse is also more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay. Serious adverse events from surgery with iFuse are infrequently reported in controlled studies but may be higher in usual practice based on evidence from uncontrolled studies. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or that evaluates procedures other than iFuse.

ES 1. Background

We designed 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 pain that may originate from the joint between bones in the spine and hip (sacrum and ilium). The clinical presentation of 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 30 percent of cases of mechanical low back pain.[2,3] However, estimating an accurate prevalence of SI joint pain is challenging because no universally accepted gold standard for diagnosis exists. The current reference standard for diagnosis is relief of pain after anesthetic SI joint injection.[2]

ES 1.3 Technology Description

SI joint fusion procedures are typically reserved for persons who fail conservative and less invasive treatments. Fusion of the SI joint can be performed as an open procedure (i.e., direct visualization), or since the late 1990s, as a minimally invasive procedure (i.e., indirect visualization). 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 immediate fixation with decortication and insertion of a bone graft to promote solid bone growth across the joint space for what some consider to be a 'true' fusion of the joint space.[4] 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 percent in 2009 to 88 percent in 2012.[5]

ES 1.4 Regulatory Status

The U.S. Food and Drug Administration (FDA) has cleared (through the 510k process) or approved (under Title 21 CFR Part 1271) at least 20 SI joint fusion systems made by various manufacturers. Detailed information is provided in ***Table 1*** of the Full Technical Report.

ES 1.5 Policy Context

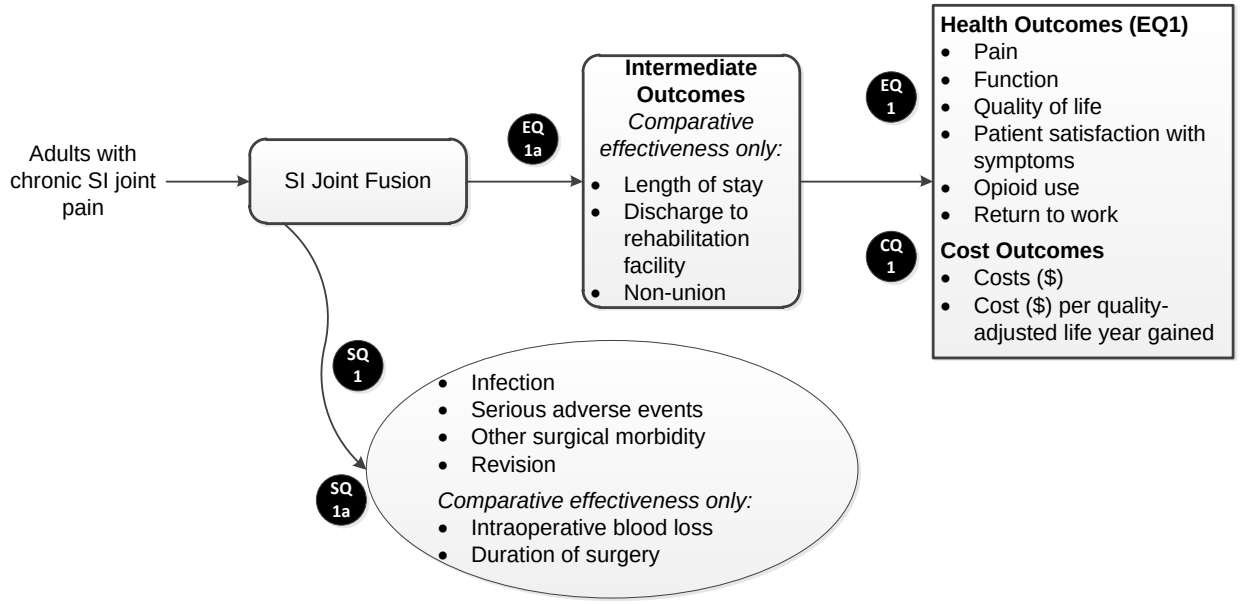
The State of Washington Health Care Authority selected SI joint fusion as a topic for an HTA based on high concerns for efficacy, safety, and cost. This HTA was conducted to assist the State of Washington's independent Health Technology Clinical Committee in determining coverage for SI joint fusion procedures to treat SI joint pain related to degenerative sacroiliitis or SI joint disruption.

ES 2. Methods

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

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 2 contextual questions related to diagnosis of SI joint pain.

ES 2.1.1 Data Sources and Search

We searched MEDLINE®, Embase, and a clinical trials registry for relevant English-language studies from inception to June 20, 2018. We searched the Centers for Medicare and 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 2.1.2 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, 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): RCTs, controlled trials, CCSs, and systematic reviews of similar scope; we also considered uncontrolled studies for 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.[6]
- Other: English-language, no restrictions on time period included.

ES 2.1.3 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.[6] This review did not include studies conducted among children or adolescents. It was designed to focus primarily 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.

ES 2.1.4 Data Abstraction and Risk of Bias Assessment

Two team members extracted relevant study data into a structured abstraction form, and the lead investigator checked those data for accuracy. Two team members conducted independent risk of bias assessments on all included studies. We used the Cochrane Risk of Bias (RoB 2.0) tool[7] to assess the risk of bias for RCTs, the ROBINS-I tool[8] to assess the risk of bias for nonrandomized comparative studies (e.g., CCSs) and the Quality of Health Economic Studies Instrument[9] to assess cost analyses. We used a checklist for critical appraisal of uncontrolled studies based on several existing instruments designed for case series.[10,11] For all study designs, risk of bias was assessed as low, some concerns, or high.

ES 2.1.5 Data Synthesis and Quality 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 percent confidence intervals (CI) when not provided by study authors. We identify all values that we calculated in the text and tables with *italics*. Two team members independently graded the quality of each body of evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. With GRADE, the quality of evidence can be graded as "very low," "low," "moderate," or "high". ***Table 3*** in the Full Technical Report defines these levels.[12]

ES 2.2 Clinical Practice Guideline Synthesis

In addition to the systematic evidence review of primary research studies, we synthesized clinical practice guidelines and appraised each guideline using the Appraisal of Guidelines for Research & Evaluation II (AGREE) instrument.[13,14] With this instrument, 6 domains are assessed and an overall score of between 1 (lowest quality) and 7 (highest quality) are assigned to reflect the overall quality of the guideline.

ES 3. Results

ES 3.1 Literature Yield

We included a total of 43 studies published between 1987 and 2018. Eight studies (2 RCTs, 6 CCSs) provided evidence on efficacy or comparative effectiveness (EQ1), 39 studies (2 RCTs, 5 CCSs, and 32 uncontrolled studies) provided evidence on safety (SQ1), and 3 studies provided evidence on costs or cost-effectiveness (CQ1).

ES 3.2 Minimally Invasive Fusion Compared with Conservative Management

We identified 2 RCTs[15,16] and 1 CCS[17] that compared minimally invasive SI joint fusion with the iFuse Implant System to conservative management and 1 CCS[18] that compared open fusion to no treatment. The quality 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.

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

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Change in pain at 6 months (Visual Analog Scale)						
2 RCTs[15, 16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with iFuse compared to conservative management; between-group difference -40.5 mm (95% CI, -50.1 to -30.9) in 1 study[16] and -38.1 mm (95% CI NR, P < 0.0001) in other study.[15]	⊕⊕⊕◯ MODERATE Favors iFuse
Change in pain at 6 months to 3.5 years (Visual Analog Scale)						
1 CCS[17]	Very serious[b]	Not serious[c]	Not serious	Not serious[d]	Total N = 137. Significantly larger improvement with iFuse compared to SI denervation (between-group difference: -4.5 cm, P < 0.001) and to conservative management (between-group difference: -6 cm, P < 0.001).	⊕◯◯◯ VERY LOW Favors iFuse
Change in physical function at 6 months (Oswestry Disability Index)						
2 RCTs[15, 16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with iFuse compared to conservative management, between-group difference -25.4 points (95% CI, -32.5 to -18.3, P < 0.0001) in 1 study[16] and -19.8 (95% CI NR, P < 0.0001) in other study.[15]	⊕⊕⊕◯ MODERATE Favors iFuse
Change in physical function at 6 months to 3.5 years (Oswestry Disability Index)						
1 CCS[17]	Very serious[b]	Not serious[c]	Not serious	Not serious[e]	Total N = 137. Significantly larger improvement with iFuse 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 iFuse
Change in quality of life at 6 months (EQ-5D and SF-36)						
2 RCTs[15, 16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with iFuse compared to conservative management; EQ-5D between-group difference 0.24 (95% CI, 0.16 to 0.32) in 1 study[16] and 0.21 (95% CI NR, P < 0.0001) in other study.[15] 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.[16]	⊕⊕⊕◯ MODERATE Favors iFuse
Opioid Use at 6 months						
1 RCT[16]	Serious[a]	Not serious[f]	Not serious	Serious[g]	Total N = 148. No significant difference in percentage of participants using opioids; *ARD -12.0% (95% CI, -28.6% to 4.5%, RR 0.83 (95% CI, 0.64 to 1.07)*.	⊕⊕◯◯ LOW No difference

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Opioid Use at 6 months to 3.5 years						
1 CCS[17]	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: iFuse (3.1 mg/day), SI denervation (32.2 mg/day), conservative management (38.5 mg/day).	⊕◯◯◯ VERY LOW Favors iFuse
Serious adverse events						
2 RCTs[15, 16]	Serious[a]	Not serious	Not serious	Serious[h]	Total n = 249. In one study, 21 serious events among 102 iFuse participants and 6 serious events among 46 conservative management participants (p=0.3241).[16] In other study, 8 events among 52 iFuse participants and 10 events among 49 conservative management participants.[15]	⊕⊕◯◯ LOW No difference
1 CCS[17]	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[15, 16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. In one study, incidence 3.4% at 2 yrs. among 89 iFuse participants with follow-up data and 2.6% among 30 conservative management participants that crossed over to surgery.[16] In other study, no revisions among 52 iFuse participants and 1 revision among 21 patients that crossed over to surgery.[15]	⊕⊕⊕◯ MODERATE NA
1 CCS[17]	Very serious[b]	Not serious[f]	Not serious	Very serious[j]	Total N = 137. No revision surgery reported among participants who received iFuse.	⊕◯◯◯ VERY LOW NA

Notes: We calculated values in italics.
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); confidence interval 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.

Abbreviations: ARD = absolute risk difference; cm = centimeters; CCS = controlled cohort study; CI = confidence interval; EQ-5D = EuroQOL measure of generic health status; N = number of participants; mm = millimeters; 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).

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

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Pain at 11 to 23 years (Visual Analog Scale)						
1 CCS[18]	Very serious[a]	Not serious[b]	Not serious	Serious[c]	Total N = 78. No significant between-group difference: -6 mm (95% CI, -10.2 to 22.2).	⊕◯◯◯ VERY LOW No difference
Physical function at 11 to 23 years (Oswestry Disability Index)						
1 CCS[18]	Very serious[a]	Not serious[b]	Not serious	Serious[d]	Total N = 78. No significant between-group difference: -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[18]	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

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. Confidence intervals around subscale estimates were wide and overlapping between groups.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; 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 quality of evidence for efficacy and safety outcomes is provided in ***Table ES-3***.

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

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Change in pain over 2 years (Visual Analog Scale)						
1 CCS[19]	Very serious[a]	Not serious[b]	Not serious	Not serious	Total N = 263; significantly larger improvement for iFuse compared to open fusion (between-group repeated measures difference -3.0 cm [95% CI, -2.1 to -4.0]).	⊕◯◯◯ VERY LOW Favors iFuse
Change in physical function at 13 to 15 months (Oswestry Disability Index)						
2 CCS[20,21]	Very serious[a]	Serious[c]	Not serious	Serious[d]	Total N = 83; mixed findings. Compared with open fusion, significantly larger improvements for iFuse in 1 study[20] (between-group difference -33 points, P < 0.0008); no difference in other study[21] (between-group difference 4.9 points, P = 0.272).	⊕◯◯◯ VERY LOW Mixed findings

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Length of Hospital Stay						
3 CCS[19-21]	Very serious[a]	Not serious	Serious[e]	Not serious	Total N = 346; significantly shorter length of stay for iFuse participants compared to open fusion participants; range of differences were 1.3 to 3.8 days across studies.	⊕◯◯◯ VERY LOW Favors iFuse
Adverse Events						
3 CCS[19-21]	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 2.3% to 35% across groups.	⊕◯◯◯ VERY LOW No difference
Revision Surgery						
3 CCS[19-21]	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)[20,21]; significantly fewer revisions in iFuse in third study *(ARD -51.3% [95% CI, -60.1% to -42.4%], RR 0.10 [95% CI, 0.04 to 0.26])*.[19]	⊕◯◯◯ VERY LOW Mixed findings

Notes: We calculated values in italics.
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[21] observed similar improvements between groups and the other study[20] shows significantly larger improvements among iFuse participants.
d. Based on SDs observed for this measure at follow-up in Ledonio et al.[21]; a sample size of 1,040 participants is 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 across studies was highly variable across studies likely reflecting 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[20,21]; large difference between iFuse and open surgery in third study.[19]

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; cm = centimeter; N = number of participants; RR = risk ratio.

ES 3.4 Minimally Invasive Fusion With Implants Compared to Screws

We identified 1 CCS that compared minimally invasive fusion with implants (iFuse) compared to percutaneous screw fixation. The study did not report any eligible efficacy outcomes; the quality of evidence for safety outcomes is provided in ***Table ES-4***.

Table ES-4. Summary of findings and quality of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) to screw fixation

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Revision Surgery at 2.8 to 4.6 Years						
1 CCS[22]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N = 292; significantly fewer revisions with iFuse (4.6%) compared to screws (65.5%); *ARD -57.5% (95% CI, -74.8% to -40.2%), RR 0.40 (95% CI, 0.26 to 0.63).*	⊕◯◯◯ VERY LOW Favors iFuse

Notes: We calculated values in italics.
[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; N = number of participants; RR = risk ratio.

ES 3.5 Safety Outcomes From Uncontrolled Studies

In addition to the 2 RCTs and 6 CCSs evaluating SI joint fusion, we identified 32 uncontrolled studies that reported safety outcomes from various SI joint fusion procedures. Eight studies[23-30] evaluated open fusion procedures, and the rest evaluated various minimally invasive fusion procedures. We rated 17 studies as having a high risk of bias, 13 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.[31,32] Some studies reported only whether major complications of surgery occurred.

Among the 8 studies evaluating open fusion, the frequency of adverse events ranged from "no major complications" to 75 percent experiencing complications. The frequency of revision surgery, which was reported only among 6 of the 8 studies, ranged from 4.1 percent to 64.7 percent.

Among the 13 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 percent to 30 percent. 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.[33] Study authors could not report the specific procedures or systems used based on available data. The overall incidence of complications was 13.2 percent at 90 days and 16.4 percent at 6 months among 469 claimants that had received surgery.

Among the 13 studies evaluating the iFuse Implant System, the frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market 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.[34]

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.[35-37] ***Table ES-5*** summarizes these outcomes.

Table ES-5. Summary of findings and quality of evidence comparing costs of minimally invasive sacroiliac joint fusion (iFuse Implant System) to conservative management

Certainty Assessment					Summary of Findings	QUALITY
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Costs over 3 to 5 years in a commercially insured population						
1 CCA (model) [35]	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[36] (model)	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						
1 CEA[37] (model)	Not serious	Not serious[a]	Not serious	Serious[b]	Minimally invasive SI joint fusion with iFuse costs $13,313 per QALY gained; breakeven costs at 13 years.	⊕◯◯◯ VERY LOW

Notes:
a. Not applicable, single study body of evidence.
b. No information provided (e.g., standard error, standard deviations, confidence intervals) 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 Clinical Practice Guideline Synthesis

We identified 2 publicly accessible clinical practice guidelines (CPGs).

- National Institute for Health and Care Excellence (U.K.) Intervention Procedure Guidance 578 (Minimally invasive sacroiliac joint fusion for chronic sacroiliac pain)[38]

Published in 2017, we appraised this guideline as a "4" on the AGREE-II scale from 1 (lowest quality) to 7 (highest quality). This guidance document concluded 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.

- AIM Specialty Health (U.S.). Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion[39]

Published in 2018, we appraised this guideline as a "3" on the AGREE-II scale from 1 (lowest quality) to 7 (highest quality). This guideline states that percutaneous/minimally invasive SI joint fusion may be considered medically necessary when selected criteria are 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.

ES 3.8 Contextual Question 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.[40] The International Association for the Study of Pain (IASP) recommends that diagnosis be based on the presence of pain in the area of the SI joint (i.e., positive Fortin finger test), which should be reproducible by performing specific pain provocation tests, or should be completely relieved by infiltration of the symptomatic SI joint with local anesthetics.[41] Details of specific criteria, such as recommended provocation tests, vary in the literature. In addition, there is variation in the extent to which experts agree on how definitive a positive response to a SI joint injection is for confirming the diagnosis.[42]

We identified 1 systematic review[43] published in 2009 of diagnostic test accuracy for SI joint dysfunction; authors included 18 studies that evaluated 1 or more clinical test (or combination of tests). All compared the index clinical test with contrast-enhanced intraarticular injection with local anesthetics as a reference test. Reference test administration varied across studies in terms of the volume of injected medications, 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).[43] Presence of pain in the SI joint region alone had relatively poor accuracy based on 1 study (sensitivity of 76% and specificity of 47%). Pooled analyses of studies comparing 3 or more positive provocation tests had better accuracy (sensitivity of 85% and specificity of 76%) than pain distribution or single provocation tests alone. We found no literature describing usual clinical practice in the approach to diagnosing SI joint pain, such as surveys of providers. Most included trials and controlled studies of SI joint fusion in our review used the following diagnostic criteria: positive Fortin finger test, provocative physical exam findings (at least 3 of 5), and 50 percent or greater reduction in pain after SI joint block

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 improves pain and physical function. The quality of evidence for these findings is moderate for outcomes at 6 months and very low for outcomes between 6 months and 3.5 years. Quality of life is also improved compared to conservative management at 6 months (moderate quality of evidence), but findings are mixed with respect to opioid use (low to very low quality of evidence). No differences in serious adverse events exist between surgery and conservative management (low to very low quality of evidence). The incidence of revision surgery is likely no higher than 3.4 percent at 2 years (moderate quality of evidence). Minimally invasive surgery with iFuse costs $13,313 per additional quality of life-adjusted year gained compared to conservative management; an amount that most would consider cost-effective. No differences exist between open fusion and conservative management with respect to pain,

function, and quality of life based on very low quality of evidence; no safety outcomes were reported for this comparison.

Minimally invasive SI joint fusion with the iFuse Implant System improves pain over 2 years and is associated with a shorter length of hospital stay compared to open fusion, but findings are inconsistent for physical function. The incidence of adverse events was 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 quality of evidence.

Compared to minimally invasive fusion with screw fixation, minimally invasive fusion with iFuse results in fewer revisions (very low quality of evidence).

We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events and revision surgery across the 8 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 24 uncontrolled studies of minimally invasive surgery (iFuse and other systems) is also very heterogenous, likely reflecting differences in outcome definitions and ascertainment or heterogeneity in study populations. 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 post-market surveillance.

ES 4.2 Limitations of the Evidence Base

Most studies we identified were uncontrolled studies, which prevents a comparative assessment. Eleven studies (3 CCSs and 8 uncontrolled studies) evaluated an open approach to fusion; however, the outcomes reported from these studies were limited. Of the seven controlled studies evaluating minimally invasive fusion, all evaluated the iFuse Implant System, which limits the generalizability of findings to 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.

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 Other Related HTAs

We identified several related HTAs. Assessments conducted by Hayes, Inc., ECRI institute, and Blue Cross Blue Shield Association are only available by subscription; they are not publicly accessible.[44-47]

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-6***. Details for these SI joint fusion coverage policies are provided in ***Table 22*** of the Full Technical Report. The Center for Medicare & Medicaid Services does not have a national coverage determination for SI joint fusion procedures though several Medicare Administrative Contractors (MAC) do cover this procedure, including 1 that operates in the State of Washington (Noridian Healthcare Solutions).[48] According to information supplied to the state's HTA Program by the manufacturer of iFuse, 44 state Medicaid programs cover iFuse as of May 2018.

Table ES-6. Overview of payer coverage policies for sacroiliac joint fusion for degenerative sacroiliitis, sacroiliac joint dysfunction, or sacroiliac joint pain

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

Notes: ✓ = covered; ✕ = not covered; — = no policy identified;
[a] Covered when clinical criteria are met and only covered for minimally invasive fusion with triangular, titanium coated implants (i.e., iFuse).
[b] Covered when clinical criteria are met.

Abbreviations: MAC = Medicare Administrative Contractor.

ES 4.5 Limitations of this HTA

We limited the scope to English-language publications. We did not search for unpublished data and did not use data presented only in conference abstracts. Lastly, we did not consider efficacy outcomes from uncontrolled studies.

ES 4.6 Ongoing Research and Future Research Needs

Three studies of SI joint fusion are ongoing; all are sponsored by device manufacturers. One is an uncontrolled trial of the SI-LOK joint fixation system (NCT01861899), one is an extended follow-up from 2 multicenter trials of the iFuse Implant System (NCT02270203), and the third is an uncontrolled, postmarket study of the SImmetry device (NCT02074761).

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. 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, minimally invasive SI joint fusion surgery with the iFuse Implant System is more effective than conservative management for reducing pain, improving function, and improving quality of life; and is likely cost-effective. Minimally invasive SI joint fusion surgery with iFuse is also more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay. Serious adverse events from surgery with iFuse are infrequently reported in controlled studies but may be higher in usual practice based on evidence from uncontrolled studies. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or that evaluates procedures other than iFuse.

Full Technical Report

1. Background

We conducted 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.

1.1 Condition Description

SI joint fusion is a surgical treatment used to address pain that originates 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.[1,4] 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 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 locations for pain.[1,2,4] 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 30 percent of cases of mechanical low back pain.[2,3] However, estimating an accurate prevalence of SI joint pain is challenging because no universally accepted gold standard for diagnosis exists. Debate exists about the accuracy of history and physical exam for establishing a diagnosis of SI joint pain; thus, 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 as a primary diagnostic modality. Thus, provocative physical exam tests (e.g., thigh thrust test, compression test) may have a role as part of a stepwise approach to diagnosis.[3] 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]

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.[3,4,49,50] 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 (i.e., direct visualization), or since the late 1990s, as a minimally invasive procedure (i.e., indirect visualization). 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 immediate fixation with decortication and insertion of a bone graft to promote solid bone growth across the joint space for what some consider to be a 'true' fusion of the joint space.[4]

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.[51] 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; however, it is not clear whether differences in efficacy between the 2 approaches exist.[51] 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 percent in 2009 to 88 percent in 2012.[5] 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 to enhance postoperative rehabilitation.[51]

1.4 Regulatory Status

We identified 15 devices with U.S. Food and Drug Administration (FDA) 510k clearance and 5 devices with Title 21 CFR Part 1271 FDA approval that are currently on the market in the U.S. We identified another 2 devices not currently on the market: 1 (SI-DESIS) has 510k clearance, and a second (DIANA) does not have FDA clearance but is available for use in Europe. ***Table 1*** provides detailed information about available devices, including their manufacturers, whether they are intended for minimally invasive or open procedures, FDA clearance or approval details, and product website links.

As noted above, the FDA cleared most of the SI joint fusion systems described in ***Table 1*** through the 510(k) process, which is based on evidence that the device is 'substantially equivalent' to a device that the FDA has already cleared or that was marketed before 1976. Devices that are designed to be used with allografts or other biologic materials received 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

Company	Product	MIS/Open	Clearance or Approval Type	Most Recent Clearance or Approval Date	510k Clearance Number	Company Product Link(s)	Surgical Approach Used
Alevio Spine	SiCure Sacroiliac Fusion System	Unclear	21 CFR Part 1271	Not available	k141106	SiCure	Lateral or Posterior
Alevio Spine	Re-Live Multi-Point Structural Allograft Sacroiliac Joint Fusion System	Unclear	21 CFR Part 1271	Not available	Not applicable	Re-Live	Posterior
Camber Spine	Siconus SI Joint Fixation System Prolix SI Fusion System (meant to be used in conjunction with Siconus system)	MIS	510k	January 18, 2017	k162121	Siconus Prolix	Lateral
Captiva Spine	TransFasten Posterior Sacroiliac Fusion System	Unclear	21 CFR Part 1271	Not available	Not applicable	TransFasten	Posterior
CoreLink, LLC	Entasis Sacroiliac Joint Fusion System	MIS	510k	February 4, 2016	k152237	Entasis	Lateral
Globus Medical, Inc.	SI-LOK Sacroiliac Joint Fixation System	MIS	510k	December 9, 2011	k112028	SI-LOK	Lateral
L&K Biomed Co., Ltd.	PathLoc-SI Joint Fusion System (no longer on market as of June 2018)	Unclear	510k	Nov 14, 2016	k153656	None specific to this device	Posterior
Life Spine	SImpact Sacroiliac Joint Fixation Screw System Tri-Fin Sacroiliac Joint Fixation Screw System	MIS	510k	February 22, 2015	k141246	SImpact Tri-Fin	Lateral
Medacta International SA	M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System	MIS or open	510k	August 2, 2017	k171595	M.U.S.T.	Not specified
Medical Designs, LLC (distributed by Orthofix)	SambaScrew System	Unclear	510k	August 20, 2012	k121148	SambaScrew	Lateral
Medtronic	SI-Fix Sacroiliac Joint Fusion System	MIS	510k	May 29, 2012	k110472	None, but according to 510(k) approval notice, this device served as the primary predicate (i.e., legally	Lateral

Company	Product	MIS/Open	Clearance or Approval Type	Most Recent Clearance or Approval Date	510k Clearance Number	Company Product Link(s)	Surgical Approach Used
						marketed device) against which the INTERFIX Rialto SI Fusion System was evaluated. The SI-Fix system does not appear to be in active use at this time.	
Medtronic	INTER FIX Rialto SI Fusion System	MIS	510k	August 12, 2016	k161210	INTERFIX or Rialto	Posterior
Omnia Medical	PsiF System	Unclear	21 CFR Part 1271	December 28, 2017	Not applicable	PsiF	Posterior
SI-Bone, Inc.	iFuse SI Joint Fusion System	MIS	510k	April 17, 2015	k150714	iFuse	Posterior
SICAGE, LLC	SICAGE Bone Screw System	MIS	510k	May 5, 2017	k170475	SICAGE	Lateral
SIGNUS Medizintechnik	Distraction Interference Arthrodesis of the Sacroiliac Joint (DIANA)	Open	Implant not FDA approved	N/A	Not applicable	DIANA device	Posterior
SI-Technology, LLC	SI-DESIS Sacroiliac Joint Fusion Screw System	MIS	510k	August 12, 2015	k151462	SI-DESIS	Posterior
SpineFrontier	SIJFuse Sacroiliac Joint Fusion Device System	MIS	510k	April 24, 2015	k150017	SIJFuse	Lateral
Tenon Medical, Inc.	Catamaran Sacroiliac Joint Fusion System (CAT SIJ Fixation System)	MIS	510k	June 13, 2018	k180818	Catamaran	Posterior
VGI Medical, LLC	SiJoin	MIS or open	21 CFR Part 1271	January 17, 2018	Not applicable	SiJoin	Posterior
X-spine Systems, Inc.	Silex Sacroiliac Joint Fusion System (same as Zimmer's TriCor, but marketed under a different name)	Open	510k	March 25, 2014	k140079	Silex Tricor	Lateral
Zyga Technology, Inc.	SImmetry Sacroiliac Joint Fusion System	MIS	510k	February 27, 2013	k130092	SImmetry	Lateral

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

1.5 Policy Context

Numerous surgical and nonsurgical approaches to the management of SI joint pain are routinely used within current clinical practice. In addition to standard open surgical techniques (e.g., Smith-Petersen technique), minimally invasive surgical techniques that use percutaneous lateral or posterior approaches are now available. The State of Washington Health Care Authority selected SI joint fusion as a topic for an HTA based on high concerns for efficacy, safety, and cost. This HTA 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 retrieved data on the use of SI joint fusion procedures for the time period 2014 to 2017. Details are described in ***Appendix A***. The aggregate number of patients receiving a SI joint fusion was less than the minimum permitted for public reporting.

2. Methods

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

2.1 Research Questions and Analytic Framework for Systematic Review of Primary Research Studies

We developed the following research questions and analytic framework (***Figure 1***) to guide the systematic evidence review of primary research studies:

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?

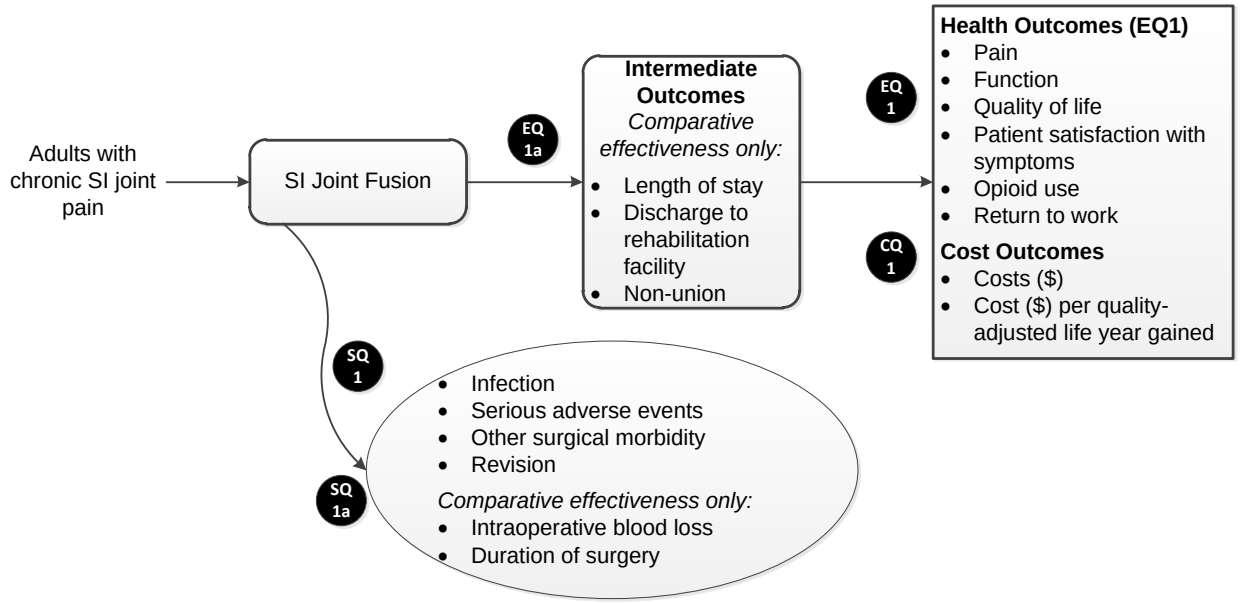
> **Safety Question 1a (SQ1a):** What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

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 June 20, 2018 to July 5, 2018. The final key questions and response to public comments on the draft key questions are available at the Program's website.[52] Two independent, external peer reviewers will review a draft version of this evidence report, and it will also be posted for public comment from October 12, 2018 until November 13, 2018. Feedback from peer reviewers and from public comments will be incorporated into the

Final Evidence Report; responses to public and peer review comments will be summarized in a separate document also available at the Program's website.[52]

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 questions:

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

2. What is known about the approach to diagnosis of sacroiliac joint pain or disruption in usual clinical practice?

Contextual questions were not systematically reviewed and are not shown in the analytic framework.

2.1.1 Data Sources and Searches

We searched MEDLINE® (via PubMed), Embase, and a clinical trials registry (clinicaltrials.gov) for relevant English-language studies. Date ranges for the PubMed and Embase searches ranged from inception to June 20, 2018. We searched the Centers for Medicare and 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, and other HTAs on this topic 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.

2.1.2 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 the lead 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, 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
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 no treatment	*EQ1 and 1a:* No comparator group
Outcomes	*EQ1:* • Pain • Physical functioning • Quality of life • Patient satisfaction with symptoms • Opioid use • Return to work *EQ1a only:* • Length of stay • Non-union • Discharge to acute or sub-acute rehabilitation facility *SQ1:*	Other outcomes not specifically listed as eligible. Pain, quality of life, and functional outcomes not measured using valid and reliable instruments or scales[53,54]

Domain	Included	Excluded
	• Infection • Serious adverse events (e.g., cardiovascular events, thromboembolism, etc.) • Other surgical morbidity • Revision surgery *SQ1a only:* • Intraoperative blood loss • Duration of surgery *Cost and cost-effectiveness:* • Costs • Cost per quality-adjusted life year gained • Cost per disability-adjusted life year gained	
Setting	Inpatient or outpatient settings in countries[a] categorized as "very high" on United Nations Human Development Index.[6]	Studies conducted in countries not categorized as "very high" on United Nations Human Development index.
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)
Language and Time Period	English, no restrictions on time period included	Languages other than English

Notes. [a] Andorra, Argentina, Australia, Austria, Bahrain, Belgium, Brunei Darussalam, Canada, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Arab Emirates, United Kingdom, United States.

Abbreviations: CCA = comparative cost analysis; CCS = controlled cohort study; CCT = controlled clinical trial; CEA = cost-effectiveness analysis; CQ = cost question; CUA = cost-utility analysis; CBA = cost-benefit analysis; EQ = efficacy question; HTA = health technology assessment; RCT = randomized controlled trial; SI = sacroiliac; SQ = safety question; SR = systematic review.

2.1.2.1 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.

2.1.2.2 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 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.

2.1.2.3 Outcomes

For the research question on efficacy (EQ1), studies that reported outcomes related to pain, quality of life, patient satisfaction, opioid use, and functional outcomes 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 quality of evidence ratings. Additionally, hospital length of stay, non-union, and discharge to rehabilitation facility were eligible for EQ1a. 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. 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 gained (DALY) were eligible for selection.

2.1.2.4 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.[6] We excluded studies conducted in countries with a development rating designated as less than "very high."

2.1.2.5 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.

2.1.2.6 Time Period

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

2.1.3 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.[6] This review did not include studies conducted among children or adolescents. It was designed to focus primarily 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. This review also excluded case reports because they provide the weakest evidence for assessing benefit or safety.

2.1.4 Data Abstraction and Risk of Bias Assessment

Two team members extracted relevant study data into a structured abstraction form, and the lead investigator checked those data for accuracy.

We used the Cochrane Risk of Bias (RoB 2.0) tool to assess the risk of bias for each included RCT.[7] 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.[8] 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.[10,11] 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.[9] 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 included studies; discrepancies were resolved by discussion.

2.1.5 Data Synthesis and Quality 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 percent confidence intervals (CI). We identify all values that we calculated in the text and tables with *italics*.

To determine whether quantitative synthesis was appropriate, we assessed the number of studies and the clinical and methodological heterogeneity present based on established guidance.[55,56] 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 quality of evidence for each comparison using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach.[57] Two team members independently graded each body of evidence and we resolved discrepancies through discussion. With GRADE, the quality of evidence can be graded as "very low," "low," "moderate," or "high", which reflects the overall certainty of the findings. ***Table 3*** defines these levels.[12] We graded bodies of evidence from RCTs separately from other study designs. Bodies of RCT evidence begin with a 'high' quality 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" quality rating and can be downgraded for the same domains as used to evaluate RCTs but can also be upgraded from "low" quality for other considerations (e.g., large effect, evidence of dose-response).

Table 3. Quality of evidence grades and definitions[12]

Grade	Definition
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.
Insufficient	**We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome**. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

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.[58] To do this, we calculated the sample size requirement for a single, adequately powered trial (based on 80 percent power, alpha level of 0.05, and two-tailed tests) to detect a MID for continuous measures (using average standard deviations [SD] reported by studies) or a relative risk reduction of at least 20 percent for categorical measures using OpenEpi version 3.01. We downgraded bodies of evidence that did not meet OIS criteria. If OIS criteria were met but the confidence intervals were either not provided or could not exclude a meaningful benefit or harm, then we downgraded for imprecision by 1 level.

2.2 Clinical Practice Guideline Synthesis

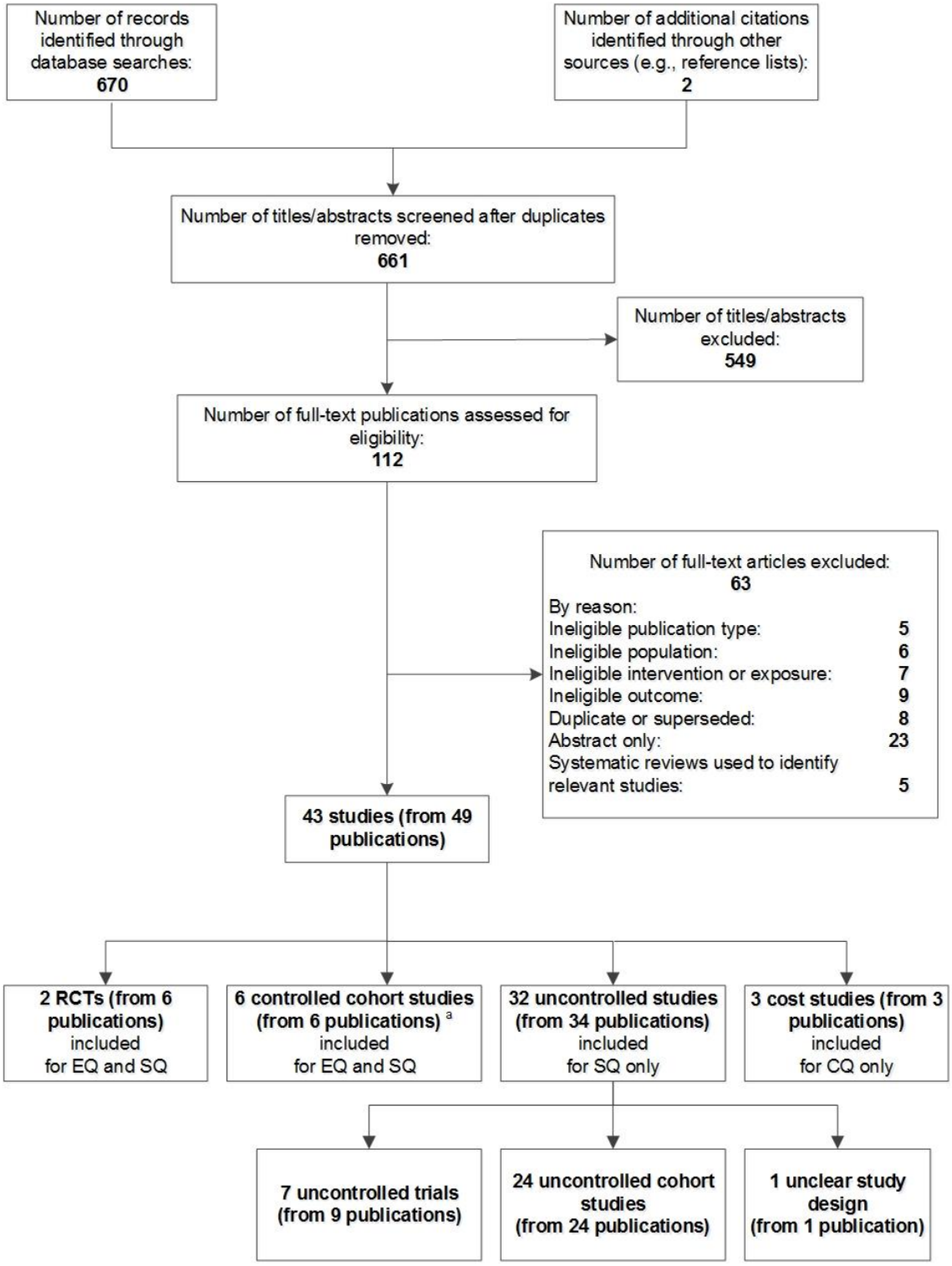
In addition to the systematic evidence review portion of this HTA, we synthesized CPGs in a tabular format. Specifically, we searched for relevant CPGs and appraised each guideline using the Appraisal of Guidelines for Research & Evaluation II (AGREE) instrument.[13,14] With this instrument, 6 domains are assessed and an overall score of between 1 (lowest quality) and 7 (highest quality) are assigned to reflect the overall quality of the guideline.

3. Results

3.1 Literature Search

Figure 2 depicts the study flow diagram. We identified and screened 661 unique citations. We excluded 549 citations after title and abstract review. We reviewed the full text of 112 articles and included a total of 43 studies reported in 49 articles published between 1987 and 2018. Eight studies (2 randomized controlled trials [RCTs], 6 controlled cohort studies [CCSs]) provided evidence on efficacy or comparative effectiveness (EQ1), 39 studies (2 RCTs, 5 CCSs, 32 uncontrolled studies) provided evidence on safety (SQ1), and 3 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 based on 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 HTA on sacroiliac joint fusion



[a] Five out of 6 controlled cohort studies (in 5 publications) reported SQ outcomes.

Abbreviations: CQ = cost question; EQ = efficacy question; RCT = randomized controlled trial; SQ = safety question

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 and summarize relevant CPGs. Last, we summarize the evidence to address the contextual questions related to diagnosis of SI joint pain and dysfunction.

3.2 Sacroiliac Joint Fusion Compared to Conservative Management

We identified 2 RCTs[15,16] and 1 CCS[17] that compared minimally invasive SI joint fusion to the iFuse Implant System with conservative management and 1 CCS[18] that compared open fusion to no treatment. The quality of evidence (GRADE rating) for efficacy and safety outcomes comparing iFuse to conservative management is provided in ***Table 4*** and comparing open fusion to no surgery is provided in ***Table 5***.

Table 4. Summary of findings and quality of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) with conservative management

Certainty Assessment						QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	
Change in pain at 6 months (Visual Analog Scale)						
2 RCTs[15,16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with iFuse compared to conservative management; between-group difference -40.5 mm (95% CI, -50.1 to -30.9) in 1 study[16] and -38.1 mm (95% CI NR, P < 0.0001) in other study.[15]	⊕⊕⊕◯ MODERATE Favors iFuse
Change in pain at 6 months to 3.5 years (Visual Analog Scale)						
1 CCS[17]	Very serious[b]	Not serious[c]	Not serious	Not serious[d]	Total N = 137. Significantly larger improvement with iFuse compared to SI denervation (between-group difference: -4.5 cm, P < 0.001) and to conservative management (between-group difference: -6 cm, P < 0.001).	⊕◯◯◯ VERY LOW Favors iFuse
Change in physical function at 6 months (Oswestry Disability Index)						
2 RCTs[15,16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with iFuse compared to conservative management, between-group difference -25.4 points (95% CI, -32.5 to -18.3, P < 0.0001) in 1 study[16] and -19.8 points (95% CI NR, P < 0.0001) in other study.[15]	⊕⊕⊕◯ MODERATE Favors iFuse
Change in physical function at 6 months to 3.5 years (Oswestry Disability Index)						

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
1 CCS[17]	Very serious[b]	Not serious[c]	Not serious	Not serious[e]	Total N = 137. Significantly larger improvement with iFuse 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 iFuse
Change in quality of life at 6 months (EQ-5D and SF-36)						
2 RCTs[15, 16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. Significantly larger improvement with iFuse compared to conservative management; EQ-5D between-group difference 0.24 (95% CI, 0.16 to 0.32) in 1 study[16] and 0.21 (95% CI NR, P < 0.0001) in other study.[15] 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.[16]	⊕⊕⊕◯ MODERATE Favors iFuse
Opioid Use at 6 months						
1 RCT[16]	Serious[a]	Not serious[f]	Not serious	Serious[g]	Total N = 148. No significant difference in percentage of participants using opioids; *ARD -12.0% (95% CI, -28.6% to 4.5%, RR 0.83 (95% CI, 0.64 to 1.07)*.	⊕⊕◯◯ LOW No difference
Opioid Use at 6 months to 3.5 years						
1 CCS[17]	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: iFuse (3.1 mg/day), SI denervation (32.2 mg/day), conservative management (38.5 mg/day).	⊕◯◯◯ VERY LOW Favors iFuse
Serious adverse events						
2 RCTs[15, 16]	Serious[a]	Not serious	Not serious	Serious[h]	Total N = 249. In one study, 21 serious events among 102 iFuse participants and 6 serious events among 46 conservative management participants (p=0.3241).[16] In other study, 8 events among 52 iFuse participants and 10 events among 49 conservative management participants.[15]	⊕⊕◯◯ LOW No difference
1 CCS[17]	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[15, 16]	Serious[a]	Not serious	Not serious	Not serious	Total N = 249. In one study, incidence 3.4% at 2 yrs. among 89 iFuse participants with follow-up data and 2.6% among 30 conservative management participants that crossed over to surgery.[16] In other study, no revisions among 52 iFuse participants and 1 revision among 21 patients that crossed over to surgery.[15]	⊕⊕⊕◯ MODERATE NA
1 CCS[17]	Very serious[b]	Not serious[f]	Not serious	Very serious[i]	Total N = 137. No revision surgery reported among participants who received iFuse.	⊕◯◯◯ VERY LOW NA

Notes: We calculated values in italics.

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); confidence interval 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.

Abbreviations: ARD = absolute risk difference; cm = centimeters; CCS = controlled cohort study; CI = confidence interval; EQ-5D = EuroQOL measure of generic health status; mm = millimeters; 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).

Table 5. Summary of findings and quality of evidence comparing open sacroiliac joint fusion with no surgery

Certainty Assessment						QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision	Summary of Findings	
Pain at 11 to 23 years (Visual Analog Scale)						
1 CCS[18]	Very serious[a]	Not serious[b]	Not serious	Serious[c]	Total N = 78. No significant between-group difference: -6 mm (95% CI, -10.2 to 22.2).	⊕◯◯◯ VERY LOW No difference
Physical function at 11 to 23 years (Oswestry Disability Index)						
1 CCS[18]	Very serious[a]	Not serious[b]	Not serious	Serious[d]	Total N = 78. No significant between-group difference; -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[18]	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

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. Confidence intervals around subscale estimates were wide and overlapping between groups.

Abbreviations: CCS = controlled cohort study; CI = confidence interval; N = number of participants; OIS = optimal information size; SD = standard deviation; SF-36 = Short Form 36-item Survey.

3.2.1 Study Characteristics

Table 6 describes study and population characteristics, including the methods used to diagnosis sacroiliac 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.[15,16] One study called INSITE enrolled participants at 19 U.S. centers and analyzed 148 participants.[16] The other study, called iMIA, enrolled participants at 9 centers in Belgium, Germany, Italy, and Sweden and analyzed 101 participants.[15] 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. Although the surgical intervention was the same in both studies (iFuse Implant system), 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. Both studies allowed participant crossover from conservative management to surgery after 6 months; by 1 year, 42.9 percent and 79.5 percent 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 was not blinded and outcome assessment was not blinded. We considered outcomes reported after 6 months as high risk of bias because of extensive crossover. The INSITE trial reported outcomes separately for participants who crossed over and those who did not; iMIA used the last observation carried forward method to estimate outcomes after 6 months for those assigned to conservative management. For these reasons, we did not grade the quality of evidence for outcomes after 6 months; but those findings are provided in ***Appendix C***, ***Table C-2***.

One CCS[17] 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[18] conducted at a single center in Norway compared an open fusion procedure using a dorsal approach to a group of participants that 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.

Table 6. 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)[16,59,60] U.S.	RCT; some concerns	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 (102)	Conservative management (46 at 6 mos.). 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% had crossover to surgery
iMIA (2016)[15,61,62] Multiple European Countries	RCT, some concerns	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 (52)	Conservative management (49 at 6 mos.) 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
Vanaclocha et al. (2018)[17] Spain	Controlled cohort, high	Single center, 2007 to 2015 Mean age iFuse: 48.0 SI denervation: 48.0 Conservative management: 51.4	Positive Fortin finger test, ≥ 3 provocative exam findings, ≥ 50% pain relief after SI joint block	iFuse (27)	1) SI denervation (47) 2) Conservative management (63)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Population Characteristics	Method of Diagnosis	Intervention (N Analyzed)	Comparator (N Analyzed)
		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)			
Kibsgard et al. (2013)[18] Norway	Controlled cohort, 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: mos. = months; N = number of participants; NR = not reported; RCT = randomized controlled trial; SI = sacroiliac; U.S. = United States; yr. = year.

3.2.2 Findings-Efficacy Outcomes

All 4 studies reported efficacy outcomes. ***Table 7*** 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. For the 2 RCTs, we focus our synthesis on outcomes reported at 6 months since extensive crossovers occurred in both trials after 6 months. We describe efficacy outcomes reported beyond 6 months in the last part of this section.

Table 7. Key efficacy outcomes from the 2 randomized controlled trials and 2 controlled cohort studies evaluating sacroiliac joint fusion compared to conservative management (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)[16,59,60] U.S.	RCT; some concerns	iFuse compared to CM: 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)	iFuse compared to CM: 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)	iFuse compared to CM at 6 mos: 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)*	Change in use at 6 mos. iFuse: -9% CM: 7.5% (P = 0.08) *ARD -12.0% (95% CI, -28.6% to 4.5%)* *RR: 0.83 (95% CI, 0.64 to 1.07)*
iMIA (2016)[15,61,62] Multiple European Countries	RCT, some concerns	iFuse compared to CM: 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]	iFuse compared to CM: 6 mos. -19.8 points (P < 0.0001) 1 yr. *-20.1 points* (P < 0.0001)[d]	iFuse compared to CM: EQ-5D 6 mos. 0.21 (P < 0.0001) 1 yr. 0.22 (P= 0.0009)[d]	NR
Vanaclocha et al. (2018)[17] Spain	CCS, high	At 6 mos. to 3.5 yrs. iFuse compared to SI denervation: RM difference: -4.5 cm (P < 0.001) iFuse compared to CM: RM difference: -6 cm (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: 385 (0 to 98) P < 0.001
Kibsgard et al. (2013)[18] Norway	CCS, high	Open fusion difference from no surgery at 11 to 32 years 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 years *-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: We calculated the values in italics based on data provided in the study.
[a] Scores range from 0 to 10 cm or 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; mos. = months; NR = not reported; NS = nonsignificant; PM = evening; RCT = randomized controlled trial; 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. = year.

Pain

Both RCTs[15,16] and the CCS[17] 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 difference of -40.5 mm (INSITE[16]) and -38.1 mm (iMIA[15]) compared to conservative management, both above a typical minimally important difference for this measure (i.e., 7 to 11 mm). The CCS[17] 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.[15] 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.[16]

The CCS[18] comparing open fusion to no surgery reported a nonsignificant difference in VAS scores at follow-up between 11 and 32 years; the mean difference was -6 mm (95% CI, *-13.0 to 25.0*).

Physical Functioning

Both RCTs[15,16] and the CCS[17] 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 (INSITE[16]) and -19.8 points (iMIA[15]) compared to conservative management. The CCS[17] reported similar statistically significant 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. Both RCTs also 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***).

The CCS[18] comparing open fusion to no surgery reported a nonsignificant difference in ODI scores at follow-up between 11 and 32 years: the adjusted mean difference (AMD) between groups was -4 points (95% CI, *-9.1 to 17.1*).

Quality of Life

Both RCTs[15,16] 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. The INSITE trial[16] also reported the physical health (PCS) and mental health (MCS) component scores of the Short-Form 36 survey (SF-36) and reported statistically significant improvements in both scores for participants allocated to iFuse compared to conservative management.

The CCS[18] 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 trial reported on change in opioid use.[16] At 6 months, authors observed no significant differences between groups in the percentage of participants using opioids (*ARD -12.0% [95% CI, -28.6% to 4.5%*]). 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.[15,62] At baseline, 44.2 percent of participants in the iFuse group were not working because of low back pain, and 52.9 percent in the conservative management group were not working. At 6 months, these proportions were 39.2 percent and 57.1 percent, respectively ($P = 0.07$).

Other Efficacy Outcomes

The INSITE trial reported a measure of global recovery as its primary study endpoint using a Bayesian analysis.[16] 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 percent of participants (95% Credible Interval, 72.4% to 88.4%) allocated to surgery and 23.9 percent 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 percent of participants allocated to iFuse reported that they were “much better” compared to 8.2 percent of participants allocated to conservative treatment ($P < 0.0001$).

Both the INSITE trial[16] and the iMIA trial[15] measured self-reported treatment satisfaction (***Appendix C, Table C-2***). In INSITE, 77.2 percent of participants allocated to iFuse reported being 'very satisfied' with treatment at 6 months compared to 27.3 percent of participants allocated to conservative management.[15] This level of satisfaction was durable at 1 and 2 years among participants allocated to iFuse.[59,60] At 1 year, a similar proportion (71.0%) of participants that crossed over from conservative management to iFuse reported being very satisfied.[60] 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%).[15]

Trial efficacy outcomes beyond 6 months

Both RCTs reported VAS pain and ODI measures beyond 6 months; some analyses were conducted as intent-to-treat whereas others were conducted based on treatment received. Because extensive 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.

In the iMIA trial[15,61], the change in VAS low back pain scores between baseline and 6 months (-43.3 mm) persisted at 1 year (-41.6 mm) among those allocated to fusion. At 1 year, the difference between participants allocated to fusion and those allocated to conservative management was -27.6 mm ($P < 0.0001$) based on carrying forward the VAS score from the 6-month follow-up for participants allocated to conservative management that crossed over. By 1 year, 69 percent of participants allocated to fusion had at least a 20-mm improvement on VAS in contrast to 27 percent of participants in the conservative management group who did not cross over to fusion ($P < 0.0001$). In the INSITE trial,[16,59,60] the authors observed a similar pattern. In participants allocated to fusion, 81.6 percent achieved a 20-mm reduction in VAS low back pain scores at 1 year and 83.1 percent achieved a 20-mm reduction at 2 years, in contrast to 12.5 percent and 10.0 percent, respectively, among participants allocated to the conservative management group (all crossovers were considered failures in this analysis). A similar pattern was observed for the ODI; findings among participants allocated to fusion were durable at 1- and 2-year follow-up, and authors observed significantly larger improvements among participants allocated to fusion compared to participants who remained in the conservative management group.

3.2.2 Findings-Safety Outcomes

Three of the 4 studies also reported safety outcomes. ***Table 8*** summarizes safety outcomes that studies reported. The 2 RCTs[16,63] observed no significant difference in serious adverse events at 6 months, and no serious adverse events were reported in the CCS.[17] In the INSITE trial,[16] treatment-related adverse events occurred in 16.7 percent of participants allocated to iFuse compared to 8.7 percent of those allocated to conservative management. The incidence of revision surgery was higher in the INSITE trial (2.6% among crossovers, 3.4% among allocated to fusion) compared to the iMIA trial (1.4%); no revisions were reported in the CCS.

Table 8. 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)[16,59,60] U.S.	RCT; some concerns	Serious adverse events at 6 mos. iFuse: 21 events Conservative management: 6 events (P= 0.3241) Adverse events related to device at 6 mos. iFuse: 3 (2.9%) Adverse events related to treatment procedure(s) at 6 mos. iFuse: 17 (16.7%) Conservative management: 4 (8.7%)	At 2 years: iFuse: 3 (3.4%, among 89 with follow-up) Conservative management: 1 (2.6%, among 39 that crossed over to surgery)
iMIA (2016)[15,61,62] Multiple European Countries	RCT, some concerns	Serious adverse events at 6 mos. iFuse: 8 events (none related to device, 2 related to procedure) Conservative management: 10 events	Mean follow-up 21.5 months iFuse: 0 Conservative management: 1 (1.4%) (in a patient that crossed over to surgery
Vanaclocha et al. (2018)[17] 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

Notes: We calculated the values in italics based on data provided in the study.

Abbreviations: CCS = controlled cohort study; mos. = months; NR = not reported; RCT = randomized controlled trial; SI = sacroiliac; U.S. = United States.

3.3 Minimally Invasive Sacroiliac Joint Fusion Compared With Open Fusion

We identified 3 CCSs that compared minimally invasive fusion with open fusion. The quality of evidence for efficacy and safety outcomes is provided in ***Table 9***.

Table 9. Summary of findings and quality of evidence comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) to open fusion

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Change in pain over 2 years (Visual Analog Scale)						
1 CCS[19]	Very serious[a]	Not serious[b]	Not serious	Not serious	Total N = 263; significantly larger improvement for iFuse compared to open fusion (between-group repeated measures difference -3.0 cm [95% CI, -2.1 to- 4.0]).	⊕◯◯◯ VERY LOW Favors iFuse
Change in physical function at 13 to 15 months (Oswestry Disability Index)						
2 CCS[20,21]	Very serious[a]	Serious[c]	Not serious	Serious[d]	Total N = 83; mixed findings. Compared with open fusion, significantly larger improvements for iFuse in 1 study (between-group differences -33 points, P < 0.0008)[20]; similar improvements in other study (between-group difference 4.9 points, P = 0.272).[21]	⊕◯◯◯ VERY LOW Mixed findings
Length of Hospital Stay						
3 CCS[19-21]	Very serious[a]	Not serious	Serious[e]	Not serious	Total N = 346; significantly shorter length of stay for iFuse participants compared to open fusion participants; range of differences were 1.3 to 3.8 days across studies.	⊕◯◯◯ VERY LOW Favors iFuse
Adverse Events						
3 CCS[19-21]	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 2.3% to 35% across groups.	⊕◯◯◯ VERY LOW No difference
Revision Surgery						
3 CCS[19-21]	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)[20,21]; significantly fewer revisions in iFuse in third study *(ARD -51.3% [95% CI, -60.1% to -42.4%], RR 0.10 [95% CI, 0.04 to 0.26])*.[19]	⊕◯◯◯ VERY LOW Mixed findings

Notes: We calculated values in italics.
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[21] observed similar improvements and the other study[20] shows significantly larger improvements.
d. Based on SDs observed for measure at follow-up in Ledonio et al.[21]; 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[20,21]; large difference between iFuse and open surgery in third study.[19]

Abbreviations: ARD = absolute risk difference; CCS = controlled cohort study; CI = confidence interval; cm = centimeter; 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 10***. All were conducted in the U.S.; 1[21] 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[20,21] 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.[19,20] No studies reported the mean duration of symptoms. Notably, the proportion of participants that had a prior lumbar fusion was higher among participants that received iFuse in all 3 studies, and notably higher in the Smith et al.[19] 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 10. 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)[21] 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)[20] 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)[19] 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[20] is the same open fusion group reported in Ledonio et al.[21]

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

Table 11. 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)[21] U.S.	CCS, High	NR	Oswestry Disability Index[a] iFuse difference from open fusion: 13 to 15 months: *4.9 points* (P =0.272)	Mean (SD) iFuse: 2 (NR) Open: 3.3 (NR) (P = 0.002)
Ledonio et al. (2014)[20] U.S.	CCS, High	NR	Oswestry Disability Index[a] iFuse 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)[19] U.S.	CCS, High	VAS (cm)[b] iFuse difference from open fusion 1 year: -3.6 (95% CI NR) 2 year: -3.7 (95% CI NR) Adjusted RM[c]: -3.0 (95% CI, -2.07 to - 3.99)	NR	Mean (SD) iFuse: 1.3 (0.5)[d] Open: 5.1 (1.9) (P < 0.0001)

Notes: We calculated values in italics based on data provided in the study.
[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 10 centimeters; 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.[19] reported pain using the VAS (in centimeters) 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 3.0-cm larger improvement for iFuse participants compared to open fusion. In a subgroup analysis of participants by prior lumbar fusion surgery status, no differences in effect were observed.[19]

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 (between-group difference 4.9, P = 0.272),[21] whereas the other study observed significantly larger improvements in the iFuse group (between-group difference -33, P < 0.0008). 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 12 summarizes safety outcomes reported by the 3 studies comparing minimally invasive SI joint fusion to open fusion.[19-21] 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 2.3 percent to 35.3 percent, 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[20,21]; 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%).

Table 12. 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
Ledonio et al. (2014)[21] U.S.	CCS, High	0 intraoperative complications in iFuse group, NR in open group; Pulmonary embolism iFuse 1 (2.3%); Open 1 (2.3%); *P = 1.00* *ARD 0.0% (95% CI, -70.9% to 70.9%)* *RR 1.0 (95% CI, 0.24 to 4.13)*	*iFuse: 2 (9.1%); Open 2 (9.1%); P = 1.00* *ARD 0.0% (95% CI, -51.5% to 51.4%)* *RR 1.0 (95% CI, 0.36 to 2.79)*
Ledonio et al. (2014)[20] U.S.	CCS, High	0 intraoperative complications in iFuse group, NR in open group; Postoperative complications iFuse 6 (35.3%); Open 3 (13.6%), *P = 0.13* *ARD 32.3% (95% CI, -0.03% to 67.2%)* *RR 1.93 (95% CI, 0.997 to 3.77)*	iFuse: 1 (5.9%); Open 2 (9.1%); *P = 1.00* *ARD -11.1% (95% CI, -66.9% to 44.7%)* *RR 0.75 (95% CI, 0.15 to 3.87)*
Smith et al. (2013)[19] U.S.	CCS, High	0 intraoperative complications in either arm; Postoperative complications iFuse: 20 (18%); Open: 34 (21%); P = 0.294; ARD -7.9% (95% CI, -22.5% to 6.6); RR (0.82 (95% CI, 0.56 to 1.2)	iFuse: 4 (3.5%); Open: 66 (44.3%); *P < 0.001* *ARD -51.3% (95% CI, -60.1% to -42.4%)* *RR 0.10 (95% CI, 0.04 to 0.26)*

Notes: We calculated values in italics based on data provided in the study.

Abbreviations: ARD = risk difference; CCS = controlled cohort study; CI = confidence interval; NR = not reported; RR = risk ratio; U.S. = United States.

3.4 Minimally Invasive Sacroiliac Joint Fusion With Implants Compared to Screws

We identified 1 CCS that compared minimally invasive fusion with the iFuse Implant System compared to percutaneously screw fixation. The study did not report any eligible efficacy outcomes; the quality of evidence for safety outcomes is provided in ***Table 13***.

Table 13. Summary of findings and quality of evidence ratings comparing minimally invasive sacroiliac joint fusion with implants (iFuse) compared to screws

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Revision Surgery at 2.8 to 4.6 Years						
1 CCS[22]	Serious[a]	Not serious[b]	Not serious	Not serious	Total N = 292; significantly fewer revisions with iFuse (4.6%) compared to screws (65.5%); *ARD -57.5% (95% CI, -74.8% to -40.2%); RR 0.40 (95% CI, 0.26 to 0.63).*	⊕◯◯◯ VERY LOW Favors iFuse

Notes: We calculated values in italics.
[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; N = number of participants; RR = risk ratio.

3.3.1 Study Characteristics

The study characteristics for the 1 CCS comparing minimally invasive SI joint fusion using the iFuse Implant System to percutaneous screw fixation are summarized in ***Table 14***. We rated this study as having some concerns for bias because of confounding and differential attrition.

Table 14. Study and population characteristics of the 1 controlled cohort study evaluating minimally invasive sacroiliac joint fusion with implants (iFuse) compared to screws

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)[22] U.S.	CCS, Some concerns	Single center Mean duration of symptoms NR N with prior lumbar fusion NR	NR	iFuse 274 treated 263 analyzed	Percutaneous fixation with screws (Synthes) 38 treated 29 analyzed

Notes:

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

3.3.2 Findings-Efficacy Outcomes

The 1 CCS comparing minimally invasive SI joint fusion with iFuse to percutaneous screw fixation did not report any efficacy outcomes.[22]

3.3.3 Findings-Safety Outcomes

Table 15 summarizes safety outcomes reported by the 1 CCS comparing minimally invasive SI joint fusion with iFuse to percutaneous screw fixation.[22] In this study, no significant predictors of revision were identified other than the initial surgery used.

Table 15. Safety outcomes from the 1 controlled cohort study evaluating minimally invasive sacroiliac joint fusion with implants (iFuse) compared to screws (SQ1)

Author (Year); Study Name; Country	Study Design; Risk of Bias	Adverse Events	Revision Surgery
Spain et al. (2017)[22] U.S.	CCS, Some concerns	NR	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, ARD -57.5% (95% CI, -74.8% to -40.2%), RR 0.40 (95% CI, 0.26 to 0.63)*

Notes: We calculated values in italics.

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

3.5 Safety Outcomes from Uncontrolled Studies

In addition to the 2 RCTs and 6 CCSs evaluating SI joint fusion, we identified 32 uncontrolled studies that reported safety outcomes from various SI joint fusion procedures. 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

Seven studies[25,27,30,31,64-66] were uncontrolled trials; 2 studies[32,67] were uncontrolled prospective cohorts; 20 studies[23,24,28,29,33,34,68-81] were uncontrolled retrospective cohorts; 2 studies[26,82] were uncontrolled cohorts, but we were unable to determine whether they were conducted prospectively or retrospectively; and 1 uncontrolled study[83] 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 11,388; 10 studies were multicenter,[30-34,64,77,80-82] and the rest were conducted at a single center. These studies were conducted from 1987 to 2018. The types of procedures evaluated varied and are summarized in ***Table 16***. Eight studies[23-30] evaluated open fusion procedures, and the rest evaluated various minimally invasive fusion procedures. We rated 17 studies as having a high risk of bias, 13 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***).

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.[31,32] 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. 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.

Table 16. Summary of fusion procedures evaluated in 32 uncontrolled studies

Procedure	Number of Studies
Open fusion	8 studies total: 2 studies using posterior approach[23,24] 2 studies using anterior approach[25,26] 1 study using anterior approach with symphysiodesis[27] 1 study using Verral and Pitkin technique(bilateral)[28] 1 study using modified Smith-Petersen technique[29] 1 study using distraction interference arthrodesis[30]
iFuse Implant System (triangular, titanium coated implants) [Minimally invasive]	13 studies total: 12 studies using iFuse only[31,32,34,70,71,74,77-81,83] 1 study using iFuse or Samba [72]
SImmetry System (titanium cannulated and antirotational implants with surface roughness) [Minimally invasive]	3 studies[64,75,82]
Percutaneous fusion using hollow modular anchorage screw [Minimally invasive]	3 studies[67,68,73]
SI-LOK Sacroiliac Joint Fusion System [Minimally invasive]	1 study[65]
INTERFIX system (single-threaded titanium cage filled with rhBMP-2) [Minimally invasive]	1 study[69]
Fusion using dual fibular dowel allografts [Minimally invasive]	1 study[76]
Fusion using threaded fusion cages [Minimally invasive]	1 study[66]
Various types of minimally invasive procedures based on insurance claims using CPT code 27279	1 study[33]

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

3.5.2 Findings-Safety Outcome

Among the 8 studies evaluating open fusion procedures, the frequency of adverse events ranged from "no major complications" to 75 percent experiencing complications. The frequency of revision surgery, which was reported only among 6 of the 8 studies, ranged from 4.1 percent to 64.7 percent. We were unable to compare the frequency of adverse events and revisions from these studies to the frequency reported in the 1 CCS[18] evaluating open fusion because this study did not report any safety outcomes.

Among the 13 studies evaluating the iFuse Implant system, the frequency of adverse events ranged from 0 percent to 91 percent; however, when limited to adverse events definitely or probably related to the device or procedure, the range was from 0 percent to 30 percent. Though a few uncontrolled studies reported a higher frequency than those observed in the 2 RCTs[15,16] and 1 CCS,[17] most uncontrolled studies reported a similar or lower frequency. The frequency of revision surgery ranged from 0 percent to 8 percent. The largest of these studies reported the incidence of revision based on the manufacturer's post-market 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.[34]

Among the 3 studies evaluating the SImmetry system, the frequency of adverse events varied. One study reported 2 serious events among 50 participants[64] over 2 years, 1 study reported 4 operative complications among 17 procedures,[75] and 1 study reported no procedure complications or serious events but did report 6 nonserious events over 2 years among 19 participants.[82] The frequency of revision was 0 percent in 1 study,[75] 2 percent in 1 study,[64] and not reported in the third study.[82]

Among the 3 studies evaluating percutaneous fusion using a hollow modular anchorage screw, 1 study reported 2 adverse events among 9 participants,[68] 1 study reported 2 events among 55 participants,[67] and 1 study reported 0 events.[73] Study authors of 2 studies[67,68] did not report the frequency of revision; the frequency of revision was 0 percent in the third study.[73]

One study[33] 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 percent at 90 days and 16.4 percent at 6 months among 469 claimants that received surgery. The most prevalent complication reported was neuritis or radiculitis (6.2% at 6 months).

3.6 Cost Effectiveness

Three studies reported on cost outcomes; all compared minimally invasive SI joint fusion surgery with iFuse to conservative management.[35-37] ***Table 17*** summarizes these outcomes.

Table 17. Summary of findings and quality of evidence ratings comparing costs of minimally invasive sacroiliac joint fusion (iFuse Implant System) to conservative management

Certainty Assessment					Summary of Findings	QUALITY/ Direction of Effect
№ of Studies	Risk of Bias	Inconsistency	Indirectness	Imprecision		
Costs over 3 to 5 years in commercially insured populations						
1 CCA[35] (model)	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[36] (model)	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						
1 CEA[37] (model)	Not serious	Not serious[a]	Not serious	Serious[b]	Minimally invasive SI joint fusion with iFuse costs $13,313 per QALY gained; breakeven costs at 13 years.	⊕◯◯◯ VERY LOW

Notes:
a. Not applicable, single study body of evidence.
b. No information provided (e.g., standard error, standard deviations, confidence intervals) to be able to judge precision of estimates.

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

3.6.1 Study Characteristics

Study characteristics and findings reported are summarized in ***Table 18***. We rated all 3 studies as low risk of bias (***Appendix E, Tables E-16, E-17, and E-18***). Two studies were comparative cost analyses,[35,36] and 1 was a cost-effectiveness analysis.[37] The 2 comparative cost analyses (by the same author) used similar methods to estimate differences in costs associated with minimally invasive fusion versus nonoperative management; 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 percent of the nonoperative care group would experience chronic pain.[35] 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 percent of the nonoperative group experienced chronic pain.[36] In both studies, the expected success rate of surgery was 82 percent (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.

One cost-effectiveness analysis reported incremental costs and quality-adjusted life years (QALYs) gained with surgical treatment with the iFuse Implant System compared to nonoperative care from a payer perspective.[37] Direct health care utilization costs were based on data from 1 RCT (INSITE[16]) and 1 uncontrolled trial (SIFI[31]); quality of life was measured by the EQ-5D. Authors modeled outcomes in a population that was 50 years old at the time of surgery and had an expected surgery success rate of 82 percent; in the nonoperative care group, 72 percent were assumed to have chronic pain despite treatment.[37]

Table 18. Study characteristics and cost or cost effectiveness outcomes comparing minimally invasive sacroiliac joint fusion (iFuse Implant System) to conservative management (CQ1)

Author (Year) Country	Intervention	Comparator	Key Analysis Parameters	Outcomes
Ackerman (2014)[35] U.S.	Minimally invasive SI joint fusion (unilateral)	Nonoperative care	Comparative cost analysis 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	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)[36] U.S.	Minimally invasive SI joint fusion (unilateral)	Nonoperative care	Comparative cost analysis 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	Mean per-patient lifetime costs: Fusion: $48,185 Nonoperative care: $51,543 Difference: $3,358
Cher (2016)[37] U.S.	Minimally invasive SI joint fusion with iFuse Implant System	Nonoperative care	Cost-effectiveness analysis U.S. dollars, year of currency NR Payer perspective Time horizon: 5 years Utility measure: EQ-5D	Base case Cost: Fusion: $22,468 Nonoperative care: $12,636 Difference: $-9,833 QALYs Fusion: 3.20 Nonoperative Care: 2.46 Difference: -0.74 Incremental cost-effectiveness ratio: $13,313 per QALY gained Breakeven costs at 13 years

Abbreviations: EQ-5D = EuroQOL instrument for measuring generic health status; NR = not reported; QALY = quality-adjusted life year; SI = sacroiliac; U.S. = United States.

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.

The comparative cost analysis based on a younger, commercially-insured population (mean age of 45) found higher costs in the surgery group than nonoperative group at 3 years (higher by $14,545) and 5 years postsurgery (higher by $6,137).[35] 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 postsurgery (lower by $100,493).[35] 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) 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).[36]

The cost-effectiveness analysis from the third study estimated an incremental cost-effectiveness ratio (ICER) over 5 years of $13,313 per QALY gained with surgery compared to nonoperative care in a population assumed to be 50 years old.[37] 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 break-even costs achieved at 13 years.[37]

3.7 Clinical Practice Guideline Synthesis

We identified several CPGs related to SI joint fusion. One developed by MCG Health (Milliman Care Guidelines) is proprietary and not publicly accessible and will not be discussed further.[84] ***Table 19*** summarizes the publicly available guidelines related to this procedure, which includes one from the National Institute for Health and Care Excellence (United Kingdom) and one from AIM Specialty Health. We identified a policy related to minimally invasive SI joint fusion from the International Society for the Advancement of Spine Surgery (ISASS),[85] but it was related to coverage of the procedure and was not a CPG. We also identified a coverage policy recommendation from the North American Spine Society; however, this policy is only available by subscription so we cannot assess whether it was a CPG.[86]

Table 19. Clinical practice guidelines related to sacroiliac joint fusion

Title/Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment
Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578[38] 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." NICE expects to release a guidance document focuses specifically on iFuse in October 2018.[87]	Based on 2 RCTs, 2 SRs, 3 prospective cohort studies, and 2 retrospective case series; quality of evidence assessment not performed.

Title/Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment
Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion AIM Specialty Health[39] Quality Rating: 3 out of 7	2018	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 5 cm or greater and ODI of 30 or greater • Failure of 6 months of conservative management • Confirmation of pain (typical pattern, positive Fortin test, 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

Abbreviations: AIM = acronym not defined; cm = centimeters; NICE = National Institute for Health and Care Excellence; ODI = Oswestry Disability Index; RCTs = randomized clinical trials; SI = sacroiliac; SR = systematic reviews; VAS = visual analog scale.

3.8 Contextual Questions

In addition to the key research questions, we sought evidence to address 2 contextual questions related to the diagnosis of SI joint pain or disruption; the recommended approaches to diagnosis and accuracy of tests (CQ1) and what is known about the approach to diagnosis in usual clinical practice (CQ2).

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.[40] The International Association for the Study of Pain (IASP) recommends that diagnosis be based on the presence of pain in the area of the SI joint, which should be reproducible by performing specific pain provocation tests, or should be completely relieved by infiltration of the symptomatic SI joint with local anesthetics.[41] The Musculoskeletal Program Clinical Appropriateness Guidelines from AIM Specialty Health (summarized in ***Table 19***) and several expert reviews on SI joint management concur with the IASP recommendations and recommend using a combination of pain distribution and provocation tests, followed by SI joint anesthetic injection to guide diagnosis.[88,89] Details of specific criteria, such as recommended provocation tests, vary in the literature. For example, 1 expert review recommends that SI joint injection be performed when there is a positive history, positive Fortin finger test (patient indicates pain that is in the SI joint region), negative lumbar and hip examination, and 3 of 5 provocative maneuvers eliciting SI joint pain.[88] In addition, there is variation in the extent to which experts agree on how definitive a positive response to a SI joint injection is for confirming the diagnosis.[42]

3.8.1 Accuracy of Clinical Tests

Many clinical tests for the SI joint pain have been reported in the literature;[40] these are generally physical exam maneuvers that put stress or force on the SI joint. They are considered positive if the test aggravates the patient's typical pain.[40] We identified 1 systematic review[43] published in 2009 of diagnostic test accuracy for SI joint dysfunction; authors included 18 studies that evaluated 1 or more clinical test (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 clinical test with contrast-enhanced intraarticular injection with local anesthetics as a reference test. Reference test administration varied across studies in terms of the volume of injected medications, 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).[43] Clinical tests related to the IASP criteria are summarized in ***Table 20***. Presence of pain in the SI joint region alone had relatively poor accuracy based on 1 study. Pooled analyses of studies comparing 3 or more positive provocation tests had better accuracy (sensitivity of 85% and specificity of 76%) than pain distribution or single provocation tests alone.

Table 20. Diagnostic accuracy of common SI 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] (1 study)	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)	55 (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.[43]
[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.

Considerations regarding SI joint block as a reference standard

Temporary pain relief obtained by fluoroscopy guided SI joint block with no more than 2.5 ml of local anesthetic is widely considered the reference standard test for diagnosing primary SI joint pain. However, there is not agreement on the level of pain improvement that constitutes a positive diagnostic test. Some experts recommend 75 percent temporary pain relief or more after SI joint injection,[40,88] and others recommend a lower range, such as 50 percent or greater.[88]

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. An analysis using combined data from 2 trials (1 RCT [INSITE] and 1 uncontrolled trial [SIFI], 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.[90] Potential reasons for this may include patient characteristics (presence of pain in other areas), procedure characteristics (differences in SI joint block procedure), and others.[90] For example, 1 limitation associated with SI joint injection as a reference standard is the potential for insufficient anesthesia of the entire joint or extravasation of the injectate outside of the joint (which may serve to anesthetize other structures in close proximity to the SI joint).[90]

3.8.2 Diagnosis in Usual Practice

We found no literature describing usual clinical practice in the approach to diagnosing SI joint pain, such as surveys of providers. Most included trials and controlled studies of SI joint fusion in our review used the following diagnostic criteria: positive Fortin finger test, provocative exam findings (at least 3 of 5), and 50 percent or greater reduction in pain after SI joint block (***Appendix C, Tables C-1, C-6,*** and ***C-11***).

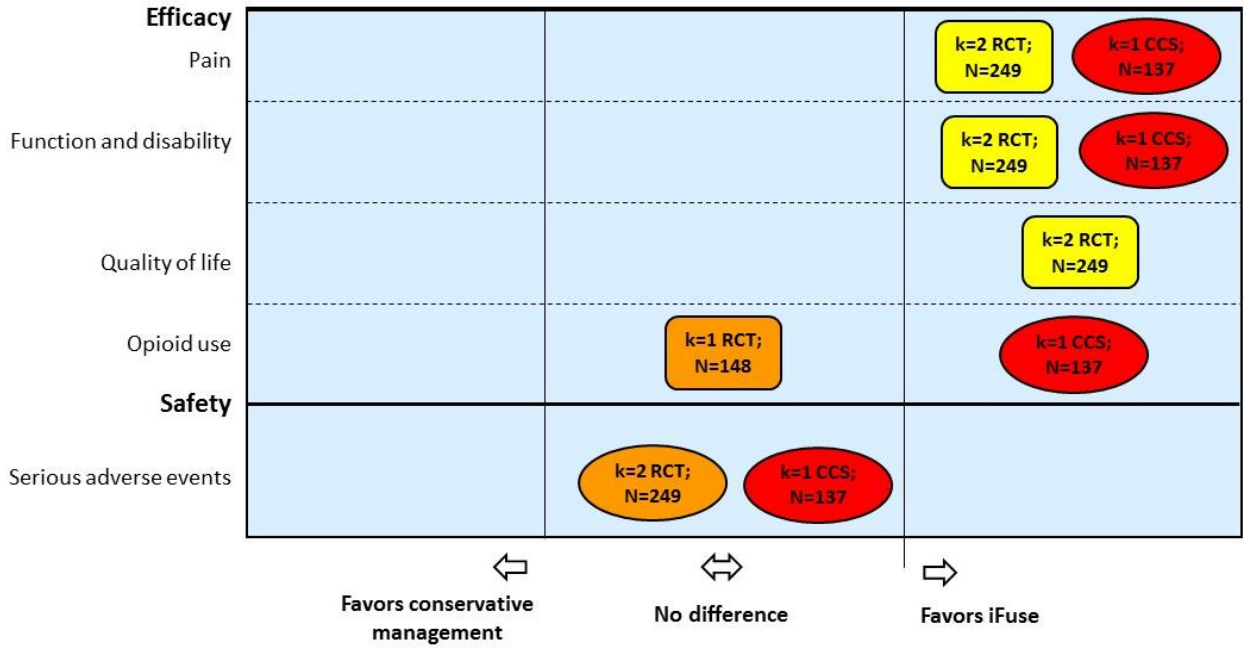
4. Discussion

4.1 Summary of the Evidence

As depicted in ***Figure 3***, compared to conservative management, minimally invasive SI joint fusion surgery with the iFuse implant system improves pain and physical function; the quality of evidence for these findings is moderate for RCT outcomes at 6 months and very low for observational study outcomes between 6 months and 3.5 years. Quality of life is also improved compared to conservative management at 6 months (moderate quality of evidence), but findings are mixed for opioid use (low to very low quality of evidence). No differences in serious adverse events exist between surgery and conservative management (low to very low quality of evidence). The incidence of revision surgery is likely no higher than 3.4 percent at 2 years. Minimally invasive surgery with iFuse costs $13,313 per additional quality of life-adjusted year gained compared to conservative management; an amount that most would consider cost-effective.

As depicted in ***Figure 4***, no differences exist between open fusion and conservative management with respect to pain, function, and quality of life based on very low quality of evidence; no safety outcomes were reported for this comparison.

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



Legend

GRADE Quality of Evidence

Very low | Low | Moderate | High

Timing of Follow-up

Short to medium-term (up to 6 months)

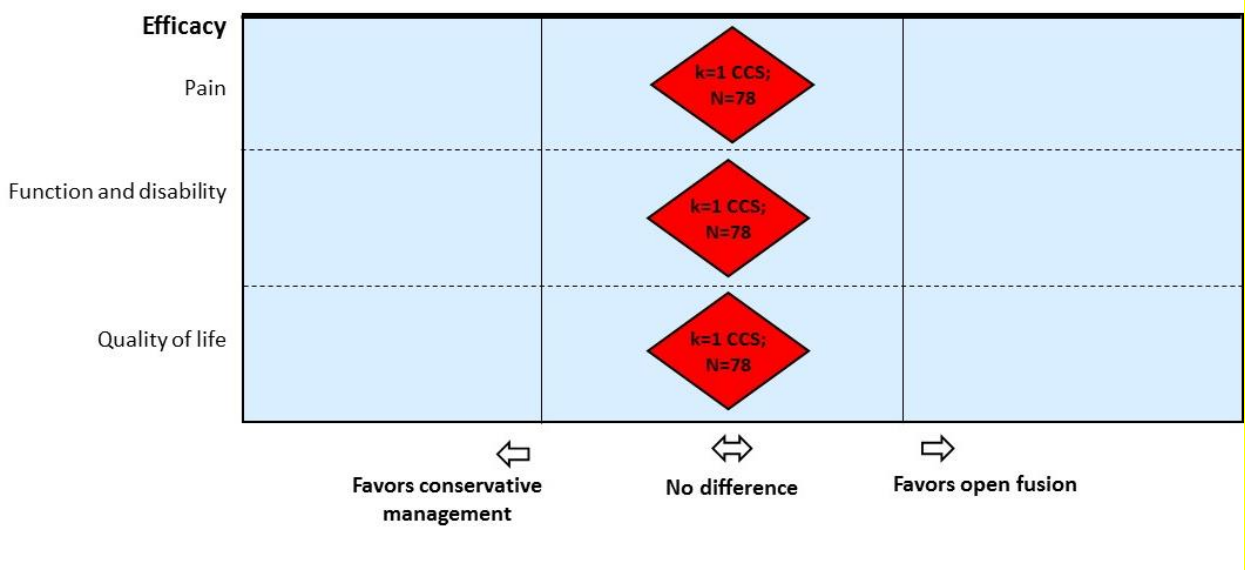
Long-term (1 year or longer)

Short, medium, and long-term

k = number of studies
N = total number of participants

Note: placement of shape along the X-axis does not indicate magnitude of effect

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



Legend

GRADE Quality of Evidence

Very low | Low | Moderate | High

Timing of Follow-up

Short to medium-term (up to 6 months)

Long-term (1 year or longer)

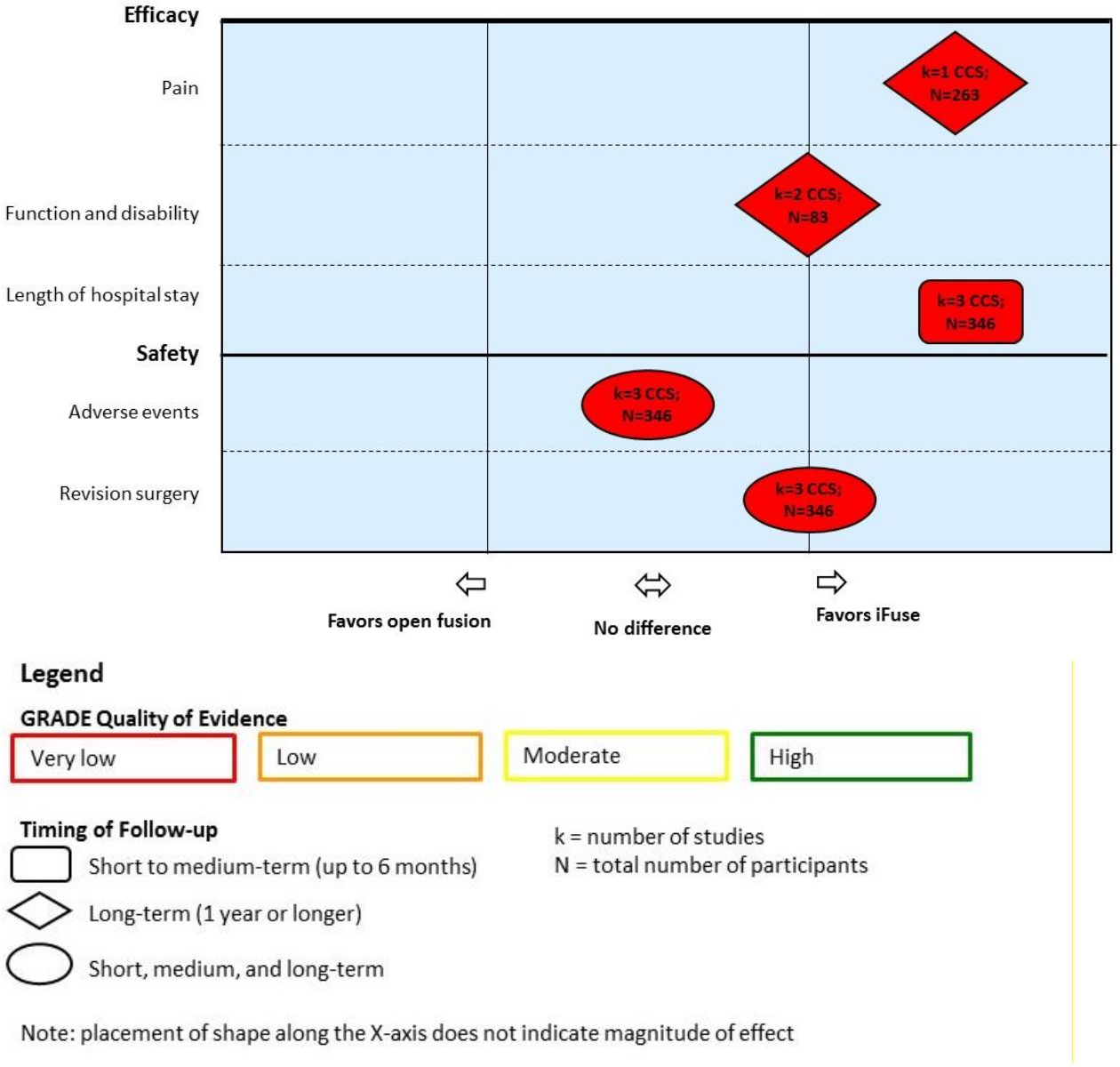
Short, medium, and long-term

k = number of studies
N = total number of participants

Note: placement of shape along the X-axis does not indicate magnitude of effect

As depicted in ***Figure 5***, minimally invasive SI joint fusion surgery with the iFuse implant system improves pain over 2 years and is associated with a shorter length of hospital stay compared to open fusion, but findings are inconsistent with respect to physical function. The incidence of adverse events was 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 quality of evidence.

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



Compared to minimally invasive fusion with screw fixation, minimally invasive fusion with iFuse results in fewer revisions (very low quality of evidence).

We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events and revision surgery across the 8 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 procedures) is also very heterogenous, likely reflecting differences in outcome definitions and ascertainment and heterogeneity in the study populations. 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. However, the incidence of revision surgery reported using post-market surveillance database was similar to the incidence reported in trials.

4.2 Limitations of the Evidence Base

The evidence we identified for inclusion in this HTA has several limitations. Most studies we identified were uncontrolled studies, which prevents a comparative assessment. Eleven studies (3 controlled cohort and 8 uncontrolled studies) evaluated an open approach to fusion; however, the outcomes reported from these studies were limited. Of the seven controlled studies evaluating minimally invasive fusion, all evaluated the iFuse implant system, which limits generalizability of findings to 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,[61] or by considering all crossovers as failures in threshold analyses.[60] 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 not be a valid assumption.

Last, 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.

4.3 Other Related HTAs

We identified several related HTAs. Assessments conducted by Hayes, Inc., ECRI institute, Blue Cross Blue Shield Association are only available by subscription; they are not publicly accessible.[44-47]

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 21***. Details for these SI joint fusion coverage policies are provided in ***Table 22***. The Center for Medicare & Medicaid Services does not have a national coverage determination for SI joint fusion procedures though several Medicare Administrative Contractors (MAC) do cover this procedure, including 1 that operates in the State of Washington (Noridian Healthcare Solutions).[48] According to information supplied to the state's HTA Program by the manufacturer of iFuse, 44 state Medicaid programs cover iFuse as of May 2018.

Table 21. Overview of payer coverage policies for sacroiliac joint fusion for degenerative sacroiliitis, sacroiliac joint dysfunction, or sacroiliac joint pain

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

Notes: ✓ = covered; ✕ = not covered; — = no policy identified.
[a] Covered when clinical criteria are met and only covered for minimally invasive fusion with triangular, titanium coated implants (i.e., iFuse).
[b] Covered when clinical criteria are met.
Abbreviations: MAC = Medicare Administrative Contractor.

Two commercial payers (Regence Blue Shield and United HealthCare Medicare Advantage) cover minimally invasive fusion when certain clinical criteria are met, though Regence specifies that it only covers procedures that use a triangular, titanium coated implant (i.e., iFuse). 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.

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. We did not seek unpublished data and did not use data presented only in conference abstracts. Last, we did not consider efficacy outcomes from uncontrolled studies.

Table 22. Payer coverage policies for sacroiliac joint fusion procedures for any indication

Payer; Date	Policy
Aetna [91] August 16, 2018	SI joint fusion performed by means of the iFuse System and the SImmetry Sacroiliac Joint Fusion System is considered experimental and investigational.
Cigna[92] January 15, 2018	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 prior to 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. 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 or minimally invasive SI joint stabilization (e.g., iFuse Implant System, SImmetry SI Joint Fusion System) for SI joint fusion (CPT code 27279) is considered experimental, investigational or unproven.
Humana[93] December 7, 2017	SI joint fusion performed by an open approach, or through minimally invasive or percutaneous approaches with IFuse system, Siconus SI Joint Fixation system, Silex Sacroiliac Joint System, SImmetry Sacroiliac Joint Fusion System, and SImpact Sacroiliac Joint Fixation System are considered experimental/investigational.
Kaiser Permanente (Washington)[94] September 6, 2016	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 prior to 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. 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	Specific details not available.
Premera (Blue Cross)[95] March 1, 2018	Premera may consider open SI joint fusion procedures medically necessary when one of the following criteria is met: • As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum; OR • As an adjunct to the medical treatment of SI joint infection/sepsis; OR • As a treatment for severe traumatic injuries associated with pelvic ring fracture. SI joint fusion performed by an open procedure for any other indication is not considered medically necessary. Percutaneous and minimally invasive SI joint fusion/stabilization procedures (listed below) are considered investigational: • iFuse® Implant System (SI Bone) • Rialto™ SI Joint Fusion System (Medtronic) • SIJ-Fuse (Spine Frontier) • SImmetry® Sacroiliac Joint Fusion System (Zyga Technologies) • Silex™ Sacroiliac Joint Fusion System (XTANT Medical) • SambaScrew® (Orthofix) • SI-LOK® Sacroiliac Joint Fixation System (Globus Medical)
Regence (Blue Shield)[96] July 1, 2018	Regence may consider open SI joint fusion procedures medically necessary when one of the following criteria is met: • As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum; OR • As an adjunct to the medical treatment of SI joint infection (e.g., osteomyelitis, pyogenic sacroiliitis)/sepsis; OR • 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 a titanium triangular implant may be considered medical necessary when ALL of the following criteria have been met: A. 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 B. 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 C. 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 D. A trial of a therapeutic SI joint injection (i.e., corticosteroid injection) has been performed on at least one occasion; and E. There is an absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia); and F. Clinical documentation that pain is caudal to the lumbar spine (L5 vertebra), localized over the posterior SI joint, and consistent with SI joint pain; and

Payer; Date	Policy
	G. 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; and H. There is a positive response to a cluster of 3 provocative tests (e.g., thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test). I. Diagnostic imaging studies include ALL of the following: 1. Imaging (plain radiographs and a CT [computed tomography] or MRI [magnetic resonance imaging]) of the SI joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the SI joint; and 2. Imaging of the SI joint indicates evidence of injury and/or degeneration; and 3. Imaging of the lumbar spine (CT or MRI) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; and 4. Imaging of the pelvis (anterior-posterior plain radiograph) rules out concomitant hip pathology. 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 and with any other devices not listed above in criteria IV.
UnitedHealthCare Medicare Advantage[97] February 14, 2018	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: • Have undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, and active physical therapy; AND • 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 • 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 • Positive response to the thigh thrust test OR compression test AND 2 of the following additional provocative tests: Gaenslen's test, distraction test, Patrick's sign; AND • Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); AND • Diagnostic imaging studies that include ALL of the following: ○ 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; ○ Imaging of the pelvis (AP plain radiographs) to rule out concomitant hip pathology; ○ 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 • 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.
UnitedHealthCare Commercial[98] 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.

Abbreviations: AP = anteroposterior; CPT = Current Procedural Terminology; CT = computed tomography; MRI = magnetic resonance imaging; ODI = Oswestry Disability Index; RCTs = randomized controlled trials; SI = sacroiliac; SR = systematic reviews; VAS = visual analog scale.

4.6 Ongoing Research and Future Research Needs

Three studies of SI joint fusion are ongoing; these studies are summarized in ***Table 23***. We also identified identified 3 studies of SI joint fusion that have been terminated or withdrawn according to Clinicaltrials.gov.[99-101]

Table 23. 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	Recruiting	11/2018
NCT02270203	SI-BONE, Inc.	Extended follow-up from 2 ongoing multicenter prospective U.S. clinical trials to evaluate long-term safety and effectiveness of SI joint fusion using the iFuse Implant System. Primary outcomes: patient success (composite endpoint defined as back pain [VAS] improvement by ≥20 mm, absence of device-related SAEs, absence of neurological worsening related to sacral spine, and absence of surgical reintervention on target SI joint[s]), radiographic fusion (bone apposition to sacral and iliac sides of ≥2 of 3 implants) Secondary outcomes: pain (VAS), disability (ODI), QoL, return to work, radiographic fusion (bridging bone across SI joint), SAEs	103	Active, not recruiting	12/2019
NCT02074761	Zyga Technology, Inc.	Prospective, non-randomized 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 months Secondary outcomes: pain (VAS) at 12 months, disability (ODI), QoL	250	Active, not recruiting	8/2020

Abbreviations: ODI = Oswestry Disability Index; QoL = quality of life; SAE = serious adverse event; SI = sacroiliac; U.S. = United States; VAS = visual analog scale.

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. Continued standardization of diagnostic criteria 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.

5. Conclusion

Among patients meeting diagnostic criteria for SI joint pain or dysfunction, minimally invasive SI joint fusion surgery with the iFuse Implant System is more effective than conservative

management for reducing pain, improving function, improving quality of life, and is likely cost-effective. Minimally invasive SI joint fusion surgery with iFuse is also more effective than open fusion for reducing pain and is associated with a shorter hospital length of stay. Serious adverse events from surgery with iFuse are infrequently reported in controlled studies but may be higher in usual practice based on evidence from uncontrolled studies. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years. Limited evidence is available that compares open fusion to minimally invasive fusion or that evaluates procedures other than iFuse.

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Appendix A. State of Washington Health Care Authority Utilization Data

Populations

The Sacroiliac Joint Fusion analysis examined member utilization and cost claims data from the following agencies:

PEBB/UMP (Public Employees Benefit Board Uniform Medical Plan); PEBB Medicare; Department of Labor and Industries (LNI) Workers' Compensation Plan; and the Medicaid Fee-for-Service (FFS) and the Managed Care (MCO) programs.

The analysis period covered 4 calendar years, 2014 through 2017. Extract inclusion criteria included age greater than 17 years old at time of service AND having at least 1 designated CPT/HCPCS codes on a paid claim:

Designated CPT/HCPCS

27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device (effective January 1, 2015).

27280 Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed (effective January 1, 1989).

The analysis excluded denied claims.

Findings

Utilization data findings are suppressed. The aggregate number of patients receiving a sacroiliac joint fusion was less than the minimum permitted for public reporting.

Appendix B. Search Strategy

PubMed searched from inception-6/20/2018

#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 SI-LOK[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 SI-DESIS[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 SI-LOK[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 SI-DESIS[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

#5 #4 NOT (miRNA[tiab] OR microRNA[tiab]) Filters: English

Yield: 468

Embase searched from inception to 6/20/2018

#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)

#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)

#3 (#1 OR #2)

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

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

Total Yield: 416 (202 unique from PubMed)

ClinicalTrials.Gov Search from inception to 6/20/2018

Terms: sacroiliac joint AND fusion; limits: Adult 18-65, Senior 66+

Total Yield: 14

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

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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15]; 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) years C: 4.5 (0.45 to 23) years N (%) with prior lumbar fusion I: 18 (34.6) C: 19 (37.3) *Key inclusion criteria:* Ages 21 to70 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 year) pelvic fracture with documented malunion, non-union 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 weeks), 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)[59] Polly (2015)[60] Polly (2016)[16]; INSITE; NCT01681004; U.S.; SI-BONE, Inc.	N eligible: NR N enrolled: 159 N randomized: 158 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.)	Participants enrolled between January 2013 and May 2014 at 19 spine surgery clinics 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, yr. (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:* ages 21 to 70; confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis and/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.	Combination of a history of SI joint pain, positive provocative testing on at least 3 of 5 tests (distraction, compression, FABER test, thigh thrust, Gaenslen's), 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.	I: iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 26/102 bilateral 76/102 unilateral Individualized physical therapy twice a week for 6 weeks beginning 1 to 3 weeks 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; LBP = low back pain; mos. = months; N = number of participants; NR = not reported; ODI = Oswestry Disability Index; SI = sacroiliac; VAS = visual analog scale; yrs. = years

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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15] iMIA	VAS LBP in mm, mean (SD) I: Baseline: 77.7 (11.3) 1 mo.: 35.4 (28.4) Change: *-42.3* 3 mos.: 33.6 (27.2) 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) C: Baseline: 73.0 (13.8) 1 mo.: 66.0 (17.7) Change: *-7.0* 3 mos.: 67.5 (22.3) Change: *-5.5* 6 mos.: 67.8 (20.3) Change: -5.7 (24.4) (P = 0.1105) 1 yr.: 58.9 (28.2)[a] Change: -14.0 (33.4) Between-group differences (I-C) 1 mo.: *-35.3* 3 mos.: *-38.6* **6 mos.: -38.1 (adjusted P<0.0001)** 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)[a] 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	ODI, mean (SD) 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* C: Baseline: 55.6 (13.7) 3 mos.: 50.6 (15.5) Change: *-5.0* 6 mos.: 50.2 (17.2) Change: -5.8 (NR) (P=0.0114) 1 yr.: 46.9 (20.8)[a] Change: *-8.7* Between-group differences (I-C) 6 mos.: -19.8 (P < 0.0001) 1 yr.: *-20.1* (P < 0.0001)[a] At least 15-point improvement: I: 6 mos.: *37* (71.2%) 1 yr.: NR (65%) C: 6 mos. *12* (24.5%) 1 yr. (crossovers): NR 1 yr. (noncrossovers): 13 (25%)[a] (P < 0.0001 for both 6 mos. and 1 yr. comparison) Self-reported walking distance, N (%) able to walk each distance I:	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* C: 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)[a] Change: *0.17* Between-group differences (I-C) 6 mos.: 0.21 (P < 0.0001) 1 yr.: *0.22* (P = 0.0009)[a]

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	At least 20-mm improvement on VAS LBP: I: 6 mos. *41* (78.8%) 1 yr. NR (69%) C: 6 mos. *11* (22.4%) 1 yr.(crossovers): NR 1 yr. (noncrossovers): 14/28 (27%)[a] (*P*< 0.0001 for both 6 mos. and 1 yr. comparisons) VAS RLP in mm, mean (SD) I: Baseline: 52.7 (31.5) 1 mo.: 20.0 (23.4) Change: *-32.7* 3 mos.: 19.0 (22.2) Change: *-33.7* 6 mos.: 22.6 (25.1) Change: *-30.1* (P < 0.01) 1 yr.: 24.0 (27.8)[a] Change: *-28.7* C: Baseline: 47.1 (31.1) 1 mo.: 50.0 (30.5) Change: *2.9* 3 mos.: 45.6 (32.5) Change: *-1.5* 6 mos.: 46.5 (31.4) Change: *-0.6* (P = 0.80) 1 yr.: 41.7 (32.4)[a] Change: *-5.4* Between-group differences (I-C) 1 mo.: *-35.6*	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) C: 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 Between-group differences 6 mos.: P = 0.17721		

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	3 mos.: *-32.2* 6 mos.: *-29.5* 1 yr.: *-23.3* (P = 0.0002)[a]			
Whang (2015)[59]; Polly (2015)[60]; Polly (2016)[16] INSITE	VAS SI joint pain in mm, mean (SD) I: Baseline: 82.3 (11.9) 1 mo.: 33.3 (27.3) 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 mos.: 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. NR Between-group differences (I-C) 1 mos. *–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, -50.3 to -30.7;* P < 0.0001)	ODI, mean (SD) I: Baseline: 62.2 (14.5) 1 mo.: 44.8 (22.1) 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 mos.: 57.1 (17.5) Change: -3.7 (11.6) 3 mos.: 51.1 (21.5)-230.-4.9 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) Between-group differences 1 mos. *-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, -31.9 to -18.9;* P < 0.0001) 1 yr. (crossovers) *-1.1 (95% CI, -8.9 to 6.7; P = 0.78)*	Self-reported treatment satisfaction as “very satisfied” 6 mos. I: NR (77.2%) C: NR (27.3%) (P< 0.001) 1 yr. I: NR (77.6%) C (crossovers): NR (71.0%) C (noncrossovers): NR 2 yrs. I: NR (73.3%) C: NR	SF-36 Physical Health Component Score I: Baseline: 30.2 (6.2) 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. (noncrossovers): 37.8 (9.5) Change 5.3 (8.2) Between-group difference 6 mos. *11.5 (95% CI, 8.1 to 14.9)* (P < 0.0001) 1 yr. NR 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)

Author (Year) Study Name	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	1 yr. (crossovers): *-5.7 (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 At least 20 mm improvement: I: 1 mos. 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 mos. 13/45 (28.9%) 3 mos. 17/44 (38.6%) 6 mos. 12/44 (27.3%) 1 yr. 5/40 (12.5%)[b] 2 yrs. 4/40 (10%)[b] Between-group difference at 6 mos. ARD *60.8% (95% CI, 47.7% to 73.8%; P < 0.001)* RR *3.84 (95% CI, 2.30 to 6.39, P < 0.001)*	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 mos. 49/100 (49.0%) 3 mos. 72/100 (72.0%) 6 mos. 74/101 (73.3%) 1 yr. 71/98 (72.4%) 2 yrs. 60/88 (68.2%) C: 1 mos. 6/45 (13.3%) 3 mos. 13/44 (29.5%) 6 mos. 6/44 (13.6%) 1 yr. 4/40 (10.0%)[b] 2 yrs. 3/40 (7.5%)[b] Between-group difference at 6 mos. ARD *59.6% ((5% CI, 46.3% to 73.0%; P < 0.001)* RR *5.37 (95% CI, 2.53 to 11.41; P < 0.001)*		6 mos.: 44.0 (12.5) Change: 0.6 (9.7) 1 yr. (crossovers): 50.7 (9.4) Change: 7.8 (12.0) 1 yr. (no crossover): 46.2 (9.8) Change 2.3 (7.2) 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 0.31 (0.22) 1 yr. (no crossover): 0.74 (0.12) Change: 0.20 (0.17) Between-group difference 6 mos. *0.24 (95% CI, 0.16 to 0.32)* (P < 0.0001) 1 yr. NR

Notes: We calculated values in italics; values in **bold type** are the primary study endpoints designated by study authors.

[a] Because of extensive crossovers after 6 months, the last observation carried forward method was used to estimate the 12-month outcomes for the participants in the conservative management group that crossed over.

[b] 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; I = intervention group; LBP = low back pain; mos. = months; mm = millimeters; NR = not reported; ODI = Oswestry Disability Index; RLP = referred leg pain; RM = repeated measures; SD = standard deviation; SI =- sacroiliac; VAS = visual analog scale; yrs. = years.

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

Author (Year) Study Name	Opioid Use	Return to Work	Non-Union	Length of Stay	Global Recovery or 'Success'
Dengler (2017);[61] Dengler (2016);[62] Sturesson (2016)[15] iMIA	NR	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)	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

Author (Year) Study Name	Opioid Use	Return to Work	Non-Union	Length of Stay	Global Recovery or 'Success'
		6 mos.: Not working due to LBP: 28 (57.1) Not working due to other reason: 0 (0) Retired: 5 (10.2) Working with limitations: 10 (20.4) Working normal hours/type: 6 (12.2) 1 yr.: NR Between-group differences 6 mos.: P = 0.0711			
Whang (2015)[59]; Polly (2015)[60]; Polly (2016)[16] INSITE	N (%) using opioid analgesics for SI joint pain I: Baseline: 69 (67.6%) 6 mos.: *58* (58.0%) 1 yr.: *51* (52.0%) 2 yrs.: *43* (48.3%) C: Baseline: 29 (63.0%) 6 mos.: 31 (70.5%) 1 yr.: 21 (55%) Between-group difference at 6 mos. I: -9.0% C: 7.5% (P = 0.08) *RR 0.83 (95% CI, (95% CI, 0.64 to 1.07)* *ARD -12.04% (95% CI, -28.6% to 4.5%)*	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:

Author (Year) Study Name	Opioid Use	Return to Work	Non-Union	Length of Stay	Global Recovery or 'Success'
	Between-group difference at 1 yr. I: *-15.6%* C: *-8.0%* RR 0.94 (95% CI, 0.67 to 1.33) ARD -3.22% (95% CI, -21.9% to 15.4%)				Degenerative sacroiliitis 70/86 (81.4% [95% Credible Interval, 71.6% to 89.0%]) 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:

Author (Year) Study Name	Opioid Use	Return to Work	Non-Union	Length of Stay	Global Recovery or 'Success'
					Yes 25/33 (75.8% [95% Credible Interval, 57.7% to 88.9%]) 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%)

Note: We calculated values in italics; values in **bold type** are the primary study endpoints designated by study authors.
Abbreviations: ARD = absolute risk difference; C = control group; CI = confidence interval; I = intervention group; LBP = low back pain; mos. = months; N = number of participants; NR = not reported; ODI = Oswestry Disability Index; RR = risk ratio; SD = standard deviation; SI = sacroiliac joint; VAS = visual analog scale; yrs. = years.

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

Author (Year) Study Name	Adverse Events	Revision
Dengler (2017);[61] Dengler (2016);[62] Sturesson (2016)[15] iMIA N analyzed = 101	Total adverse events at 6 mos. I: 10 (among 9 participants) C: 14 (among 13 participants) Mean number of events per subject I: 0.19 C: 0.27 (*P*=0.0918) Serious adverse events at 6 mos. I: 8 (none related to device) 2 related to procedure (postoperative hematoma, postoperative neural impingement related to incorrect device placement) C: 10 Over total follow-up (mean 21.5 months) most were unrelated to device or procedure I: 25 (2 recurrent pain due to possible device loosening ~1 yr.) C: 24 (1 recurrent pain due to possible device loosening after crossover procedure, hematoma after crossover procedure)	1 yr. and beyond (mean follow-up of 21.5 mos. per group) I: 0 C: 1 (a crossover patient, which is 1.4% of all patients who received surgery)
Whang (2015)[16]; Polly (2015)[60]; Polly (2016)[59] INSITE N analyzed = 148	Total adverse events at 6 mos. I: 133 events C: 48 events (*P* NR) Mean number of events per subject 6 mos. I: 1.3 C: 1.0 (*P*=0.1857) 1 yr. I: 1.8 C: 1.9 (*P*=0.45) Total severe adverse events 6 mos. I: 21 events	2 yrs. I: 3/89 (3.4%) C (crossovers): 1/39 (2.6%)

	C: 6 events (*P*=0.3241) 2 yrs. I: 55 (5 were procedure or device related) C: 23 Adverse events related to device at 6 mos.: I: Definitely related 2 (2.0%) Probably related 1 (1.0%) Total 3 (2.9%) Sacral nerve root impingement, hairline fracture of ilium, contralateral SI joint pain Adverse events related to assigned treatment procedure(s) at 6 mos. I: Definitely related 7 (6.9%) Probably related 10 (9.8%) Total 17 (16.7%) Neuropathic symptoms (2), postoperative medical problems (4), SI joint pain/bursitis (4), surgical wound (5), iliac fracture (1), asymptomatic exam finding (1) C: Definitely related 3 (6.5%) Probably related 1 (2.2%) Total 4 (8.7%) Increased back or joint pain after treatment (3), flushing and shortness of breath after injection (1) Infection at 6 mos. I: 3 (2.9%) C: 3 (6.5%) (*P* =0.3752) Surgical wound complication at 6 mos. I: 6 (5.9%) C: 0 (0%) (*P*=0.1774)	

Abbreviations: C = control group; CI = confidence interval; I = intervention group; mos. = months; NR = not reported; RR = risk ratio; SD = standard deviation; SI = sacroiliac joint; yrs. = years.

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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15] iMIA	NR	Mean (range): 57 (19 to 107) mins
Whang (2015);[16] Polly (2015);[60] Polly (2016)[59] INSITE	Estimated blood loss, cc Mean (SD, range) 32.7 (32.8, 0.5 to 250)	Procedure time, minutes Mean (SD, range) 44.9 (22.3, 14 to 140)

Abbreviations: 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
Kibsgard (2013)[18] 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 year 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 weeks. C: Nonsurgery group, no specific details regarding treatment was provided, but this group appear to have been enrolled from a later time period when open fusion was becoming less commonly used.
Ledonio, 2014[21] U.S.; Funding source NR	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 (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 weeks 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 MIS SI joint fusion, confirmed diagnosis of SI joint dysfunction/sacroiliitis, and failed nonoperative treatment, minimum follow-up of 1 year *Key exclusion criteria:* NR		C: Open anterior ilioinguinal approach, local bone grafting, and anterior plating; at 6 weeks the participants were treated with pool therapy for 4 weeks with progressive weightbearing followed by 8 weeks of land-based therapy
Ledonio, 2014[20] U.S.; Funding source NR	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 weeks C: Open anterior ilioinguinal approach, local bone grafting, and anterior plating; at 6 weeks the participants were treated with pool therapy for 4 weeks with progressive weightbearing followed by 8 weeks 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 year of follow-up information		
Smith (2013)[19] U.S.; 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	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 weeks beginning 7 weeks 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
		modification, physical therapy, and SI joint injections; both 12 and/or 24 mos. postoperative pain scales documented in medical chart *Key exclusion criteria:* NR		
Spain (2017)[22] 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)[17] Spain; Funding source NR	N with suspected SI joint pain: 423; N with initial conservative management: 406; N failing initial conservative management: 193;	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)	Diagnosis based 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 eligible: 152 (positive response to joint infiltration); N received treatment/N analyzed: I: 27/27; C1: 51/47; C2: 74/63	C2: 51.4 (range 29 to 70) N (%) Female I: 19 (70.4) C1: 25 (53.2) C2: 36 (57.1) Mean (SD) duration of pain, yrs. 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:* Ages 21 to 75 years old with pain for ≥3 months 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,		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 months if no improvement seen), 3) use of NSAIDs (indomethacin, naproxen sodium, or ibuprofen), 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
		arthropathy, Reiter's syndrome, psoriatic arthritis, enteric arthritis); 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		

Notes: [a]The same participants receiving open fusion were used in the Ledonio et al., 2014[20] and Ledonio et al.[21] studies.
Abbreviations: = C = control group; CA = California; I = intervention group; = ; LBP = low back pain; mos. = months; mm = millimeters; N = number of participants; NR = not reported; NSAIDs = nonsteroidal anti-inflammatory drugs; ODI = Oswestry Disability Index; rhBMP = recombinant human Bone Morphogenetic Protein-2; SD = standard deviation; SI = sacroiliac; U.S. = United States; VAS = visual analog scale.

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
Kibsgard (2013)[18]	Morning VAS score in mm, adjusted mean (95% CI) at 11 to 32 yrs. I: 44 (31 to 57) C: 50 (41 to 59) 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) 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) 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

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
				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 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 as 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[21]	NR	ODI, mean (SD) I: Baseline: 61.5 (12.5)	NR	NR

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
		Postoperative (mean follow-up 15 months): 52.0 (16.9) Change: *-9.5* C: Baseline: 61.8 (10.8) Postoperatively (mean follow-up 13 months): 47.4 (21.7) Change: *-14.4* Between-group differences (I-C): *4.9* (*P*= 0.272)		
Ledonio, 2014[20]	NR	ODI, median (range) I: Baseline: 53 (14 to 84) ~ 15 mos.: 13 (0 to 38) 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 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	NR	NR
Smith (2013)[19]	VAS pain score in cm, mean (SD) I: Baseline: 8.3 (1.6) (based on N=113) 1 yr.: 2.3 (2.6) (based on N=94) Adjusted change: -6.2 (3.1)	NR	NR	NR

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	2 yrs.: 1.7 (2.9) (based on N=38) Adjusted change: -5.6 (3.5) C: Baseline: 7.1 (1.9) (based on N=139) 1 yr.: 4.6 (3.0) (based on N=114) Adjusted change: -2.7 (3.2) 2 yrs.: 5.6 (2.9) (based on N=58) Adjusted change: -2.0 (3.3) Between-group differences (I-C) 1 yr.: -3.6 2 yrs.: -3.7 RM adjusted: -3.02 (95% CI, -2.07 to -3.99) (adjusting for age and sex and history of prior lumbar fusion) Improvement in VAS ≥ 2 cm, 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 ≥ 2.5 cm decrease or raw score < 3.5 cm), 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			

Author (Year)	Pain	Physical Functioning	Patient Satisfaction	Quality of Life
	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)[22]	NR	NR	NR	NR
Vanaclocha (2018)[17]	VAS LBP in cm, 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): -4.5 (P < 0.001) RM mean difference (I-C2): -6 (P < 0.001)	ODI, mean Baseline and follow-up datapoints 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) ODI, n/N 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)	NR	NR

Notes: [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; LBP = low back pain; MCID = minimal clinically important difference; mos. = months; mm = millimeters; N = number of participants; NR = not reported; ODI = Oswestry Disability Index; RM = repeated measures; SD = standard deviation; SF-36 = short form survey (36 item); VAS = visual analog scale; 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'	Non-Union	Length of Stay
Kibsgard (2013)[18]	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[21]	NR	NR	NR	NR	I: 2 C: 3.3 *P* = 0.002
Ledonio, 2014[20]	NR	NR	NR	NR	I: 1 (1 to 2 days) C: 3 (2 to 6) *P* < 0.0001

Author (Year)	Opioid Use	Return to Work	Global Recovery or 'Success'	Non-Union	Length of Stay
Smith (2013)[19]	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)[22]	NR	NR	NR	NR	NR
Vanaclocha (2018)[17]	N (%) taking opioids I: Baseline: 17 (63.0) 1 mo: 4 (14.8) Change: -13 (-48.2) 6 mos.: 2 (7.4) Change *-15 (-55.6)* Last follow-up: 2 (7.4) 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) Change *-18 (-38.3)* Last follow-up: 40 (85.1) Change *14 (29.8)* (p=0.0012, baseline vs. last follow-up) C2: Baseline: 31 (49.2) 1 mo.: 27 (42.9) Change: *-4 (-6.3)* 6 mos.: 28 (44.4) Change *-3 (-4.8)* Last follow-up: 53 (84.1)	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'	Non-Union	Length of Stay
	Change *22 (34.9)* (P <0.0001, baseline vs. last follow-up) 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)* Change in use (I-C1) 1 mo.: *-9.9%* 6 mos.: *-17.3%* Last follow-up: *-85.4%* 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, -90.1% to 63.34%; P < 0.001)* Change in use (I-C2) 1mo.: *-41.9%* 6 mos.: *-50.8%* Last follow-up: *-90.5%* 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				

Notes: Values that are italicized are values we calculated based on data provided in the study.
Abbreviations: ARD = absolute risk difference; C = control group; I = intervention group; mo(s) = month(s); N = number of participants; NR = not reported; SD = standard deviation; SI = sacroiliac.

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

Author (Year)	Adverse Events	Revision
Kibsgard (2013)[18] N analyzed = 78	NR	NR
Ledonio, 2014[21] N analyzed = 44	Pulmonary embolism I: 1 (2.3%) C: 1 (2.3%) *P = 1.00* *ARD 0.0% (95% CI, -70.9% to 70.9%)* *RR 1.0 (95% CI, 0.24 to 4.13)*	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* *ARD 0.0% (95% CI, -51.5% to 51.4%)* *RR 1.0 (95% CI, 0.36 to 2.79)*
Ledonio, 2014[20] N analyzed = 39	Intraoperative complications I: 0 C: NR Postoperative complications I: 6 *(35.3%)* 1 hematoma at operative site 3 transient trochanteric bursitis 1 transient toe numbness 1 malpositioned implant C: 3 (*13.6%*) 1 pulmonary embolism 2 nerve root irritation *P = 0.08* *ARD 32.3% (95% CI, -0.03% to 67.2%)* *RR 1.93 (95% CI, 0.997 to 3.77)*	Revision surgery I: 1 *(5.9%)* (removal of device due to malposition) C: 2 *(9.1%)* (failed implant and nerve root irritation) *P = 1.00* *ARD -11.1% (95% CI, -66.9% to 44.7%)* *RR 0.75 (0.15 to 3.87)*
Smith (2013)[19] 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* *ARD -7.9% (95% CI, -22.5% to 6.6%)* *RR 0.82 (0.56 to 1.2)* Wound infection I: 1 *(0.9%)* C: 3 *(2.0%)*	Removal or repositioning of spinal implants I: 4 (3.5%) C: 66 (44.3%) *P < 0.001* *ARD -51.3% (95% CI, -60.1% to -42.4%)* *RR 0.10 (95% CI, 0.04 to 0.26)* 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).

Author (Year)	Adverse Events	Revision
	Cellulitis I: 3 *(2.0%)* C: 1 *(0.9%)* Wound-related issues (dehiscence, seroma) I: 0 C: 6 *(4.0%)* Various types of pain (low back, facet, buttock, iliotibial band, piriformis, neuropathy, etc.) I: *10 (8.8%)* C: *18 (12.1%)* Falls I: 4 *(3.5%)* C: 0 Deep vein thrombosis or pulmonary embolism I: 0 C: 3 *(2.0%)*	In the C arm, implants were removed mostly because of pain at the iliac or sacral screw.
Spain (2017)[22] N analyzed = 292	NR	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* *ARD -57.5% (95% CI, -74.8% to -40.2%)* *RR 0.40 (95% CI, 0.26 to 0.63)* 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)[17]	Serious adverse events	Revision surgery

Author (Year)	Adverse Events	Revision
N analyzed = 137	I: NR C1: 0 C2: 0 Temporary postoperative sciatic pain due to advancement of Steinman pin into sacral foramen I: 2 (*7.4%*)	I: 0

Notes: Values that are italicized are values we calculated based on data provided in the study.
Abbreviations: ARD = absolute risk difference; C = control group; CI = confidence interval; I = intervention group; NR = not reported; RR = risk ratio.

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

Author (Year)	Intraoperative Blood Loss	Duration of Surgery
Kibsgard (2013)[18] N analyzed = 78	NR	NR
Ledonio, 2014[21] 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 min, mean (SD) I: 68.3 (26.8) C: 128.0 (27.9) *P* < 0.001
Ledonio, 2014[20] N analyzed = 39	NR	Surgical time in minutes, mean (range) I: 27 (18 to 72) C: 128 (73 to 180 minutes) *P* < 0.0001
Smith (2013)[19] N analyzed = 263	Estimated blood loss in cc, 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)[22] N analyzed = 292	NR	NR
Vanaclocha (2018)[17] 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; 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)[68]; 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), mos.: 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 months' 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)[64] 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 years; 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 and/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)[69] 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 and/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)[23] U.S.; Funding source NR	Retrospective uncontrolled cohort N analyzed: 4	Single site, 10 year 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-year 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, and/or Gaenslen's sign; radiographic evidence of SI arthrosis; a 2-week 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)[83] Germany; Funding 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 test, 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)[29] 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, yrs. (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 months follow-up *Key exclusion criteria:* Concomitant other procedures at the time of SI joint fusion; fewer than 24 months follow-up	Complaints of low back, buttock, and/or leg pain; failed traditional conservative treatment; palpation tests, Patrick's test, Gaenslen's test, 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 (2015);[34] 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
Cross (2018)[82] NCT02425631; U.S.;	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)	NR	SImmetry System (titanium cannulated and antirotational im plants with surface roughness to

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Zyga Technology, Inc.		Mean duration of symptoms/pain: NR N (%) with prior lumbar fusion: NR *Key inclusion criteria:* Minimally invasive SI joint fusion within prior 1 yr. *Key exclusion criteria*: None		promote bony growth combined with autologous bone or demineralized bone matrix; minimally invasive lateral approach 0 bilateral 19 unilateral
Cummings (2013)[70] 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 months	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac approach 0 bilateral 18 unilateral
Darr (2018);[32] 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: 96	12 sites, 2012-ongoing Mean age (SD): 50.8 (10.8) N (%) female: 75 (72.8) Mean duration of symptoms/pain, yrs. (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	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

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		autoimmune or inflammatory conditions and osteoporosis		
Duhon (2013);[31] Duhon (2016);[102] Duhon (2016);[103] Sacroiliac Joint Fusion with iFuse Implant System (SIFI); NCT01640353; U.S.; SI-BONE, Inc.	Uncontrolled trial N eligible: 194 N treated: 184 N analyzed: 172 at 1 yr.; 169 at 2 yrs.	26 sites, 2012 to 2015 Mean age (range): 50.9 (23.5 to 71.6) N (%) female: 120 (69.8) Mean duration of pain, yrs. (range): 5.1 (0.43 to 41.08); N (%) with prior lumbar fusion: 76 (44.2) *Key inclusion criteria:* Adults ages 21 to 70 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	Clinical history of pain at or near SI joint; ≥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 14 bilateral 158 unilateral
Fuchs (2018)[30] 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, yrs.: 4.5 N (%) with prior lumbar operation: 77 (45)	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.	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,

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: Chronic SI joint pain persisting for ≥ 6 mos.; failed conservative treatment lasting ≥ 6 mos. *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	More specifically, combination of provocation tests; peri- or intra-articular 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	combined with use of allograft material); open posterior approach 7 bilateral *164* unilateral
Gaetani (2013)[71] 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)[72] 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

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
				37 patients (37 cases) unilateral
Khurana (2009)[73] 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 non-traumatic 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 test, 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)[27] 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 yrs.: 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 and/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)[74]; U.S.; Funding source NR (all but 2 authors disclosed financial relationships with multiple	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, yrs.: 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

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
drug and/or medical device manufacturers)		*Key inclusion criteria*: Ages 18 to 85; failed at least 6 months of nonoperative management.		with O-arm and StealthStation navigation 41 unilateral 6 bilateral
Kube (2016)[75]; 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, yrs.: 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
Mason (2013)[67]; 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, yrs.: NR N (%) with prior lumbar fusion: 22 (40) *Key inclusion criteria:* Exhausted conservative management, including SI joint specific rehabilitation Key exclusion criteria: NR	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 Chester, PA, USA) prior to insertion N bilateral vs. unilateral NR
McGuire (2012)[76]; 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, yrs.: 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	NR	Minimally invasive fusion using dual fibular dowel allografts 36 unilateral *1* bilateral

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
		computed tomographic (CT)–directed injections with long- and short-duration anesthetic *Key exclusion criteria:* patients not obtaining relief from diagnostic blocks		
Miller (2013)[77]; 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, yrs.: 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
Nystrom (2017)[25]; Sweden; Funding source NR	Uncontrolled trial N treated: 55 N analyzed: 49	Single site, 2000 to 2006 Mean age (range): 45 (28 to 65) N (%) female: 55 (100) Mean duration of pain (range), yrs.: 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
Rappoport (2017)[65]; U.S.; Globus Medical Inc. and the Musculoskeletal Education and research Center (a division of Globus Medical, Inc.)	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 N (%) with prior lumbar fusion: NR *Key inclusion criteria:* Ages between 21 and 70, diagnosis of sacroiliac joint dysfunction	Diagnosis was based on clinical presentation of SI joint dysfunction supported by medical history, physical examination, and lumbar magnetic resonance imaging showing absence of disease that would correlate with clinical presentation, diagnostic	SI-LOK Sacroiliac Joint Fusion System; minimally-invasive, lateral approach that uses hydroxyapatite coated screws with graft slot option 0 bilateral 32 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: 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	injections only used in patients who failed to respond to nonoperative treatment	
Rudolf (2012);[78] 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, and/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)[79] 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-month 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
Sachs (2014)[80] 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)	Detailed clinical history, ≥ 3 positive physical provocative maneuvers, diagnostic imaging, and, when clinical, physical, and	iFuse Implant System (triangular titanium implant coated with porous titanium plasma spray); minimally invasive lateral transiliac 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 inclusion criteria: Underwent minimally invasive SI joint fusion using iFuse; must have had preoperative and minimum 12-month follow-up data available; failure of 6 mos. of conservative treatment *Key exclusion criteria*: NR	imaging findings were concordant, SI joint diagnostic injections with positive result (i.e., 75% reduction in pain immediately after injection);	26 bilateral 118 unilateral
Sachs (2016)[81] U.S.; SI-BONE, Inc. (San Jose, Callifornia)	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 yrs., 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)[33]; 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 *Key exclusion criteria*: Previous diagnoses of pelvic ring fracture or pelvic neoplasms; procedures performed as revision surgery	NR	Minimally invasive SI joint fusion based on CPT codes 27280, 27299, or 22899 N bilateral vs. unilateral NR
Schutz (2006)[28]; 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), yrs.: 6.6 (1 to 20)	Varied approaches to diagnosis used, including diagnostic injections (14 of 17) patients, temporary	Bilateral, open fusion using dorsal interlocking technique described by Verral and Pitkin

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 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	selective external immobilization of joint (3 of 17 patients) and various physical and radiologic exams	
Slinkard (2013)[26]; 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%) *Key inclusion criteria*: Patients with history of SI joint dysfunction at least 1 year; 6 to 12 weeks of physical therapy and nonsteroidal medications without improvement; relief of 50% of symptoms from diagnostic intraarticular SI joint injection *Key exclusion criteria*: NR	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
Waisbrod (1987)[24]; 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 tests; 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 tests, 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
Wise (2008)[66]; U.S.;	Uncontrolled trial	Single site, 2004 Mean age (range): 53 (45 to 62)	Positive history and physical exam, intraarticular	Minimally invasive SI joint fusion with threaded fusion cages

Author (Year) Study Name; Registry Number; Country; Funding Source	Study Design and Number of Participants	Study Setting and Population	Method of Diagnosis	Intervention Description
Funding source NR	N treated: 13	N (%) female: 12 (92) Mean duration of symptoms: NR N (%) with prior lumbar fusion: 8 (62) *Key inclusion criteria:* failed conservative therapy for at least 6 months, 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	injections of local anesthetic and corticosteroid with at least 75% reduction in pain within 30 minutes and lasting at least 2 hours	(Medtronic Sofamor Danek, 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).[80] The study author was contacted for clarification but did not reply.
[b] Includes patients that were reported in Sachs (2016).[81] We are unable to determine the overlap in study population between this study and Sachs (2013).[79] The study author was contacted for clarification but did not reply.
[c] Included patients that were also reported in Sachs (2014).[80]
Abbreviations: CPT = Current Procedural Terminology; CT = computed tomography; DIANA = distraction interference arthrodesis; HMA = Hollow Modular Anchorage; ICD = International Classification of Disease; ISASS = International Society for the Advancement of Spine Surgery; MRI = Magnetic resonance imaging; mm = millimeters; N = number of participants; NR = not reported; ODI = Oswestry Disability Index; SD = standard deviation; SI = sacroiliac; U.K. = United Kingdom; U.S. = United States; VAS = visual analog scale.

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)[68] N analyzed = 9	1 development of degenerative lumbar disease 2 yrs. postoperatively 1 deep wound infection 0 loosening, screw failure, or breakage events	NR
Araghi (2017)[64] EVSI; NCT02074761 N analyzed = 50	2 serious adverse events: 1 radiculopathy postsurgery due to nerve impingement 1 ongoing low back pain requiring hospitalization for management	At 6 mos.: 1 (2%) to change implant to a shorter device to relieve nerve impingement causing radiculopathy
Beck (2015)[69] N analyzed = 20	0 bleeding events, infections, or medical complications	NR
Belanger (2001)[23] N analyzed = 4	Authors reported "no major complications"	Timeframe unspecified: 1 (25%) to remove hardware and allow exploration of patient's fusion and alleviate postoperative local pain and tenderness
Bornemann (2017)[83] N analyzed = 24	0 events during surgery 0 device or surgery-related events during 2 yrs. follow-up	At 2 yrs.: 0 revisions
Buchowski (2005)[29] N analyzed = 20	N (%) participants/N events: 4 (20%) /6 events 3 pseudarthrosis 2 deep wound infection 1 device-related event (painful hardware)	Timeframe unspecified: 3 (15%) participants with 5 revision surgeries 3 revisions to resolve nonunions 2 to resolve pseudarthrosis
Cher (2015);[34] N analyzed = 11,388	NR	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-year survival rate free from revision surgery: 96.5% with revision rates decreasing significantly over time (p<0.0001); 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%

Author (Year) Study Name; Registry Number; N analyzed	Adverse Events	Revision Surgery
		Reasons for revision surgeries, N (%) Symptomatic malposition: 121 (38.4); Most cases (86.8%) occurred within first 6 mos.; 4-year probability: 1.0%; Recurrence of symptoms: 150 (47.6); Most cases (87.9%) occurred after first 6 mos.; 4-year probability: 1.9%; 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-month all-cause revision rates (p=0.0041) Cases 1 to 20: 1.6%; Cases 21 to 50: 1.1%; Cases 51 to 100: 0.8%; Cases >100: 0.7% Among surgeons performing >20 surgeries: 12-month all-cause revision rates (p=0.0952) 2009: 6.0% 2010: 2.5% 2011: 1.5% 2012: 1.8% 2013: 0.7%
Cross (2018)[82] NCT02425631 N analyzed = 19	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)[70]	0 intraoperative complications	Timeframe unspecified:

Author (Year) Study Name; Registry Number; N analyzed	Adverse Events	Revision Surgery
N analyzed = 18	N (%), Postoperative adverse events (major) 1 yr.: 1 (5) (unspecified as to event) N (%) Postoperative adverse events Trochanteric bursitis: 3 (17) Hematoma: 1 (5) Fluid retention: 1 (5) Toe numbness: 1 (5) Implant malposition: 1 (5)	1 (5%) for implant removal
Darr (2018);[32] LOIS (Long Term outcomes from INSITE and SIFI); NCT02270203 N analyzed = 96	0 severe device- or procedure-related adverse events Overall adverse events: 75 patients (*78%*, 168 events) *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)	At 3.7 yrs.: 1 (*1%*) revision at patient's request by non-study physician for pain relief; believed to originate from progressive lumbar scoliosis
Duhon (2013);[31] Duhon (2016);[102] Duhon (2016);[103] SIFI; NCT01640353; N analyzed = 172 at 1 yr.; 169 at 2 yrs.	N (%) patients with adverse events/N events: 153 (91%)/454 (33 [*7.2%*] were device or procedure related) N adverse events either definitely or probably device-related: 7 (*1.5%*) total; 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 either definitely or probably procedure-related:26 (*5.7%*) total; 6 severe 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%);	At 2 yrs.: Revision of index SI joint: 8 (4.7%): 2 revisions for new onset leg pain which resolved when implants were repositioned 4 revisions for minimal improvement in symptoms thought to be due to suboptimal implant placement 1 revision for pain recurrence 6 months 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 revision 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
	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 [*1.5%*] 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[30] N analyzed = 137 at 1 yr.; 132 at 2 yrs.	N (%) Postoperative complications: 1 (0.6) Radiculitis from bone substitute that was applied too liberally	Timeframe unspecified: 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)[71] N analyzed = 10	N (%) Postoperative complications: 3 (30) 2 Local hematoma 1 Intense low back pain treated successfully with facet joint injections	NR
Kancherla (2017)[72] N analyzed = 41 patients (45 cases)	N (%) 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)[73] N analyzed = 15	0 postoperative neurological or wound complications 0 screw placement problems 0 implant failure events	Mean (range) of follow-up, mos.: 17 (9 to 39) 0 revisions
Kibsgard (2014)[27] NCT00900601; N analyzed = 8	N (%) complications: 6 (75) 1 complex regional pain syndrome with drop-foot 1 loss of bladder sensation 1 deep wound infection	NR

Author (Year) Study Name; Registry Number; N analyzed	Adverse Events	Revision Surgery
	3 transient sensitivity loss to lateral femoral cutaneous nerve	
Kleck (2016)[74] N analyzed = 47	N (%) Intraoperative complications: 2 (4.3) Both involved a guide pin breaking in situ.	0 for patients at least 1 year postoperative (though mean follow-up of the group was only 35.6 weeks)
Kube (2016)[75] N analyzed = 15 patients/17 procedures	N operative 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
Mason (2013)[67] N analyzed = 55	N (%) Postoperative complications: 2 (4) Both were nerve pain immediately postoperatively needed return to operating room	NR
McGuire (2012)[76] N analyzed = 34 at 1 yr.; 30 at 2 yrs.	N Infections: 0	Timeframe unspecified: 4 revisions for non-union, successfully treated by secondary bone grafting and iliosacral compression screw fixation
Miller (2013)[77]; N analyzed = 5,319 patients	N (%) with postoperative 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 (%) 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	N (%) revisions: 96 in 94 patients (1.8) 56 early revisions (median 19 days postoperatively); 10 to correct an improperly sized implant, 46 to correct a symptomatic malpositioned implant 40 late revisions (median 279 days postoperatively); 34 to treat symptom recurrence, 6 for unknown etiology

Author (Year) Study Name; Registry Number; N analyzed	Adverse Events	Revision Surgery
	N device-related events 43 Pin bind/bend/break 14 Pin advancement 13 Radiographic halo 4 Migration N procedure-related events 72 Improper device placement 36 Improper device size	
Nystrom (2017)[25] N analyzed = 49	4 (*8.2%*) total 3 patients had decreased sensation in distribution of the lateral femoral cutaneous nerve postoperative; 1 patient with weakness of muscles innervated by femoral nerve	Timeframe unspecified: 2 (*4.1%*) reoperations because of persistent symptoms and defective bone healing based on CT scan
Rappoport (2017)[65] N analyzed = 32	NR	At 1 yr.: 2 revisions 1 for screw loosening at 11 mos. 1 for remove and replace screw at 3 mos.
Rudolf (2012);[78] N analyzed = 50	N (%) 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 1 implant placed too cephalad in patient with unrecognized hemi-sacralized L5 transitional vertebrae 1 non-displaced fracture at edge of ilium Late complications 1 case of loosened implants causing persistent, gradually increasing SI joint pain 3 yrs. postsurgery	At 2 yrs. 4 (*8%*) revision surgeries 3 for implant malposition 1 for implant loosening
Sachs (2013)[79] N analyzed = 40 patients/41 procedures[a]	N intraoperative events: 0 At 1 yr.: N (%) with postoperative events/N events: 2 (5%) /3 2 trochanteric bursitis 1 piriformis syndrome	At 1 yr.: 0 revisions

Author (Year) Study Name; Registry Number; N analyzed	Adverse Events	Revision Surgery
	1 new low back pain	
Sachs (2014)[80] N analyzed = 144[b]	N intraoperative events: 0 Mean follow-up of 16 mos. (range: 12 to 26 mos.) N postoperative events: 28 Fall: 5 (3.5%) Trochanteric bursitis: 4 (2.8%) Piriformis syndrome: 3 (2.1%) 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%)*	At 1 yr.: 1 (*0.7%*) revision
Sachs (2016)[81] N analyzed = 107[c]	N adverse events related to SI joint fusion: 3 1 Mild ileus 1 Suture material extending from wound 1 Adhesive tape allergic reaction	At mean of 3.7 yrs. (range: 3.0-4.7 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 non-union and possible loosening of 1 implant and inadequate placement of another 1 for recurrent pain at 6 mos. possibly due to malposition, placement of a bone graft 1 for inadequate pain relief possibly due to malposition 1 for injury sustained in motor vehicle accident
Schoell (2016)[33] N analyzed = 469	N (%) overall incidence of complications: 90 days: 62 (13.2) 6 mos.: 77 (16.4) N (%) Neuritis 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 (%) Joint derangement 90 days: ≤11 (no other data reported) 6 mos.: ≤11 (no other data reported) 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 (%) 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)	
Schutz (2006)[28] N analyzed = 17	N (%) Intraoperative complications: 1 (5.8) Dorsal iliac crest fracture	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)[26] N analyzed = 19	N (%) with postoperative complications: 4 (16) 1 wound hematoma 1 nonunion 1 posterior superior iliac spine irritation 1 non-fatal pulmonary embolism related to pelvic deep vein thrombosis	Timeframe unspecified: Reoperations: 3 (16%) All were to resolve surgical complications
Waisbrod (1987)[24] N analyzed = 21 patients/22 procedures	N (%) with complications: 3 (14) 2 nonunions 1 infection	NR
Wise (2008)[66]	0 infections reported	Timeframe unspecified:

Author (Year) Study Name; Registry Number; N analyzed	Adverse Events	Revision Surgery
N analyzed = 13	0 neurovascular complications reported	N (%) with revisions: 1 (8) Revision to address nonunion

Notes: We calculated values in italics

[a] We are unable to determine the overlap in study population between this study and Sachs (2014).[80] The study author was contacted for clarification but did not reply.

[b] Includes patients that were reported in Sachs (2016).[81] We are unable to determine the overlap in study population between this study and Sachs (2013).[79] The study author was contacted for clarification but did not reply.

[c] Included patients that were also reported in Sachs (2014).[80]

Abbreviations: LOIS = Long Term outcomes from INSITE and SIFI; mo(s) = month(s); N = number of participants; NR = not reported.

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)[35] 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 years 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-year costs (5-year 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)[36] 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-year 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 age 84 and suffer from chronic low back pain due to SI joint disruption or degenerative sacroiliitis, and who are eligible for minimally invasive surgery;	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
		100% of procedures performed in inpatient setting; 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	
Cher (2016)[37] 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: USD, year NR Discount rate: 3% Perspective: Payer Time horizon: 5 years 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 years; 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 months; 25% received bilateral fusion; Utilities: 0.77 mild pain (good response), 0.45 severe pain (poor response); 1% yearly rate of revision	Base Case: Cost I: $22,468 C: $12,635 Difference (C-I): $-9,833 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 year horizon ICER ~ $2,300/QALY Breakeven costs at approximately 13 years

Notes: [a] Medicare prescription claims were not available, so authors estimated pharmacy costs based on a similar study they performed using commercial claims.
Abbreviations: C = control group; I = intervention group; ICER= incremental cost-effectiveness ratio; NR = not reported; QALY = quality-adjusted life year; SD = standard deviation; SI = sacroiliac.

Appendix D. Excluded Articles

List of Exclusion Codes

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

1. Abstracts for the BASS Meeting 2013. *Eur Spine J.* 2013;22(1). Exclusion code: X11.
2. Erratum: Cost-effectiveness of minimally invasive sacroiliac joint fusion [Corrigendum]. *Clinicoecon Outcomes Res.* 2016;8:305. PMID: 27445500. doi: 10.2147/ceor.s107803. Exclusion code: X2.
3. Ackerman SJ, Polly DW, Jr., Knight T, Holt T, Cummings J. Management of sacroiliac joint disruption and degenerative sacroiliitis with nonoperative care is medical resource-intensive and costly in a United States commercial payer population. *Clinicoecon Outcomes Res.* 2014;6:63-74. PMID: 24596468. doi: 10.2147/ceor.s54158. Exclusion code: X5.
4. Ahmed H, Siam AE, Gouda-Mohamed GM, Boehm H. Surgical treatment of sacroiliac joint infection. *J Orthop Traumatol.* 2013;14(2):121-129. PMID: 23558792. doi: 10.1007/s10195-013-0233-3. Exclusion code: X4.
5. Arand M, Kinzl L, Gebhard F. Computer-guidance in percutaneous screw stabilization of the iliosacral joint. *Clin Orthop Relat Res.* 2004(422):201-207. PMID: 15187858. Exclusion code: X5.
6. Ashman B, Norvell DC, Hermsmeyer JT. Chronic sacroiliac joint pain: fusion versus denervation as treatment options. *Evid Based Spine Care J.* 2010;1(3):35-44. PMID: 22956926. doi: 10.1055/s-0030-1267066. Exclusion code: X1.
7. Berthelot JM, Gouin F, Glemarec J, Maugars Y, Prost A. Possible use of arthrodesis for intractable sacroiliitis in spondylarthropathy: report of two cases. *Spine (Phila Pa 1976).* 2001;26(20):2297-2299. PMID: 11598524. Exclusion code: X4.
8. Bornemann R, Roessler PP, Wirtz DC, Pflugmacher R. Low back pain originating from the sacroiliac joint-1 year results from a randomized controlled trial of conservative management vs. Minimally invasive surgical management. *Eur Spine J.* 2017;26(11):3007-3008. doi: 10.1007/s00586-017-5336-8. Exclusion code: X11.
9. Bucciero A, Piscopo GA, Zorzi T, Olindo G, Zaccariello A, Nicosia G. Use of minimally invasive surgical procedure system SI-bone for the treatment of disease degenerative sacro-ILIAC joint. *Eur Spine J.* 2013;22(4):926. doi: 10.1007/s00586-013-2746-0. Exclusion code: X11.
10. Capobianco R, Cher D. Safety and effectiveness of minimally invasive sacroiliac joint fusion in women with persistent post-partum posterior pelvic girdle pain: 12-month outcomes from a prospective, multi-center trial. *Springerplus.* 2015;4:570. PMID: 26543705. doi: 10.1186/s40064-015-1359-y. Exclusion code: X9.
11. Capobianco R, Sachs DC, Gundanna MI, et al. Minimally invasive fusion of the SI joint: A multicenter outcomes study. *Spine Journal.* 2014;14(11):S149. doi: 10.1016/j.spinee.2014.08.361. Exclusion code: X11.

12. Cher DJ, Duhon B. Safety and effectiveness of minimally invasive sacroiliac joint fusion: A prospective study. *Spine Journal.* 2014;14(11):S179. doi: 10.1016/j.spinee.2014.08.430. Exclusion code: X11.
13. Cher DJ, Polly DW. Improvement in health state utility after sacroiliac joint fusion: comparison to normal populations. *Global Spine J.* 2016;6(2):100-107. PMID: 26933610. doi: 10.1055/s-0035-1556581. Exclusion code: X9.
14. Cher DJ, Reckling WC. Quality of life in preoperative patients with sacroiliac joint dysfunction is at least as depressed as in other lumbar spinal conditions. *Med Devices (Auckl).* 2015;8:395-403. PMID: 26396547. doi: 10.2147/mder.s92070. Exclusion code: X7.
15. Cohen SP, Hurley RW. The ability of diagnostic spinal injections to predict surgical outcomes. *Anesth Analg.* 2007;105(6):1756-1775. doi: 10.1213/01.ane.0000287637.30163.a2. Exclusion code: X5.
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18. Dengler J, Duhon B, Whang P, et al. Predictors of outcome in conservative and minimally invasive surgical management of pain originating from the sacroiliac joint: a pooled analysis. *Spine (Phila Pa 1976).* 2017;42(21):1664-1673. PMID: 28350586. doi: 10.1097/brs.0000000000002169. Exclusion code: X9.
19. Dengler J, Duhon B, Whang P, et al. Minimally invasive sacroiliac joint fusion using triangular titanium implants: Pooled analysis of 3 prospective clinical trials. *Global Spine Journal.* 2017;7(2):43S. doi: 10.1177/2192568217708577. Exclusion code: X11.
20. Dengler J, Sturesson B, Kools D, et al. Minimally invasive sacroiliac joint fusion vs. conservative management-outcomes from a randomized controlled trial. *Eur Spine J.* 2016;25:S352. doi: 10.1007/s00586-016-4726-7. Exclusion code: X11.
21. Dengler J, Sturesson B, Kools D, Prestamburgo D, Pflugmacher R, Vajkoczy P. Opioid use in relation to treatment outcome in patients with low back pain. *Eur Spine J.* 2016;25(11):3830-3831. doi: 10.1007/s00586-016-4801-0. Exclusion code: X11.
22. Dengler J, Sturesson B, Kools D, et al. Referred leg pain originating from the sacroiliac joint - Outcomes from the prospective randomized controlled iMIA trial. *Eur Spine J.* 2016;25(11):3790. doi: 10.1007/s00586-016-4801-0. Exclusion code: X11.
23. Ebraheim NA, Ramineni SK, Alla SR, Ebraheim M. Sacroiliac joint fusion with fibular bone graft in patients with failed percutaneous iliosacral screw fixation. *J Trauma.* 2010;69(5):1226-1229. PMID: 21068623. doi: 10.1097/TA.0b013e3181e4f3f8. Exclusion code: X4.
24. Endres S, Ludwig E. Outcome of distraction interference arthrodesis of the sacroiliac joint for sacroiliac arthritis. *Indian J Orthop.* 2013;47(5):437-442. PMID: 24133301. doi: 10.4103/0019-5413.118197. Exclusion code: X7.
25. Fuchs V, Hassel F, Ruhl B, Stark J. Distraction arthrodesis of the sacroiliac joint - 1-year results of a prospective, multi-center observational study in 160 patients. *Eur Spine J.* 2013;22(11):2640. doi: 10.1007/s00586-013-3050-8. Exclusion code: X11.
26. Fuchs V, Ruhl B, Stark J. Distraction arthrodesis of the sacroiliac joint - 2-year results of a prospective, multi-center observational study in 157 patients. *Eur Spine J.* 2014;23(11):2494-2495. doi: 10.1007/s00586-014-3600-8. Exclusion code: X11.
27. Gaetani P, Sturesson B, Zoia C, et al. Twelve-month outcomes from a multicenter randomized controlled trial of minimally invasive sacroiliac joint fusion with triangular titanium implants vs conservative management. *Global Spine Journal.* 2017;7(2):41S. doi: 10.1177/2192568217708577. Exclusion code: X11.

28. Garber T, Ledonio CG, Polly DW, Jr. How much work effort is involved in minimally invasive sacroiliac joint fusion? *Int J Spine Surg.* 2015;9:58. PMID: 26609513. doi: 10.14444/2058. Exclusion code: X7.
29. Giannikas KA, Khan AM, Karski MT, Maxwell HA. Sacroiliac joint fusion for chronic pain: A simple technique avoiding the use of metalwork. *Eur Spine J.* 2004;13(3):253-256. doi: 10.1007/s00586-003-0620-1. Exclusion code: X7.
30. Heiney J, Capobianco R, Cher D. A systematic review of minimally invasive sacroiliac joint fusion utilizing a lateral transarticular technique. *Int J Spine Surg.* 2015;9:40. PMID: 26273558. doi: 10.14444/2040. Exclusion code: X1.
31. Hickey B, James S, Chopra I, Davies P. Early results of distraction interference sacroiliac joint arthrodesis: How safe is this new procedure and are patients satisfied? *Eur Spine J.* 2013;22(1):S55. doi: 10.1007/s00586-013-2664-1. Exclusion code: X11.
32. Ibrahim R. Update interventional treatment of SIJ 18 month follow up of reduction in sacroiliac joint pain: Endoscopic/arthroscopic electrothermic novel procedure in comparison to SIJ radio frequency/fusion. *Pain Practice.* 2018;18:62. Exclusion code: X11.
33. Julius D, Sturesson B, Kools D, Prestamburgo D, Pflugmacher R, Vajkoczy P. Opioid use in relation to treatment outcome in patients with low back pain: Data from a prospective randomized controlled trial. *Global Spine Journal.* 2017;7(2):109S. doi: 10.1177/2192568217708577. Exclusion code: X11.
34. Kancherla V, McGowan S, Audley B, Sokunbi GO, Puccio ST. Early outcomes following percutaneous sacroiliac joint fusion. *Spine Journal.* 2015;15(10):255S. doi: 10.1016/j.spinee.2015.07.392. Exclusion code: X11.
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42. Lingutla KK, Pollock R, Ahuja S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. *Eur Spine J.* 2016;25(6):1924-1931. PMID: 26957096. doi: 10.1007/s00586-016-4490-8. Exclusion code: X1.
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48. Polly DW, Cher DJ, Whang PG, Frank CJ, Glaser JA, Sembrano JN. Randomized controlled trial of minimally invasive sacroiliac joint fusion using triangular titanium implants versus nonsurgical management for sacroiliac joint dysfunction: 12-month outcomes. *Spine Journal.* 2016;16(10):S291. doi: 10.1016/j.spinee.2016.07.419. Exclusion code: X11.
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51. Reiley MA, Amaral M, Geisler FH, et al. Simplifying sacroiliac joint arthrodesis using MIS fusion implants. *PM and R.* 2010;2(9):S66. Exclusion code: X11.
52. Rudolf L. MIS fusion of the SI joint: does prior lumbar spinal fusion affect patient outcomes? *Open Orthop J.* 2013;7:163-168. PMID: 23730380. doi: 10.2174/1874325001307010163. Exclusion code: X9.
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61. Sturesson B, Dengler J, Kools D, Pflugmacher R, Prestamburgo D. Sacroiliac minimal invasive fusion compared to physical therapy: Sixmonth outcome from a multicentre randomised controlled trial. *Spine Journal.* 2016;16(4):S73-S74. doi: 10.1016/j.spinee.2016.01.087. Exclusion code: X11.
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63. Zaidi HA, Montoure AJ, Dickman CA. Surgical and clinical efficacy of sacroiliac joint fusion: a systematic review of the literature. *J Neurosurg Spine.* 2015;23(1):59-66. PMID: 25840040. doi: 10.3171/2014.10.spine14516. Exclusion code: X1.

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 (2017);[61] Dengler (2016);[62] Sturesson (2016);[15] iMIA	Yes	No information	No	Low	None
Whang (2015);[16] Polly (2015);[60] Polly (2016)[59] 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 years) and had a higher proportion of women (74% vs. 61%).	Low	None

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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15]; iMIA	Yes	Yes	No: No crossovers through 6 mos.; participants were allowed to cross over after 6 months.	NA	No: Not at the 6-month follow-up.	NA	Low	Low for outcomes up to 6 months.
Whang (2015);[16] Polly (2015);[60] Polly (2016)[59] INSITE	Yes	Yes	No: No crossovers occurred at 6 months or earlier. After 6 months, 35 of the 44 participants in nonsurgical management group that were still participating crossed over to surgery.	NA	No: Not at the 6-month follow-up timepoint.	NA	Low	Low for outcomes up to 6 months.

Abbreviations: 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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15]; iMIA	Yes: 109 enrolled, 103 received treatment, follow-up data available for 101/109=93%	NA	NA	Low	None
Whang (2015);[16] Polly (2015);[60] Polly (2016)[59] INSITE	Yes: 159 enrolled, 148 received treatment, 6-month f/u available for 144; after 6 months there are extensive crossovers. 12-month f/u data available for 138; 24-month f/u data available for 89 of 102 assigned to fusion; f/u still ongoing in nonsurgical management group since most crossed over.	NA	NA	Low	None

Abbreviations: 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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15]; 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);[16] Polly (2015);[60] Polly (2016)[59] 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)[60] says that no participants assigned to nonsurgical management were classified as a failure for reasons other than inadequate pain reduction.

Abbreviations: 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 (2017);[61] Dengler (2016);[62] Sturesson (2016)[15]; iMIA	Yes	Probably yes	Some concerns	Multiple measures of general health-related quality of life and function reported, outcomes measured at 1, 3, and 6 months post-intervention.	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 months as extensive crossovers occurred after 6 months.
Whang (2015);[16] Polly (2015);[60] Polly (2016)[59] 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, and 6 months.	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 months as extensive crossovers occurred after 6 months.

Abbreviations: EQ = EuroQOL 5 item measure of general health status; ODI = Oswestry Disability Index.

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

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?
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	Yes	No	NA	Probably no	NA
Ledonio, 2014[20] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	No	NA	Probably no	NA
Ledonio, 2014[21] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	No	NA	Probably no	NA
Smith (2013)[19] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Yes	No	NA	Probably no	NA
Spain (2017)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	Yes	No	NA	Probably no	NA
Vanaclocha (2018)[17] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	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?
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	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[20] 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[21] 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.

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?
Smith (2013)[19] Retrospective controlled cohort study with concurrent comparator	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 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)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	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).

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)[17] 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; 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
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	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[20] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Yes	No	High	Participants had to have at least 1 year of follow-up available.
Ledonio, 2014[21] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Yes	No	High	Participants had to have at least 1 year of follow-up available.
Smith (2013)[19] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Yes	Yes	No	Yes	No	High	Participants had to have VAS pain scores recorded in their medical records at 12 and 24 months to be included in the study. Participants who did not return

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
								for follow-up or for whom surgeons did not document a pain score would not be eligible for selection into the study.
Spain (2017)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	No	NA	NA	Yes	NA	Low	None
Vanaclocha (2018)[17] 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: NA = not applicable; ODI = Oswestry Disability Index; VAS = visual analog scale.

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
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	Yes	Yes	No	Low	None
Ledonio, 2014[20] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Low	None
Ledonio, 2014[21] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	Yes	Yes	No	Low	None
Smith (2013)[19] Retrospective controlled cohort study with concurrent comparator	VAS Pain	Yes	Yes	No	Low	None
Spain (2017)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	Yes	Yes	No	Low	None
Vanaclocha (2018)[17] 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; 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
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	No	NA	Low	None
Ledonio, 2014[20] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	NA	Low	None
Ledonio, 2014[21] Retrospective controlled cohort study with concurrent comparator	ODI, safety outcomes	No	NA	Low	None
Smith (2013)[19] Retrospective controlled cohort study with concurrent comparator	VAS Pain	No	NA	Low	None
Spain (2017)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	No	NA	Low	None
Vanaclocha (2018)[17] Retrospective controlled cohort study with concurrent comparator	VAS Pain, ODI, % taking opioids, % working	No	NA	Low	None

Abbreviations: ODI = Oswestry Disability Index; 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
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	No	No	Yes	Yes	No information	High	I: 50/81=61.7% C: 28/48=58.3%
Ledonio, 2014[20] 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[21] 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.
Smith (2013)[19] 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.

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
Spain (2017)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	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)[17] 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 timepoint. 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 = change; MIS = minimally invasive surgery; mos. = months; ODI = Oswestry Disability Index; VAS = visual analog scale; yr. = year.

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
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	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[20] 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.
Ledonio, 2014[21] 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
Smith (2013)[19] 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)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	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.
Vanaclocha (2018)[17] 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; 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
Kibsgard (2013)[18] Retrospective controlled cohort study with historical comparator	VAS, ODI, global success	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[20] 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[21] 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.
Smith (2013)[19] 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)[22] Retrospective controlled cohort study with historical comparator	Revision surgery	No	No	No	Low	None	High	Some concerns for bias due to confounding and differential attrition.

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
Vanaclocha (2018)[17] 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 timepoints greater than 1 yr. and use of repeated measures analysis through all timepoints; some concerns for bias in other domains including selection of participants, confounding, classification of intervention and measurement of outcome.

Abbreviations: ODI = Oswestry Disability Index; 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)[68]	Yes	Unclear	Unclear as only patients with at least 24 months of follow-up were included in the analysis	Unclear	Unclear
Araghi, 2017[64]	Yes	Unclear	Unclear	Yes	Yes
Beck (2015)[69]	No	Yes	Yes	Unclear	Yes
Belanger (2001)[23]	No	Unclear	Unclear	No	No
Bornemann, 2017[83]	No	Unclear	Unclear	Unclear	Unclear
Buchowski (2005)[29]	Yes	Yes	Unclear as only patients with at least 24 months follow-up were included in the analysis	Yes	Unclear
Cher (2015)[34]	Yes	Yes	Yes	Unclear	No information
Cross, 2018[82]	No	Unclear	Yes, 18/19 had follow-up data	Unclear	Unclear
Cummings (2013)[70]	Yes	No, only patients with at least 1 year of follow-up were included.	No, only patients with at least 1 year of follow-up were included.	Unclear	Yes
Darr (2018)[32]	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);[31] Duhon (2016);[102] Duhon (2016);[103] SIFI[68]	Yes	Unclear	Yes, 169/194=87% at 2 yrs.	Yes	Yes
Fuchs, 2018[30,64]	Yes	Unclear	Yes. (137/171=80.1% at 1 yr. and 132/171=77.2% at 2 yrs.)	Yes	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?
Gaetani (2013)[69,71]	Yes	Yes	Yes, as only reports on the first 12 cases at this single institution	Yes	Yes
Kancherla (2017)[23,72]	Yes	Probably yes	Data available for 41/57 =71.9% of patients	Unclear	Yes
Khurana (2009)[83,73]	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)[29,27]	Yes	Yes	Yes, had follow-up data for 8/9= 88.9%	Yes	Yes
Kleck (2016)[34,74]	Yes	Unclear	Unclear, data for intraoperative and postoperative complications was likely complete, but outcomes at 1 year likely incomplete.	Unclear	Unclear
Kube (2016)[75]	Unclear	Unclear	Yes, follow-up data available for 15/18=83% of patients	Unclear	Unclear
Mason (2013)[67]	Unclear	Yes	No, data available for 55/73=75% of participants	Unclear	Unclear
McGuire (2012)[76]	Unclear	Unclear	Yes, data for 34/37=91.9% at 1 yr. and 30/37=81.8% at 2 yrs.	Unclear	Unclear
Miller (2013)[77]	Yes	Yes	Yes	Unclear	Unclear
Nystrom (2017)[25]	Yes	Unclear	Yes, 49/55=89%	Unclear	Yes
Rappoport (2017)[65]	Yes	Yes	Yes, 100%	Unclear	Unclear, not all patients were required to have a diagnostic block, specific physical exam tests were NR
Rudolf (2012)[78]	Yes	Yes	Unclear	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 (2013)[79]	Yes	Unclear (if complete data required for inclusion)	Only patients with 1 yr. follow-up data were included	Unclear	Yes
Sachs (2014)[75,80]	Yes	Unclear (if complete data required for inclusion)	Only patients with complete preoperative and 1 yr. follow-up data were included	Unclear	Yes
Sachs (2016)[67,81]	Yes	No	Only patients with documented preoperative pain scores and who consented to complete questionnaire were included	Unclear	No
Schoell (2016)[33,76]	Yes	Yes	Yes	Unclear	Unclear
Schutz (2006)[28,77]	Yes	Unclear	Yes	No	No
Slinkard (2013)[25,26]	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)[24,65]	Yes	Unclear	Unclear	Unclear	Unclear, used criteria of the era during which the procedures were performed, but these criteria have evolved.
Wise (2008)[66,78]	Yes	Yes	Yes	Unclear	Unclear

Abbreviations: = SI = sacroiliac; SIFI = Sacroiliac Joint Fusion with iFuse Implant System study.

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)[68,80]	Unclear	Yes	NA	Yes
Araghi (2017)[64,81]	Unclear	Yes	NA	Yes
Beck (2015)[33,69]	Unclear	Yes	NA	Yes
Belanger (2001)[23,28]	Unclear	Yes	NA	Yes
Bornemann (2017)[26,83]	No	Yes	NA	Yes
Buchowski (2005)[24,29]	Unclear	Yes	NA	Yes
Cher (2015);[34,66]	Yes	Yes	Yes	Yes
Cross (2018)[82]	Unclear	Yes	NA	Yes
Cummings (2013)[70]	Unclear	Yes	NA	Yes
Darr (2018)[32]	Yes, per the original study protocols	Yes	NA	Yes
Duhon (2013);[31] Duhon (2016);[102] Duhon (2016)[103] SIFI	Yes	Yes	NA	Yes
Fuchs, 2018[30]	Unclear	Yes	NA	Yes
Gaetani (2013)[71]	Unclear	Yes	NA	Yes
Kancherla (2017)[72]	Unclear	Yes	NA	Yes
Khurana (2009)[73]	Unclear	Yes	NA	Yes
Kibsgard (2014)[27]	Yes	Yes	NA	Yes
Kleck (2016)[74]	Unclear	Yes	NA	Yes
Kube (2016)[75]	Unclear	Yes	NA	Yes
Mason (2013)[67]	Unclear	Yes	NA	Yes
McGuire (2012)[76]	Unclear	Yes	NA	Yes
Miller (2013)[77]				
Nystrom (2017)[25]				
Rappoport (2017)[65]				

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?
Rudolf (2012)[78]				
Sachs (2013)[79]				
Sachs (2014)[80]				
Sachs (2016)[81]				
Schoell (2016)[33]				
Schutz (2006)[28]				
Slinkard (2013)[26]	Unclear	Yes	NA	Yes
Waisbrod (1987)[24]	Unclear	Unclear	NA	Yes
Wise (2008)[66]	Unclear	Yes	NA	Yes

Abbreviations: 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)[68]	No	No	High	Only included patients who had 24 months of follow-up, unstandardized approach to diagnosis used, unclear whether study used standardized protocol for identifying and documenting adverse events.
Araghi (2017)[64]	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)[69]	Unclear	Yes	Medium	Two slightly different approaches were used for the procedure; unclear whether standardized protocol was used for safety events.
Belanger (2001)[23]	Yes	Yes	High	This describes 4 case reports in 1 paper, no standardized protocol for diagnosis of measurement of outcomes.
Bornemann (2017)[83]	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)[29]	Yes	Yes	High	Excluded patients that did not have 24 months 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 (2015)[34]	No	No	Medium	Very little clinical information about patients in the analysis and no information about diagnosis. Some concerns about how standardized and consistently cases of revision surgery were reported in the complaints database.
Cross, 2018[82]	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)[70]	No	Yes	High	Excluded patients that did not have at least 1 year 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.

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
Darr (2018);[32]	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);[31] Duhon (2016);[102] Duhon (2016);[103] 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)[30]	Unclear	Yes	Medium	Unclear whether consecutive eligible patients were enrolled and diagnostic criteria appear to have some subjectivity.
Gaetani (2013)[71]	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)[72]	Unclear	Unclear	Medium	Follow-up on less than 80% of eligible patients.
Khurana (2009)[73]	Unclear	Yes	High	Patients who required further surgery were excluded from the analysis, this introduce a high risk for selection bias.
Kibsgard (2014)[27]	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.
Kleck (2016)[74]	No	No	High	Unclear diagnostic criteria, concern over completeness of longer-term follow-up data, population not well described.
Kube (2016)[75]	Yes	Yes	Medium	Unclear diagnostic criteria, only modest attrition, unclear approach to assessing safety outcomes.
Mason (2013)[67]	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)[76]	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-year span of time, meaning risk of bias due to growth in surgeon procedural experience or changes in surgical techniques/technology over time.

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
Miller (2013)[77]	No	Unclear	Medium	No diagnostic criteria provided and very little clinical information about population; unclear whether approach to capturing adverse events may have varied across the many settings represented by the database.
Nystrom (2017)[25]	Unclear	Yes	Medium	Unclear whether systematic approach to measuring safety outcomes used, lack of some detail regarding clinical information about patient population.
Rappoport (2017)[65]	No	No	Medium	Very little clinical information about population, diagnostic criteria do not appear systematically applied.
Rudolf (2012)[78]	Unclear	Yes	Medium	Unclear whether outcomes available for nearly all patients, unclear whether systematic approach to evaluating safety outcomes was used.
Sachs (2013)[79]	Unclear	Yes	High	High potential for bias as 1-year follow-up data was required for study inclusion, unclear whether a systematic approach to evaluating safety outcomes was used.
Sachs (2014)[80]	Unclear	Yes	High	High potential for bias as both preoperative and 1-year follow-up data was required for study inclusion, unclear whether a systematic approach to evaluating safety outcomes was used.
Sachs (2016)[81]	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, non-standardized approach to diagnosis was used.
Schoell (2016)[33]	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 SIJ fusion, despite the CPT codes used to code procedures.
Schutz (2006)[28]	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.

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
Slinkard (2013)[26]	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)[24]	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.
Wise (2008)[66]	Yes	Yes	Medium	Unclear validity of diagnostic approach, unclear whether systematic approach to measuring safety outcomes used.

Abbreviations: CPT = Current Procedural Terminology; NA = not applicable; ROB = risk of bias; SI = sacroiliac; SIFI = Sacroiliac Joint Fusion with iFuse Implant System study; SIJ = sacroiliac joint.

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)[35]	Yes	Yes	Yes	NA	Yes	No	NA
Ackerman (2013)[36]	Yes	Yes	Yes	NA	Yes	No	NA
Cher (2016)[37]	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 year 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)[35]	Yes	Yes	Yes	NA	Yes	Yes
Ackerman (2013)[36]	Yes	Yes	Yes	NA	Yes	Yes
Cher (2016)[37]	Yes	Yes	Yes	Yes	Yes	Yes

Abbreviations: NA = not applicable.

Table E-18. Quality of health economic 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)[35]	Yes	Yes	Yes	93
Ackerman (2013)[36]	Yes	Yes	Yes	93
Cher (2016)[37]	Yes	Yes	Yes	99

[a] Based on scale of 0 (worst quality) to 100 (best quality).