

Health Technology Clinical Committee

Date: January 18, 2019
Time: 8:00 am – 5:00 pm
Location: SeaTac Conference Center, SeaTac, WA
Adopted: Pending

Meeting materials and transcript are available on the [HTA website](#).

Draft HTCC Minutes

Members present: John Bramhall, MD, PhD, Gregory Brown, MD, PhD; Janna Friedly, MD; Chris Hearne, BSN, DNP, MPH; Austin Mc Millin, DC; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Conor P. Kleweno, MD; Brett R. Stacey, MD

HTCC Formal Action

- 1. Call to order:** Dr. Brown, chair, called the meeting to order; members present constituted a quorum.
- 2. HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines; a high-level overview of the purpose, development, and history of the HTA program; a how-to participate in the HTCC process; upcoming topics; and a meetings calendar.
- 3. November 16, 2018 meeting minutes:** Draft minutes reviewed. Motion made and seconded to approve the minutes as written.
Action: Ten committee members approved the November 16, 2018 meeting minutes.
- 4. Tumor treating fields (Optune®) re-review - draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. No comments were received on the draft decision; one change made to remove a typo (extra parentheses). Motion made and seconded to accept the findings and decision, as amended.
Action: Eight committee members voted to approve the tumor treating fields (Optune®) findings and decision. Two committee members abstained.
- 5. Introduction of new members:** Chair introduced two new HTCC members: Janna Friedly, MD and Austin Mc Millin, DC.
- 6. Positron emission tomography (PET) scans for lymphoma re-review- draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. One public comment received: a recommendation for an exception in the timing of PET scans for advanced stage Hodgkin's lymphoma when assessing response to ABVD chemotherapy. The committee considered the recommended exception and added it to the draft. Motion made and seconded to accept the findings and decision, as amended.

Action: Eight committee members voted to approve the positron emission tomography (PET) scans for lymphoma findings and decision. Two committee members abstained.

Draft

7. Sacroiliac joint fusion:

Clinical expert: The chair introduced Conor Kleweno, MD, Assistant Professor, Department of Orthopaedics and Sports Medicine, University of Washington School of Medicine and Orthopaedic Traumatologist, Harborview Medical Center.

Agency utilization and outcomes: Emily Transue, MD, MHA, Associate Medical Director, Health Care Authority, presented the state agency perspective on sacroiliac joint fusion. Find the full presentation published with the [January 18 meeting materials](#).

Scheduled and open public comments: Chair called for public comments. Comments provided by:

- David W. Polly, Jr, MD: James W. Ogilvie Professor, Chief of Spine Surgery, Catherine Mills Davis Endowed Chair, Department of Orthopaedic Surgery, Professor of Neurosurgery, University of Minnesota. Dr. Polly was also representing the American Academy of Orthopaedic Surgeons, American Association of Neurological Surgeons and Congress of Neurological Surgeons, International Society for the Advancement of Spine Surgery, and the Washington Association of Neurological Surgeons. (By phone)

Find all public presentations published with the [January 18 meeting materials](#).

Vendor report/ HTCC question and answers: Leila Kahwati, MD, MPH, RTI-University of North Carolina Evidence-based Practice Center presented the evidence review for Sacroiliac joint fusion. Find the full report published with the [January 18 meeting materials](#).

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on sacroiliac joint fusion is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of sacroiliac joint fusion. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover minimally invasive or open sacroiliac joint fusion for sacroiliac chronic joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption for adults 18 years old and older.

	Not covered	Covered under certain conditions	Covered unconditionally
Sacroiliac joint fusion	11	0	0

Discussion

The committee reviewed and discussed the available studies for use of sacroiliac joint fusion for chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of sacroiliac joint fusion for

chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption unproven for being safer, more effective or more cost-effective than comparators.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare NCD for sacroiliac joint fusion for sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption.

The committee discussed clinical guidelines identified for sacroiliac joint fusion from the following organizations:

- National Institute for Health and Care Excellence (NICE) Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578, (2017)
- AIM Specialty Health Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion, (2018)

The committee's determination is not consistent with the NICE and AIM guidance. The HTCC determination included consideration of local, clinical expert considerations related to the complexities of revision surgeries, concerns related to diffusion and uncertainty of evidence for safety and cost-effectiveness. The quality of evidence assessment was either not performed or not reported for these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of sacroiliac joint fusion for public comment to be followed by consideration for final approval at the next public meeting.

8. HTA topic selection request for re-review topics:

Stereotactic radiosurgery and stereotactic body radiation topic is under consideration for re-review. In order for the Director of the Health Care Authority to recommend re-view, new evidence-based findings must exist which could change the previous determination. The Oregon Health and Science University Center for Evidence-based Policy provided a topic update: *Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy: An evidence update* (December 2018). The Chair presented the report's findings; the committee discussed and considered the findings. Also, during the November 2018 meeting, the committee examined two petitions for topic re-review; petitions addressed SBRT with Cyberknife technology specifically for the treatment of prostate cancer.

Action: The committee recommended the evidence update does not support a re-review at this time. The Committee decided to not recommend the topic for re-review.

9. Peripheral nerve ablation for limb pain:

Clinical expert: The chair introduced Brett Stacey, MD, Medical Director, University of Washington Center for Pain Relief and Professor of Anesthesiology and Pain Medicine, University of Washington School of Medicine.

Agency utilization and outcomes: Gary Franklin, MD, MPH, Medical Director, Department of Labor and Industries; Research Professor, University of Washington; Co-Chair, Washington Agency Medical Director Group presented the state agency perspective on peripheral nerve ablation for limb pain. Find the full presentation published with [January 18 meeting materials](#).

Scheduled and open public comments: The chair called for public comments. Comments were provided by:

- Anne Stefurak, RN, CPC, COC Vice-president Health Economics and Reimbursement - Avanos
- John DiMuro, DO, MBA - Avanos
- Diane Jackson, representing a family member

Find public presentation materials published with the [January 18, meeting materials](#).

Vendor report/ HTCC question and answer: Valerie J. King, MD, MPH, Oregon Health & Science University/Center for Evidence-based Policy presented the evidence review for Peripheral nerve ablation for limb pain. Find the presentation published with the [January 18 meeting materials](#).

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on peripheral nerve ablation for limb pain due to osteoarthritis is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of peripheral nerve ablation. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover peripheral nerve ablation, using any technique, for limb pain due to osteoarthritis or other conditions for adults and children

	Not covered	Covered under certain conditions	Covered unconditionally
Peripheral nerve ablation, using any technique, for chronic limb pain due to osteoarthritis or other conditions for adults and children.			
Foot, Shoulder, Hip	10	0	0
Knee	6	4	0

Discussion

The committee reviewed and discussed the available studies for use of peripheral nerve ablation for limb pain. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of peripheral nerve ablation for the foot, shoulder or hip, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer, more effective, or more cost-effective than

comparators. The committee found that peripheral nerve ablation of the knee, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer or more cost-effective than comparators. The committee did find that in some cases, peripheral knee ablation of the knee, using any technique, for limb pain due to osteoarthritis or other conditions may be more effective.

Additional Considerations

The committee recognizes, from information provided in the review process, that ongoing studies could impact the evidence-based determination: they will re-review this topic following publications of new research findings that could change the determination.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Medicare does not have a NCD for peripheral nerve ablation for limb pain.

The committee discussed clinical guidelines, however, none of identified clinical practice guidelines made a recommendation for the use of nerve ablation procedures for limb pain. Organizational guidelines:

- Association of Extremity Nerve Surgeons (2014)
- American College of Occupational and Environmental Medicine (2013)
- American College of Foot and Ankle Surgeons (ACFAS) (2018)
- American Academy of Orthopaedic Surgeons (2013)
- National Institute for Health and Care Excellence (NICE) (2014)
- Veterans Administration/Department of Defense (2014)

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of peripheral nerve ablation for limb pain for public comment to be followed by consideration for final approval at the next public meeting.

10. Meeting adjourned

Key Questions and Background

Sacroiliac Joint Fusion

Background

Sacroiliac joint fusion is a surgical treatment sometimes used to address pain that may be originating from the joint between bones in the spine and hip (sacrum and ilium). The sacroiliac joint (SIJ) is a diarthrodial joint with two surfaces and a fibrous capsule containing synovial fluid.^{1,2} Functionally, the SIJ 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 SIJ pain and dysfunction varies from patient to patient but buttock pain extending into the posterolateral thigh is the most common pattern.¹ The etiology of SIJ pain and dysfunction is thought to be related to axial loading and rotation, but studies suggest the entire SIJ complex (i.e., capsule, ligaments, subchondral bone) is innervated with nociceptors providing multiple locations for pain.¹⁻³ Aside from major trauma events resulting in serious pelvic injury, several predisposing factors for SIJ 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

SIJ pain and dysfunction is thought to be the primary source of pain for between 10 to 30 percent of cases of mechanical low back pain.^{3,4} However, estimating an accurate prevalence of SIJ pain and dysfunction 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 SIJ pain and dysfunction; thus, the current reference standard for diagnosis is anesthetic and provocative SIJ injections.³ However, this diagnostic standard is invasive, expensive, and may not be widely available as a primary diagnostic modality. Thus, provocative physical exam tests (e.g., distraction, FABER, etc.) may have a role as part of a step-wise approach to diagnosis.⁴ Imaging is generally not helpful in establishing a diagnosis, but may be helpful in ruling out other etiologies of low back pain.³

Several treatments for SIJ pain and dysfunction are available. These include pelvic belts and girdles; analgesics and anti-inflammatory medication; physical therapy to address strength, flexibility, or biomechanical deficits; manual manipulation; therapeutic joint injection; prolotherapy; radiofrequency denervation or ablation; and fusion surgery.^{2,4-6} Surgery, specifically SIJ fusion, is typically reserved for persons who fail conservative and less invasive treatments. Fusion of the SIJ can be performed as an open procedure, or since the late 1990s as a minimally-invasive procedure using proprietary surgical systems consisting of two to three specialized implants or screws inserted directly into the SIJ through small incisions under imaging guidance.^{2,4}

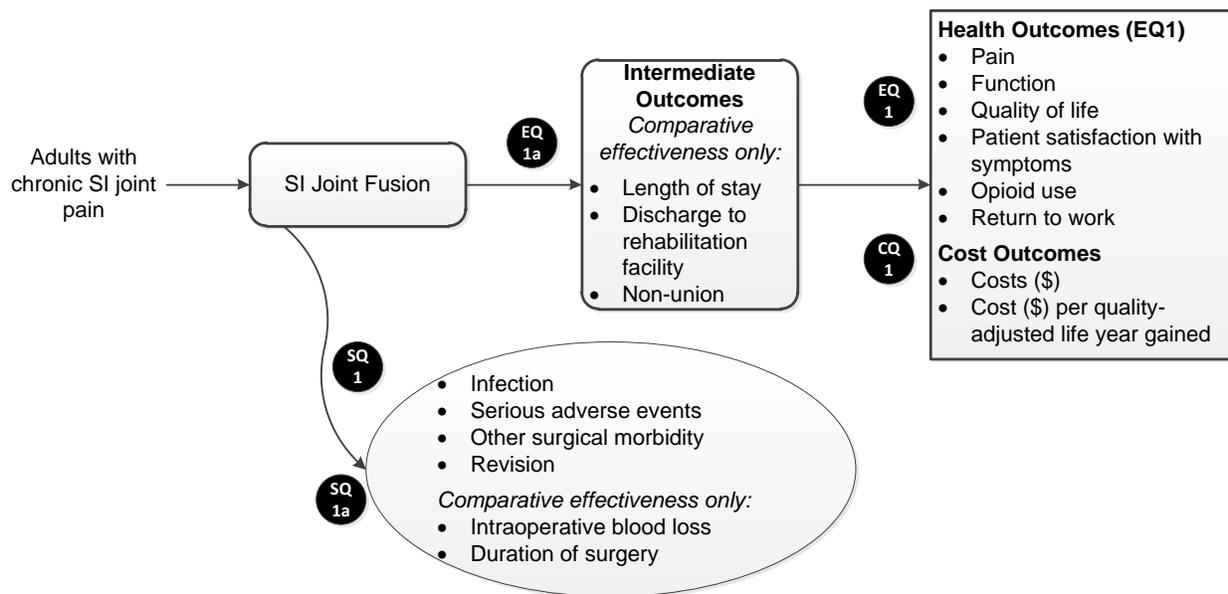
Policy Context

The State of Washington Health Care Authority selected SIJ Fusion as a topic for a health technology assessment because of high concerns for safety, efficacy, and cost.

Scope of this HTA

The analytic framework (**Figure 1**), research questions, and key study selection criteria are listed in this section.

Figure 1. Analytic Framework Depicting Scope of Proposed Health Technology Assessment



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

Efficacy Question 1a (EQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate efficacy outcomes?

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

Safety Question 1a (SQ 1a). What is the comparative effectiveness of various sacroiliac joint fusion surgeries on intermediate safety outcomes?

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

In addition, we will address the following contextual questions:

Contextual Questions:

1. What are the recommended ways to diagnose SI joint pain or disruption, and what is the accuracy of various diagnostic tests?
2. What is known about the frequency of various diagnostic approaches to SI joint pain or disruption in usual clinical practice?

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

Study Selection Criteria

Table 1 provides the study selection criteria we will use to include studies in the HTA; these criteria are organized by population, intervention, comparator, outcomes, timing, setting, and study design and risk of bias criteria.

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for HTA on Sacroiliac Joint Fusion

Domain	Included	Excluded
Population	<ul style="list-style-type: none"> • Adults age 18 years and over with chronic (≥3 months) SI joint pain related to degenerative sacroiliitis and/or SI joint disruption • Diagnosis based on positive findings on provocative physical exam tests and reduction/amelioration of pain after local SI joint injection or leakage of contrast from joint. 	<ul style="list-style-type: none"> • Less 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	<ul style="list-style-type: none"> • Open SI joint fusion • Minimally-invasive SI joint fusion 	Other spine surgeries, non-surgical interventions to treat SI Joint pain
Comparator	<ul style="list-style-type: none"> • Active Treatment <ul style="list-style-type: none"> - Physical therapy - Chiropractic therapy - Acupuncture - Analgesic and anti-inflammatory medication - Orthotics (e.g., pelvic girdles, belts) - Therapeutic joint injection - Neurotomy/denervation (e.g., radiofrequency ablation) • Placebo or no treatment 	<i>EQ1 and 1a:</i> No comparator group
Outcomes	<p><i>EQ1:</i></p> <ul style="list-style-type: none"> • Pain • Physical functioning • Quality of life • Patient satisfaction with symptoms • Opioid use • Return to work 	<p>Other outcomes not specifically listed as eligible.</p> <p>Pain, quality of life, and functional outcomes not measured using valid and reliable instruments or scales.^{7,8}</p>

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for HTA on Sacroiliac Joint Fusion

	<p><i>EQ1a only:</i></p> <ul style="list-style-type: none"> • Length of stay • Non-union • Discharge to acute or sub-acute rehabilitation facility <p><i>SQ1:</i></p> <ul style="list-style-type: none"> • Infection • Serious adverse events (e.g., cardiovascular events, thromboembolism, etc.) • Other surgical morbidity • Revision <p><i>SQ1a only:</i></p> <ul style="list-style-type: none"> • Intraoperative blood loss • Duration of surgery <p><i>CQ1:</i></p> <ul style="list-style-type: none"> • Costs • Cost per quality-adjusted life year gained • Cost per disability-adjusted life year gained 	
Setting	Inpatient or outpatient settings in countries categorized as “very high” on UN Human Development Index. ⁹	Studies conducted in countries not categorized as “very high” on UN Human Development index.
Study Design and Risk of Bias Rating	<p><i>EQ1 and 1a and SQ1a:</i> RCTs, CCTs, CCSs, and SRs of RCTs, CCTs, or CCSs with similar scope as this HTA.</p> <p><i>SQ1:</i> 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.</p> <p><i>CQ1:</i> Cost analyses, CEA, CUA, or CBA performed from the societal or payor perspective</p>	<p>Editorials, comments, letters, narrative reviews, case reports.</p> <p><i>EQ1 and 1a and SQ1a only:</i> uncontrolled studies (e.g., case series, single-arm clinical trials or cohort studies)</p>
Language and Time Period	English, no restrictions on time period included.	Languages other than English.

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

Public comment and response

Two public comments were received. In response to these comments, an additional outcome “discharge to acute or subacute rehabilitation facility” has been added as an intermediate outcome for EQ1a. Please refer to the “Response to Public Comments on Draft Key Questions” document for complete details.

References

1. Cohen SP, Chen Y, Neufeld NJ. Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment. *Expert Rev Neurother*. 2013;13(1):99-116. doi: 10.1586/ern.12.148
2. Ou-Yang DC, York PJ, Kleck CJ, Patel VV. Diagnosis and Management of Sacroiliac Joint Dysfunction. *Journal of Bone and Joint Surgery-American Volume*. 2017;99(23):2027-36. doi: 10.2106/jbjs.17.00245
3. Simopoulos TT, Manchikanti L, Singh V, et al. A systematic evaluation of prevalence and diagnostic accuracy of sacroiliac joint interventions. *Pain Physician*. 2012;15(3):E305-44.
4. Bina RW, Hurlbert RJ. Sacroiliac Fusion: Another "Magic Bullet" Destined for Disrepute. *Neurosurg Clin N Am*. 2017;28(3):313-20. doi: 10.1016/j.nec.2017.02.001
5. Cher D. Rates reported by Schoell et al. are of questionable validity. *Spine Journal*. 2017;17(1):158-. doi: 10.1016/j.spinee.2016.09.006
6. Barrick EF, O'Mara JW, Lane HE, 3rd. Iliosacral screw insertion using computer-assisted CT image guidance: a laboratory study. *Comput Aided Surg*. 1998;3(6):289-96. doi: 10.1002/(sici)1097-0150(1998)3:6<289::Aid-igs2>3.0.Co;2-6
7. Vavken P, Ganal-Antonio AK, Quidde J, Shen FH, Chapman JR, Samartzis D. Fundamentals of Clinical Outcomes Assessment for Spinal Disorders: Clinical Outcome Instruments and Applications. *Global Spine J*. 2015;5(4):329-38. doi: 10.1055/s-0034-1396046
8. Department of Health and Human Services. Patient-Reported Outcomes Measurement Information System (PROMIS). <http://www.healthmeasures.net/explore-measurement-systems/promis>. 2017. Accessed November 8, 2017.
9. United Nations Development Programme. Human Development Index. Website. <http://hdr.undp.org/en/composite/HDI>. 2016. Accessed October 15, 2017.

**Health Technology Clinical Committee
DRAFT Findings and Decision**

Topic: Sacroiliac joint fusion
Meeting date: January 18, 2019
Final adoption: Pending

Meeting materials and transcript are available on the [HTA website](#).

Number and coverage topic:

20190118A – Sacroiliac joint fusion

HTCC coverage determination:

Minimally invasive and open sacroiliac joint fusion procedures used to treat sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption is **not a covered benefit**.

HTCC reimbursement determination:

Limitations of coverage: N/A

Non-covered indicators: N/A

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Draft

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on sacroiliac joint fusion is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of sacroiliac joint fusion. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover sacroiliac joint fusion for sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption.

	Not covered	Covered under certain conditions	Covered unconditionally
Sacroiliac joint fusion	11	0	0

Discussion

The committee reviewed and discussed the available studies for use of sacroiliac joint fusion for sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of sacroiliac joint fusion for sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption unproven for being safer, more efficient or more cost-effective than comparators.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare NCD for sacroiliac joint fusion for sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption.

The committee discussed clinical guidelines identified for sacroiliac joint fusion from the following organizations:

- National Institute for Health and Care Excellence (NICE) *Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578*, (2017)
- AIM Specialty Health *Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion*, (2018)

The committee’s determination is not consistent with the NICE and AIM guidance. The HTCC determination included consideration of local, clinical expert considerations related to the

complexities of revision surgeries, concerns related to diffusion and uncertainty of evidence for safety and cost-effectiveness.

The committee chair directed HTA staff to prepare a findings and decision document on use of sacroiliac joint fusion for public comment to be followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

Sacroiliac joint fusion

Draft findings and decision Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Sacroiliac joint fusion.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	March 5, 2018	
Public comments	March 5 to 19, 2018	15
Selected technologies published	March 23, 2018	
Public comments	March 23 to April 23, 2018	32
Draft key questions published	June 20, 2018	
Public comments	June 21 to July 5, 2018	15
Final key questions published	July 18, 2018	
Draft report published	October 11, 2018	
Public comments	October 12 to November, 13, 2018	33
Final report published	December 7, 2018	
Public meeting	January 18, 2019	
Draft findings & decision published	February 6, 2019	
Public comments	February 7 to 20, 2019	14
Total		109

Overview

Category	Comment Period <i>June 15, to 28, 2018</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	3	2
Total	3	2

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. David A. Halsey, MD	President, American Academy of Orthopaedic Surgeons	Yes
<input type="checkbox"/>	2. Morgan Lorio, MD	ISASS Coding and Reimbursement Task Force International Society for the Advancement of Spine Surgery	Yes
<input type="checkbox"/>	Shelly D. Timmons MD, PhD	President, American Association of Neurological Surgeons	
<input type="checkbox"/>	Ganesh Rao, MD	President, Congress of Neurological Surgeons	
<input type="checkbox"/>	3. Michael Y. Wang, MD	Chair, American Association of Neurological Surgeons Section on Disorders of the Spine and Peripheral Nerves	
	Jean-Christophe Leveque, MD	President, Washington State Association of Neurological Surgeons	No



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

January 23, 2019
Greg Brown, MD,
Chair Health Technology Clinical Committee
Washington State Healthcare Authority
c/o Christine V. Masters at christine.masters@hca.wa.gov

Dear Dr. Brown,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Academy and Association of Orthopaedic Surgeons (AAOS) we would like to thank you for allowing our expert representative, David W. Polly, Jr., MD, to present comments on January 18, 2019, for your health technology clinical committee review of chronic sacroiliac joint pain.

We are surprised that the committee decided not to accept the recommendations of your own commissioned report by RTI on this topic. AAOS does not agree with the assertion that the diagnosis of chronic SI joint pain is unreliable. RTI found moderate evidence for the benefit of minimally invasive SI joint fusion. We agree with RTI. While we appreciate the genuine efforts of the committee, we do not understand how the committee could reject the evidence summary given that the discussion did not include contrary evidence but opinion and anecdote. We have attached detailed commentary by Dr. Polly on this topic. Hence, we urge you to help us understand how you could reject RTI's report.

AAOS is committed to working closely with the Washington State Healthcare Authority as we have done in the past. We appreciate your collegiality and look forward to hearing your response. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

David A. Halsey, MD
President, American Association of Orthopaedic Surgeons



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

January 21, 2019

Greg Brown, MD,
Chair Health Technology Clinical Committee
Washington State Healthcare Authority
c/o Christine V. Masters at christine.masters@hca.wa.gov

Dear Dr. Brown,

Thank you for allowing me to present a testimony on behalf of myself and the American Academy of Orthopedic Surgeons on January 18, 2019, for your health technology clinical committee review of chronic sacroiliac joint pain. I offer the following observations having reviewed the draft report and then listening to the four hours of presentations and discussions.

The report done by RTI from the University of North Carolina was balanced and appropriate given the specified input parameters that they utilized. It was also well presented by Dr. Leila Kahwati.

I found the discussion to perhaps take a different path among the panelists with the assertion that the diagnosis of chronic SI joint pain is unreliable. I think that opinion is an inaccurate summation of the literature. There is a very nice review article, non- industry sponsored, in BMC musculoskeletal disorders from 2017. Petersen T, Laslett M, Juhl C. Clinical Classification in Low Back Pain: Best-evidence Diagnostic Rules Based on Systematic Reviews. BMC Musculoskelet Disord. 2017 May 12;18(1):188. doi: 10.1186/s12891-017-1549-6. Review. PubMed PMID: 28499364. This article shows that diagnosing SI joint as the source of pain is as reliable, even more reliable than the diagnosing radiculopathy from lumbar disc herniation by clinical exam.

The SI joint can reliably be diagnosed by a multi test survey strategy involving five tests. There was extensive discussion about five versus six test and some studies have used six. Clearly three or five positive tests is strong evidence that the SI joint is the pain generator. The one physical exam that is less reliable is the sacral thrust test. These physical exam maneuvers placed differential torsion across the SI joint resulting in good face validity showing their usefulness. The takeaway finding is no single physical exam test is reliable but three positive tests out of the five tests results in high diagnostic reliability.

It appeared that your panels discussion then took on an anecdotal pattern. The evidence was not thoroughly discussed as presented from the evidence review. The discussion about revision strategies was not a part of the evidence review. Unfortunately, opinion won the day. I have

personal experience with more than 200 primary SI joint fusions and more than 30 revision SI fusions. I have become a source of referral for my community and perhaps the nation. My partner, who was mentioned in the discussion, Marc Swiontkowski, MD, and I do this operation together.

The removal of the implants is actually not particularly difficult. I personally use image guided technology deliver a K wire into the implant and then the company (SI Bone) makes a removal chisel that is fairly expeditious and minimizes bone damage and bone loss. The implants are invariably well fixed in the ileum but invariably loose in the sacrum as the sacral bone density is far less than the iliac bone density. Our current revision strategy involves removal of the implants bone grafting of the defects and then iliosacral screw placement either with or without washers or plates as needed based on the defect from the bone removal.

We typically then perform an open anterior ilioinguinal approach and bone grafting with autogenous iliac crest graft. We have seen good results from days although the recovery timeframe is perhaps as long as 3 to 6 months. As a piece of information, the reliability of the company database about revisions is based upon their reporting of all cases where an implant is removed. In all cases that I have done of implant removal, and all of the removals that I am aware of, have utilized the company's tools to do the removal. There may be surgeons who remove the implants without the company's tools, but this would be a very small number.

I would say that revision SI fusion surgery is analogous to revision total joint arthroplasty surgeon. It is more difficult than primary surgery. Surgeon skill and experience matters. Good clinical outcomes can in fact be achieved, albeit at a lower success rate than in primaries. This does not condemn the primary procedure.

There was also a significant discussion about durability. Durability studies were not reviewed in the evidence report. It appears that when SI joint fusion with the iFuse device failed they fail within the first six months. This is supported by the clinical trial data. There are a number of longer-term follow-up studies demonstrating that if the device is durable through the first year that there is no evidence of late loosening.

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In terms of revision rates the literature that I am aware of is:

Miller, L., Reckling, W. C. & Block, J. E. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. *Med. Devices Evid. Res.* **6**, 77–84 (2013).

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There was extensive discussion about the Vanacloacha study (noted above). The study had allocation of the patients based on their insurance coverage rather than the randomization effort it was really an observation of his particular practice. As such the groups were certainly different. I think the important piece to take away from the Vanacloacha study and supported by my extensive clinical experience and seeing these patients is that the patients who are relegated to nonsurgical treatment continue to have a profoundly diminished health related quality-of-life state most of them are on chronic opioid medication. I have not seen any of them come off of this medication and demonstrate any improvement and quality-of-life with the continued non-operative treatment.

Finally I think the counterfactual discussion is important. I heard much discussion about anecdotal experience for treating SI joint problems non-operatively. In my review of the literature, which has been extensive but not exhaustive, there is no high-level evidence demonstrating efficacy of non-surgical management. I am aware of no randomized controlled trial's much less comparative effectiveness trials of treatment versus non-treatment. Prior to insurance coverage in the state of Minnesota I had to manage many of these patients non-operatively and I have to say that I was profoundly disappointed and saw general deterioration not improvement with the continued non-operative management. This non-operative management included physical therapy by very skilled practitioners, injections, radiofrequency ablation and manual therapy techniques by physical therapists, chiropractors, osteopaths. It was common to see short term improvement with manual therapy but lack of durability.

Again, I appreciate the opportunity to have presented to this group. I offer these observations, as an independent observer who has expertise in the topic domain, of the Washington state HTA HTCC process. I appreciate the rigor with which this group must operate but feel that there was extensive anecdotal discussion today about evidence that was not presented or reviewed and deviated from the evidence that was presented. I would be delighted to provide any

further input that might be useful and again I respect the rigor and attention goals of the Washington state health technology assessment process.

Sincerely,

A black rectangular redaction box covering the signature of David W. Polly, Jr., MD.

David W. Polly, Jr., MD
Professor and Chief of Spine Surgery
University of Minnesota Medical School



February 18, 2019

Greg Brown, MD
Chair, Washington State Healthcare Authority
Health Technology Clinical Committee
P.O. Box 42712
Olympia, WA 98504-2712
Via e-mail: shtap@hca.wa.gov
Christine.masters@hca.wa.gov

Subject: Washington State Health Care Authority Draft Findings and Decision Sacroiliac Joint Fusion Meeting January 18, 2019

Dear Dr. Brown:

On behalf of the International Society for Advance of Spine Surgery, we appreciate the opportunity to once again submit comments regarding the Washington State Health Care Authority (HCA) Draft Evidence Report on Sacroiliac (SI) Joint Fusion Surgery. Please consider this letter in tandem to our comments submitted on November 9, 2018.

ISASS appreciates the comments submitted to you on January 21, 2019, from Dr. David Polly and the American Academy of Orthopedics addressing these draft findings and decision.

ISASS **does not support** the findings and decision from the Clinical Committee stated in this draft HTA. We believe, as stated in previous comments, that the current evidence supports that minimally invasive SI joint fusion is a safe, more efficient, and cost-effective treatment for pain management and improved quality of life for patients with appropriately diagnosed chronic SI joint dysfunction when compared against alternative treatment options. ISASS believes the evidence of pain control and functional improvement substantiates the medical necessity of this procedure.

ISASS recognizes Minimally Invasive SI Joint Fusion (MI-SIJ) as a medically necessary procedure for treatment of SI Joint pain. ISASS published coverage position statements in 2014 and 2016 that detail our analysis of the literature and data on MI-SIJ. We have attached those policies for reference.

For the purpose of this HTA, ISASS recommends the WSHCA reconsiders their decision and re-evaluates the clinical findings that have been substantiated and published in the literature demonstrating substantial clinical improvement experienced by patient's over comparator treatments. Please reference our comments submitted on November 9, 2018, for recommended edits and revisions to this HTA.



For further clinical input we support the comments submitted by Dr. David Polly, an ISASS member, in the attached letter from Dr. Polly and the American Association of Orthopaedic Surgery (AAOS). Dr. Polly's review of the clinical literature on MI-SIJ is thorough and warrants reconsideration of the recommendations made by the committee.

Thank you in advance for your consideration of our comments, as well as those of other Scientific Stakeholders who manage the well-being of these patients.

Please do not hesitate to contact ISASS with any questions or additional follow up needs you may have.

Sincerely,

Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force

Attachments:

- A-ISASS November 9, 2018 Letter to WSHA
- B-AAOS Dr. Polly January 21, 2019
- C-ISASS MI-SIJ Coverage Policies

Staff Contact:

Matthew Twetten, MA, MHCDS
Phone: 773-678-5705
E-mail: matthewtwetten@gmail.com



November 8, 2018

Josiah Morse, MPH, Program Director
Washington State Healthcare Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712
Via e-mail: shtap@hca.wa.gov

Subject: Washington State Health Care Authority Draft Technology Report on Sacroiliac Joint Fusion

Dear Mr. Morse:

On behalf of the International Society for Advance of Spine Surgery, we appreciate the opportunity to submit comments regarding the Washington State Health Care Authority (HCA) Draft Evidence Report on Sacroiliac (SI) Joint Fusion Surgery prepared by RTI International–University of North Carolina Evidence-based Practice Center.

We are in general agreement with the authors of the Washington State HCA Draft Evidence Report who conclude that Minimally Invasive Surgery Sacroiliac Joint (MIS SIJ) Fusion procedures provide significant benefit to carefully selected patients. Although we recognize the best available studies utilize one particular device from one manufacturer, ISASS policy does not endorse any specific MIS SIJ System. There are numerous devices available [REDACTED] have received FDA 510(k) clearance for use in minimally invasive joint fusion (MIS SIJ) stabilization. The clinical concept of creating a true arthrodesis (either anatomic or extra-anatomic) across the SI joint have been reported with favorable outcomes at one year¹ which are sustained long term (up to 5 years)^{2 3}. Of importance is the clinically documented opioid reduction for low back pain patients as a result of this procedure, agnostic to the specific MIS SIJ system^{4 5}. ISASS recommends that WSHCA revise the wording in the draft “conclusions and summary of evidence” sections to refer to MIS SIJ Fusion “procedurally” where it currently refers specifically to the “i-Fuse technology.”

¹ Richard A. Kube¹ and Jeffrey M. Muir. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery *The Open Orthopaedics Journal*, 2016, 10, 679-689

² Rudolf L, Capobianco R. Five-year clinical and radiographic outcomes after minimally invasive sacroiliac joint fusion using triangular implants. *Open Orthop J*. 2014;8:375-83. Published 2014 Oct 17. doi:10.2174/1874325001408010375

³ Vanaclocha VV, Verdú-López F, Sánchez-Pardo M, Gozalbes-Esterelles L, Herrera JM, et al. (2014) Minimally Invasive Sacroiliac Joint Arthrodesis: Experience in a Prospective Series with 24 Patients. *J Spine* 3:185. doi:10.4172/2165-7939.1000185

⁴ Vanaclocha V, Herrera JM, Sáiz-Sapena N, Rivera-Paz M, Verdú-López F. Minimally Invasive Sacroiliac Joint Fusion, Radiofrequency Denervation, and Conservative Management for Sacroiliac Joint Pain: 6-Year Comparative Case Series. *Neurosurgery*. 2018 Jan 1;82(1):48-55. doi: 10.1093/neuros/nyx185.

⁵ Araghi A, Woodruff R, Colle K, et al. Pain and Opioid use Outcomes Following Minimally Invasive Sacroiliac Joint Fusion with Decortication and Bone Grafting: The Evolution Clinical Trial. *Open Orthop J*. 2017;11:1440-1448. Published 2017 Dec 27. doi:10.2174/1874325001711011440

In addition, we also agree with the finding that comparative studies between minimally invasive SI joint fusion and open joint fusion procedures show a preference for the minimally invasive option in terms of improved post-operative pain and shorter length of hospital stay. Equally important is that the current evidence supports that the minimally invasive SI joint fusion procedure is safe and cost effective for pain management and improved quality of life for patients with chronic SI joint dysfunction.

We found the literature search and data extraction that was the basis of this report to be comprehensive; however, we would recommend updated wording in the summary of evidence section and the addition of specific citations within that section (E1.4) as suggested below.

ES 4.1 Summary of the Evidence. Compared to conservative management, minimally invasive SI joint fusion surgery improves pain, physical function and quality of life. The quality of evidence for these findings is moderate for outcomes at 6 months^{1,2} and very low for outcomes between 6 months and 6 years³. Findings are mixed with respect to opioid use (modest reductions in use with low to very low quality of evidence). From both randomized trials, no differences in the rate of serious adverse events exist between surgery and conservative management (low to very low quality of evidence). Blinded randomized trials were not done, but blinding subjects would be challenging as all implant systems are highly radiopaque and obvious on any radiographic study. The incidence of revision surgery is likely no higher than 3.4 percent at 2 years^{4,5} (moderate quality of evidence). Minimally invasive surgery costs \$13,313 per additional quality of life-adjusted year gained compared to conservative management⁶; 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, but this conclusion is based on one low quality evidence study⁷. Minimally invasive SI joint fusion improves pain over 2 years^{8,9} or longer^{3,10,11} and is associated with a shorter length of hospital stay compared to open fusion¹². The incidence of adverse events was similar for open fusion and Minimally Invasive SI Joint Fusion,¹² but findings were mixed for the comparative incidence of revision surgery. All findings related to this comparison are based on very low quality of evidence. We limited the evidence from uncontrolled studies to safety outcomes. The heterogeneity in the reporting of adverse events 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 is heterogenous, likely reflecting differences in outcome definitions and ascertainment, but is generally low. The incidence of complications from minimally invasive fusion reported from an analysis of insurance claims is higher than the incidence reported in controlled studies;¹⁴ issues regarding the identified patient population in this analysis¹⁵ make interpretation of this result challenging. The incidence of revision surgery after fusion observed in trials is similar to the incidence reported in post-market surveillance.^{4,5}

We also noted that the WA State Health Authority document cites a rate of adverse events after MIS SIJF of up to 30% in two locations; however, we are not aware of where the 30% figure comes from and believe the figure mischaracterizes the safety of most MIS procedures. Please see the abstracted sections with highlights. We recommend the Health Authority review these statements to ensure they are accurate and provide direct citations in order to allow for proper verification and documentation.

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

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

With the recommended edits and revisions, overall, we support the findings of this evidence report and welcome it as justification for continued research and study of minimally invasive SI joint fusions. Thank you for the opportunity to provide comments and edits and please do not hesitate to contact ISASS with any questions or with follow up at the staff contact below.

Sincerely,



Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force

Staff Contact:

Matthew Twetten, MA, MHCDS

Phone: 773-678-5705

E-mail: matthewtwetten@gmail.com

Citations

1. Whang, P. *et al.* Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management: Six-Month Outcomes from a Prospective Randomized Controlled Trial. *Int. J. Spine Surg.* **9**, 6 (2015).
2. Stuesson B. *et al.* Six-month outcomes from a randomized controlled trial of minimally invasive SI joint fusion with triangular titanium implants vs conservative management. *European Spine Journal* (2016). Available at: <http://link.springer.de/link/service/journals/00586/index.htm>.
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4. Cher D.J., Reckling W.C. & Capobianco R.A. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System. *Medical Devices: Evidence and Research* (2015). Available at: <https://www.dovepress.com/getfile.php?fileID=28113>.
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15. Cher, D. Rates reported by Schoell et al. are of questionable validity. *Spine J. Off. J. North Am. Spine Soc.* **17**, 158 (2017).



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AMERICAN ASSOCIATION OF
ORTHOPAEDIC SURGEONS

January 21, 2019

Greg Brown, MD,
Chair Health Technology Clinical Committee
Washington State Healthcare Authority
c/o Christine V. Masters at christine.masters@hca.wa.gov

Dear Dr. Brown,

Thank you for allowing me to present a testimony on behalf of myself and the American Academy of Orthopedic Surgeons on January 18, 2019, for your health technology clinical committee review of chronic sacroiliac joint pain. I offer the following observations having reviewed the draft report and then listening to the four hours of presentations and discussions.

The report done by RTI from the University of North Carolina was balanced and appropriate given the specified input parameters that they utilized. It was also well presented by Dr. Leila Kahwati.

I found the discussion to perhaps take a different path among the panelists with the assertion that the diagnosis of chronic SI joint pain is unreliable. I think that opinion is an inaccurate summation of the literature. There is a very nice review article, non- industry sponsored, in BMC musculoskeletal disorders from 2017. Petersen T, Laslett M, Juhl C. Clinical Classification in Low Back Pain: Best-evidence Diagnostic Rules Based on Systematic Reviews. BMC Musculoskelet Disord. 2017 May 12;18(1):188. doi: 10.1186/s12891-017-1549-6. Review. PubMed PMID: 28499364. This article shows that diagnosing SI joint as the source of pain is as reliable, even more reliable than the diagnosing radiculopathy from lumbar disc herniation by clinical exam.

The SI joint can reliably be diagnosed by a multi test survey strategy involving five tests. There was extensive discussion about five versus six test and some studies have used six. Clearly three or five positive tests is strong evidence that the SI joint is the pain generator. The one physical exam that is less reliable is the sacral thrust test. These physical exam maneuvers placed differential torsion across the SI joint resulting in good face validity showing their usefulness. The takeaway finding is no single physical exam test is reliable but three positive tests out of the five tests results in high diagnostic reliability.

It appeared that your panels discussion then took on an anecdotal pattern. The evidence was not thoroughly discussed as presented from the evidence review. The discussion about revision strategies was not a part of the evidence review. Unfortunately, opinion won the day. I have

personal experience with more than 200 primary SI joint fusions and more than 30 revision SI fusions. I have become a source of referral for my community and perhaps the nation. My partner, who was mentioned in the discussion, Marc Swiontkowski, MD, and I do this operation together.

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Again, I appreciate the opportunity to have presented to this group. I offer these observations, as an independent observer who has expertise in the topic domain, of the Washington state HTA HTCC process. I appreciate the rigor with which this group must operate but feel that there was extensive anecdotal discussion today about evidence that was not presented or reviewed and deviated from the evidence that was presented. I would be delighted to provide any

further input that might be useful and again I respect the rigor and attention goals of the Washington state health technology assessment process.

Sincerely,

David W. Polly, Jr., MD
Professor and Chief of Spine Surgery
University of Minnesota Medical School

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

Coverage Indications, Limitations, and/or Medical Necessity

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

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

Introduction

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

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

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

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

Coverage Rationale for Open and Minimally Invasive SIJ Fusion

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

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

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

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

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

Indications/Limitations of Coverage

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

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

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

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

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

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

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

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

Coding

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

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

Table 1: ICD-9 Codes That Support Medical Necessity

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

Documentation Requirements

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

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

Surgeon Qualifications

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

Table 2: MIS SIJ Fusion Surgery Published Literature

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

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

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

No

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

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

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

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

Comparative Cohort Studies of Open Surgery vs MIS

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

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

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

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ISASS Policy 2016 Update – Minimally Invasive Sacroiliac Joint Fusion

Coverage Indications, Limitations, and/or Medical Necessity

Updated July 5, 2016

(This supplements the ISASS Policy Statement – Minimally Invasive Sacroiliac Joint Fusion in IJSS)

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Rationale

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

Introduction

The sacroiliac joints (SIJ) are diarthrodial articulations of the sacrum and ilium. The SIJ serves as the biomechanical mediator between the spine and pelvis. The subchondral bone, capsule, and surrounding ligaments of the SIJ are innervated by spinal nerves.¹

Sacroiliac joint (SIJ) pain is likely responsible for chronic back pain in some patients; furthermore in some studies the prevalence is reported to be 15-30%.²⁻⁶ Convergence of the sensory pathway from the hip, the SIJ and the lumbar spine may result in overlap of pain patterns from dysfunction of these structures. As such, proper SIJ pain diagnosis is key to appropriate patient management. Patients with SIJ pain typically report pain in the buttock(s), with possible radiation into the groin or upper legs. Specific physical examination tests that stress the SIJ (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver) are typically performed in the physician's office; in combination, these tests are thought to be predictive of SIJ pain.⁷

The spectrum of pain and disability from SIJ dysfunction is wide. Patients may be affected mildly or may have substantial functional impairment (e.g., cannot sit or stand for more than five minutes, cannot perform normal activities of daily living (ADLs), cannot walk up or down stairs, may require a wheelchair). Patients with chronic SIJ dysfunction seeking surgical treatment have marked impairment of quality of life,⁸ similar to that observed in other conditions commonly treated surgically.⁹ Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. In many cases, imaging can show non-specific findings in the SIJ.¹⁰ Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration).

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

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SIJ pain should be made on the basis of typical history (bilateral symptoms), physical examination showing positive responses to SIJ-stressing

maneuvers bilaterally, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SIJ block.

While a marked response to SIJ block might be predicted to reassure the physician that treatment will produce larger responses to anatomic-based treatment, published data suggest little, if any, relationship. In two large prospective clinical trials of SIJ fusion, patients with suspected SIJ pain were included only if intraarticular SIJ block resulted in a 50% or greater amount of acute pain relief within 60 minutes after the block. The degree of improvement at 6 and 12 months after SIJ fusion was unrelated to the degree of acute pain relief during the block.¹² In a retrospective analysis of predictors of outcome success after RF ablation of lateral branches of the sacral nerve roots in patients with SIJ pain, no relationship was observed between response to lateral branch block or SIJ anesthesia and response to RF ablation.¹³ Randomized trials of RF ablation of lateral branches of the sacral nerve roots excluded patients with <75% pain reduction after lateral branch block (one block in Cohen et al¹⁴ and two blocks in Patel et al¹⁵), leaving open the question of whether the selected threshold was appropriate.

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents), physical therapy, steroid injections into the SIJ, and radiofrequency ablation of the sacral nerves and SIJ fusion. While pain medications may relieve temporarily pain and/or disability, they have not been shown to impact the underlying disease process, and opioid addiction remains an important public health concern. Apart from a single clinical trial in post-partum pelvic pain (probably related to the SIJ),¹⁶ the effectiveness of physical therapy for chronic SIJ dysfunction has not been demonstrated. Two randomized trials have shown that RF ablation of lateral branches of sacral nerve roots can temporarily reduce SIJ pain.^{14,15} One-year follow-up from one RF ablation randomized trial showed modest pain reduction.¹⁷ Responses in the non-surgical arms of two prospective randomized trials showed little, if any, improvement at 6 months.^{18,19} Given the absence of published outcomes data supporting long-term pain relief from non-surgical treatment, patients with a diagnosis of SIJ pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SIJ fusion.

Coverage Rationale for Open and Minimally Invasive SIJ Fusion

Open fusion of the SIJ, first reported in the early 1900s,²⁰ can provide pain relief but recovery times are long and complication rates are high,^{21–25} intraoperative times, bleeding and hospital length of stay are more prominent compared to minimally invasive SIJ fusion,²⁶ and recovery times are long and may require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for minimally invasive SIJ fusion.

Minimally invasive fusion of the SIJ has been performed with several types of implants, including triangular, porous, titanium coated implants,^{19,27–33} hollow modular screws,^{34–36} titanium cages,^{37,38} and allograft dowels²¹ (Table 2). Minimally invasive fusion aims to permanently stabilize the SIJ but avoid the morbidity of the open procedure.

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

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

Published Literature

Published outcomes data for minimally invasive SIJ fusion using a posterior approach are scarce. One cohort reported marginal response to use of cages placed into the SIJ through a posterior approach.³⁸ For the lateral approach, 3 retrospective case series (describing two cohorts) using hollow modular anchor (HMA) screws suggest reasonable 2- and 3-year outcomes.^{35,36} HMA screws are not FDA-cleared for SIJ fusion and are not available for use in the U.S. The remaining published literature on SIJ fusion through a lateral approach used triangular titanium implants (iFuse Implant System, SI-BONE, Inc.). This literature includes:

- A US multicenter, randomized clinical trial (INSITE, n=148)¹⁹ with an embedded cost-utility analysis³⁹
- A European multicenter, randomized clinical trial (iMIA, n=103, in press¹⁸)
- A US prospective multicenter single-arm clinical trial (n=172) with 24-month follow-up³¹
- Several single-center case series^{26,27,40-44}
- A multicenter case series³²
- 3 comparative studies comparing open and iFuse-based SI joint fusion^{26,45,46}
- An analysis of implant survivorship⁴⁷
- A systematic review and meta-analysis⁴⁸
- A systematic review.⁴⁹ Both systematic reviews focused on laterally-based procedures and products. The majority of cohorts were triangular titanium implants.

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

In a multicenter retrospective review of 263 patients undergoing either open or minimally invasive SIJ fusion with triangular titanium implants, minimally invasive SIJ fusion was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 (-2.7 points on 0-10 scale vs. -6.2 points) and 2-year (-2.0 vs. -5.6 points) follow-up (all differences are statistically significant).²⁶ Finally, two published studies report that favorable outcomes achieved at one year are sustained long term (up to 5 years).^{30,33}

The complication rate for minimally invasive SIJ fusion with triangular titanium implants is low.⁵⁰ Revision rates over 4 years (3.5%⁴⁷) are substantially lower than after lumbar fusion surgery, and revision rates in long-term retrospective^{30,33} and prospective studies^{19,31} have confirmed this low rate. Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection. Revision rates with other products are unknown. Screw-based devices rely upon different fusion strategies (HA coating, fenestrations within the screws, etc.) with different biomechanics (threaded screws vs. triangular implants that are impacted across the SI joint). Regardless of implant, salvage revision remains challenging.

Bilateral Procedures

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

Indications/Limitations of Coverage

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

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

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

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

Bilateral SIJ pain is not uncommon. Diagnosis of bilateral SIJ pain must be made on the basis of a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon fluoroscopically-guided intra-articular SIJ block with local anesthetic. Bilateral SIJ fusion is probably best performed serially as successful treatment of one side may improve pain/disability to a degree acceptable by the patient. SIJ fusion of the contralateral side may be necessary if contralateral SIJ pain continues and disability is significant for the patient. If bilateral fusion is performed at the same operative session, the surgeon must document both medical necessity and why serial fusion is not indicated in the patient.

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

Coding

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

Table 1. ICD-10-CM Diagnosis

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

Documentation Requirements

- A complete history and physical documenting the likely existence of SIJ pain;
- Performance of a fluoroscopically-guided SIJ block on the affected side (or both sides, see discussion above) which shows at least a 50% acute reduction in pain;
- A course of conservative treatment to include use of non-steroidal anti-inflammatory drugs and one of the following: (1) an adequate period of rest, (2) an adequate course of physical therapy wherein the physical therapist specifically documents lack of response to treatment
- SIJ pain has continued for a minimum of six months; and
- All other diagnoses that could be causing the patient's pain have been considered and the physician believes that SIJ fusion is clinically required

Surgeon Qualifications

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

Coverage/Conclusion

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

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

Table 2. Published literature on minimally invasive SIJ fusion.

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

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

Author, Year	Study design	N	Implant	Technique	Demographics	Results	Complications (n)
					Mean (\pm SD) or (range), unless otherwise specified	Mean (\pm SD) or (range) unless otherwise specified	
Duhon 2016 ³¹ (Prior pubs from same cohort/trial: Duhon 2015 – 12mo results ⁵² , Duhon 2013 – 6mo interim results ⁵³)	Prospective, multicenter (SIFI, ClinicalTrials.gov NCT01640353)	172	iFuse Implant System	Lateral approach	Age: 50.9 (24-72) years Sex: 120F/52M Prior lumbar fusion: 44% Follow-up: 24mo	VAS SI joint pain: 79.8 (12.8) pre-op, 30.4 (27.6) at 12mo, 26.0 (26.7) at 24mo ODI: 55.2 (11.5) pre-op, 31.5 (19.2) at 12mo, 30.9 (20.5) at 24mo SF-36 PCS: 31.7 (5.6) pre-op, 40.5 (9.6) at 12mo, 40.7 (10.3) at 24mo SF-36 MCS: 38.5 (11.3) pre-op, 48.2 (12.3) at 12mo, 49.0 (11.5) at 24mo EQ-5D TTO: 0.43 (0.18) pre-op, 0.71 (0.20) at 12mo, 0.71 (0.22) at 24mo Surgical time: 46.6 (16.1) min Fluoroscopy time: 2.7 (1.8) min EBL: 51.0 (75.8) mL Hospital stay: median 1 (range 0-7) day	Device-related: Neuropathic pain related to device malposition (3), SI joint or buttock pain (2), SI joint pain after fall associated with inadequate device placement (1), Hip pain related to periosteal bone growth around implant (1) Procedure-related: Wound drainage/irritation/infection (6), SI joint pain (5), SI joint pain (inadequate stabilization) (3), implant impingement (3), nausea/vomiting (3), buttock pain (2), foot weakness related to anesthesia (1), urinary retention (1), vascular injury (1), wound numbness (1)
Capobianco 2015 ⁵⁴	Prospective, multicenter (SIFI, ClinicalTrials.gov NCT01640353) Subsets	20 (Females with PPGP)	iFuse Implant System	Lateral approach	Age: 43.3 (9.0) years Sex: 20F Prior lumbar fusion: 30% Follow-up: 12mo	VAS SI joint pain: 81.9 (10.0) pre-op, 21.3 (17.6) at 6mo, 31.4 (30.9) at 12mo ODI: 52.2 (12.7) pre-op, 30.4 (20.0) at 6mo, 32.8 (21.4) at 12mo SF-36 PCS: 32.0 (5.6) pre-op, 40.0 (11.1) at 6mo, 41.6 (10.8) at 12mo SF-36 MCS: 42.2 (12.4) pre-op, 49.7 (9.6) at 6mo, 49.0 (10.8) at 12mo EQ-5D TTO: 0.42 (0.14) pre-op, 0.72 (0.23) at 6mo, 0.72 (0.21) at 12mo 100% very or somewhat satisfied	37 total adverse events (1.8 event rate per subject) 4 device/procedure-related: wound infection (2), numbness around wound (1), fall causing SI joint pain (1)
		100 (Females with No PPGP)	iFuse Implant System	Lateral approach	Age: 52.5 (11.1) years Sex: 100F Prior lumbar fusion: 42.2% Follow-up: 12mo	VAS SI joint pain: 79.9 (13.3) pre-op, 31.5 (27.0) at 6mo, 32.7 (28.5) at 12mo ODI: 55.0 (11.2) pre-op, 31.0 (18.7) at 6mo, 30.8 (19.1) at 12mo SF-36 PCS: 31.1 (5.6) pre-op, 40.5 (9.2) at 6mo, 40.0 (9.6) at 12mo SF-36 MCS: 37.7 (11.6) pre-op, 48.8 (10.8) at 6mo, 47.7 (12.9) at 12mo EQ-5D TTO: 0.43 (0.18) pre-op, 0.70 (0.19) at 6mo, 0.70 (0.20) at 12mo 84% very or somewhat satisfied	158 total adverse events (1.6 event rate per subject) 10 device/procedure-related: buttock pain (2), post-op neuropathy (1), post-op nausea/vomiting (3), intraop hemorrhage (1), neuropathy after contralateral SIJ fusion revision (1), urinary retention (1), wound drainage (1)

Author, Year	Study design	N	Implant	Technique	Demographics <i>Mean (±SD) or (range), unless otherwise specified</i>	Results <i>Mean (±SD) or (range) unless otherwise specified</i>	Complications (n)
		52 (Men)	iFuse Implant System	Lateral approach	Age: 50.7 (11.4) years Sex: 52M Prior lumbar fusion: 51.6% Follow-up: 12mo	VAS SI joint pain: 78.9 (12.9) pre-op, 30.2 (28.0) at 6mo, 25.0 (24.0) at 12mo ODI: 56.7 (11.5) pre-op, 36.4 (21.4) at 6mo, 31.9 (18.9) at 12mo SF-36 PCS: 32.7 (5.5) pre-op, 39.8 (10.1) at 6mo, 40.5 (8.9) at 12mo SF-36 MCS: 38.6 (10.3) pre-op, 45.1 (13.2) at 6mo, 48.0 (12.1) at 12mo EQ-5D TTO: 0.45 (0.19) pre-op, 0.64 (0.25) at 6mo, 0.72 (0.19) at 12mo 91.3% very or somewhat satisfied	88 total adverse events (1.7 event rate per subject) 7 device/procedure-related: wound infection (2), buttock pain (1), post-op neuropathy (1), SI joint pain (2), staple irritation (1)
Vanaclocha 2014 ³⁰	Single center case series	24	iFuse Implant System	Lateral approach	Age: 47.4 (32-71) years Sex: 15F/9M Prior lumbar fusion: 2 Follow-up: 23 mo (1-4.5 years)	VAS: 8.7 pre-op, 1.7 at 1yr, 2.1 at 4.5yrs ODI: 54.1 pre-op, 14.3 at 1yr, 16.3 at 4.5yrs Surgical time: 48 (range 40-65) min EBL: 58 (range 40-70) mL	Immediate post-op pain (4-resolved), temporary post-op radicular pain (2)
Rudolf 2014 ³³	Single center case series	17	iFuse Implant System	Lateral approach	Age: 58 (36-85) years Sex: 13F/4M Prior lumbar fusion: 8 (47%) Follow-up: 60 mo Bridging bone: 87% (13/15)	VAS: 8.3 (1.4) pre-op, 3.4 (2.4) at 1yr, 1.4 (2.6) at 2yrs, 2.4 (2.2) at 5yrs ODI: 21.5 (22.7) at 5yrs Surgical time: 65 (18) min	No intraoperative complications, hematoma (1), cellulitis (2), deep wound infection secondary to diverticulitis (1)
Sachs 2014 ³²	Multicenter, retrospective	144	iFuse Implant System	Lateral approach	Age: 58 (30-89) years Sex: 30F/10M Prior lumbar fusion: 62% Follow-up: 16 (12-26) mo	VAS: 8.6 pre-op, 2.7 at follow-up 91% Very or somewhat satisfied 91.7% would have surgery again Surgical time: 73min EBL: 31mL Hospital stay: 0.8 days	No intraoperative complications. 28 post-op complications, most common: fall (5), trochanteric bursitis (4), piriformis syndrome (3), facet pain (3). 1 implant revision (1-year revision rate 0.7%),
Sachs 2013 ⁵⁵	Single center, retrospective case series	40	iFuse Implant System	Lateral approach	Age: 58 (30-81) years Sex: 30F/10M Prior lumbar fusion: 30% Follow-up: 12 mo	VAS: 8.7 (1.5) pre-op, 0.9 (1.6) at 12mo 98% reached MCID 100% patient satisfaction	Piriformis syndrome (1), new LBP (1), facet joint pain (8), trochanteric bursitis (2)

Author, Year	Study design	N	Implant	Technique	Demographics	Results	Complications (n)
					Mean (\pm SD) or (range), unless otherwise specified	Mean (\pm SD) or (range) unless otherwise specified	
Cummings 2013 ⁴³	Single center, retrospective case series	18	iFuse Implant System	Lateral approach	Age: 64 (39-81) years Sex: 12F/6M Prior lumbar fusion: 61% Follow-up: 12 mo	VAS: 8.9 (1.9) pre-op, 2.3 (2.1) at 12mo 90% reached MCID ODI: 52.6 (18.8) pre-op, 13.2 (12.6) at 12mo SF-12 PCS: 37.8 (10.4) pre-op, 44.6 (10.5) at 12mo	Trochanteric bursitis (3), hematoma (1), fluid retention (1), toe numbness (1), implant malposition (1)
Gaetani 2013 ²⁹	Single center, retrospective case series	10	iFuse Implant System	Lateral approach	Age: 53.2 (36-71) years Sex: 12F Prior lumbar fusion: 8.3% Follow-up: 10 (8-18) mo	VAS: 7.7 (1.3) pre-op, 3 (1.2) at follow-up ODI: 31.4 (6.3) pre-op, 12 (3.5) at follow-up RDQ: 17.6 (1) pre-op, 3 (4.1) at follow-up Surgical time: 65 (16) min EBL: <45 mL 3 month CT scans show initial fusion	Local hematoma (2), low back pain (1)
Schroeder 2013 ⁴⁴	Single center, retrospective case series	6	iFuse Implant System	Lateral approach	Age: 50 (25-60) years Sex: 6F/0M Prior lumbar fusion: 100% (deformity correction) Follow-up: 10.25 (4-15) mo	VAS: 7.83 pre-op, 2.67 at follow-up ODI: 22.1 pre-op, 10.5 at follow-up Hospital stay: 2 days (range 1-4) Bony bridging seen in 4 patients	No intraoperative or post-operative complications.
Rudolf 2013 ⁴¹	Single center, subgroup analysis	40	iFuse Implant System	Lateral approach	Subgroup analysis from treatment on outcomes.	Rudolf 2012 to assess effect of prior lumbar fusion or lumbar Follow up: 12 and 24 months	
		18 (no prior fusion)	iFuse Implant System	Lateral approach	Age: 49 (12) Sex: 12F/6M	VAS decrease at 12mo: -5.94 (3.3) VAS decrease at 24mo: -5.47 (2.88) Surgical time: 60 (19) min	Superficial cellulitis (2), wound infection (1), revision for implant malposition (1)
		15 (prior fusion)	iFuse Implant System	Lateral approach	Age: 58 (11) Sex: 11F/4M	VAS decrease at 12mo: -3.50 (3.46) VAS decrease at 24mo: -5.81 (2.88) Surgical time: 64 (19) min	Superficial cellulitis (2), buttock hematoma (1), revision for implant malposition (1)
		7 (prior concomitant lumbar pathology treated non-surgically)	iFuse Implant System	Lateral approach	Age: 58 (17) Sex: 3F/4M	VAS decrease at 12mo: -3.71 (3.11) VAS decrease at 24mo: -4.79 (4.28) Surgical time: 64 (19) min	None

Author, Year	Study design	N	Implant	Technique	Demographics <i>Mean (±SD) or (range), unless otherwise specified</i>	Results <i>Mean (±SD) or (range) unless otherwise specified</i>	Complications (n)
Endres 2013 ³⁸	Single center, Retrospective case series	19	DIANA cage [Product not approved for use in the US]	Posterior, longitudinally inserted into SI joint	Age: 60.9 (36-76) years Sex: 5F/14M Prior lumbar fusion: 100% Follow-up: 13.2 (6-24) mo	VAS: 8.5 (7.5-9) pre-op to 6.0 (2.2-9) at follow-up ODI: 64.1 (40-82) pre-op to 56.97 (8-82) at follow-up EBL: <150mL Hospital stay: 7.3 (3-10) days Fusion rate: 78.9% (15/19 joints), defined as lack of loosening and evidence of bone bridging around the implant	No neurovascular complications
Mason 2013 ³⁶	Retrospective case series	55	HMA screw packed with DBM	Lateral approach	Age: 57 years Sex: 46F/9M Prior lumbar fusion: 40% Follow-up: 36 (12-84) mo	VAS: 8.05 (1.9) pre-op, 4.48 (2.81) at follow-up SF-36PCS: 26.6 (15.2) pre-op, 43 (22.68) follow-up Majeed scoring: 36.18 (15.08) pre- op, 64.78 (20.18) follow-up	Post-op nerve pain requiring reoperation (2)
Rudolf 2012 ²⁸	Single center, retrospective case series	50	iFuse Implant System	Lateral approach	Age: 54 (24-85) years Sex: 34F/16M Prior lumbar fusion: 44% Follow-up: 40 (24-56) mo	VAS: 7.6 pre- op, 2.0 at follow-up 82% reached MCID 82% patient satisfaction Surgical time: 65 (26) min	Superficial cellulitis (3), deep wound infection (1), hematoma (2), reoperation (3)
Sachs 2012 ⁴²	Single center, retrospective case series	11	iFuse Implant System	Lateral approach	Age: 65 (45-82) years Sex: 10F/1M Prior lumbar fusion: 18% Follow-up: 12 mo	VAS: 7.9 (2.2) pre-op, 2.3 (3.1) at 12mo Surgical time: 77.5 (31.8) min EBL: 21.8 (18.9) mL	Piriformis syndrome (1), low back pain (1)
McGuire 2012 ²¹	Retrospective case series	37	Fibular allograft dowels	Posterior, longitudinally inserted into SI joint	Age: 42.5 (23-63) Years Sex: 34F/3M Follow-up: 39.6 (8-62) mo	Baseline VAS: 9.1 Final VAS: 3.4 Fusion rate: 89.5%	Nonunion requiring revision (4) (10.5%)
Khurana 2009 ³⁵	Retrospective case series	15	HMA screw packed with DBM	Lateral approach	Age: 48.7 (37.3-62.6) years Sex: 11F/4M Prior lumbar fusion: 40% Follow-up: 17 (9-39) mo	SF-36 PF: 37.15 (14.28) pre- op, 79.33 (12.52) at follow-up Majeed's: 37 (18-54) pre- op, 79 (63-96) at follow-up Good to excellent results: 13/15 (87%) EBL: < 50 ml Hospital stay: 2.7 (1-7) days	No post-operative neurological or wound complications.

Author, Year	Study design	N	Implant	Technique	Demographics <i>Mean (±SD) or (range), unless otherwise specified</i>	Results <i>Mean (±SD) or (range) unless otherwise specified</i>	Complications (n)
Al-Khayer 2008 ³⁴	Retrospective case series	9	HMA screw packed with DBM	Lateral approach	Age: 42 (35-56) years Sex: 9F Follow-up: 40 (24-70) mo	VAS decreased: 8.1 (7-9) to 4.6 (3-7) ODI decreased: 59 (34-70) to 45 (28-60) EBL: <50 ml Hospital stay: 6.9 (2-11) days Return to work: 44.44%	Deep wound infection requiring debridement and IV antibiotics (1)
Wise 2008 ³⁷	Single center Prospective cohort	13	Titanium cage packed with BMP	Posterior, Longitudinally inserted into SIJ	Age: 53.1 (45-62) years Sex: 12F/1M Prior lumbar fusion: 61.5% Follow-up: 29.5 (24-35) mo	Back VAS improved by 4.9 pts Leg VAS improved by 2.4 pts EBL: < 100 ml Hospital stay: 1.7 days Fusion rate: 89% (17/19 joints) on CT at 6mo	Reoperation via open arthrodesis secondary to nonunion and persistent pain (1)
Comparative cohort studies of open surgery vs MIS							
Ledonio 2014 ⁴⁵	Single center, retrospective, comparative cohort study	22	iFuse Implant System	Lateral approach	<u>MIS Cohort</u> Age: 47.9 (13.1) years Sex: 17F/5M Prior lumbar fusion: 64% Follow-up: median 15 (12-26) mo	ODI: 61.5 (12.5) pre-op, 52 (16.9) at follow-up Surgical time: 68.3(26.8) min EBL: 40.5 (31.4) mL Hospital Stay: 2.0 (1.5) days	Pulmonary embolism that resolved with treatment (1), revisions due to halo formation on the sacral side with recurring sacroiliac joint pain (2)
		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	<u>Open Cohort</u> Age: 51 (9.4) years Sex:13F/9M Prior lumbar fusion: 50% Follow-up: median 13 (11-33) mo	ODI: 61.8 (10.8) pre-op, 47.4 (21.7) at follow-up Surgical time: 128 (27.9) min EBL: 168.8 (479.0) mL Hospital Stay: 3.3 (1.1) days	
Ledonio 2014 ⁴⁶	Multicenter, retrospective, comparative cohort study	17	iFuse Implant System	Lateral approach	<u>MIS Cohort</u> Age: median 66 (39-82) years Sex: 11F/6M Prior lumbar fusion: 82% Follow-up: 12 mo	<i>Values reported as median (range)</i> ODI: 53 (14-84) pre-op, 13 (0-38) at 12 mo Surgical time: 27 (18-72) min Hospital Stay: 1 (1-2) days	Transient trochanteric bursitis (3), hematoma (1), transient toe numbness (1), revision due to malpositioned implant (1)
		22	3 hole, 4.5mm plate, autograft packed within joint	Anterior approach through an ilioinguinal incision	<u>Open Cohort</u> Age: median 51 (34-74) years Sex: 82F/32M Prior lumbar fusion: 47% Follow-up: 24 mo	<i>Values reported as median (range)</i> ODI: 64 (44-78) pre-op, 46 (10-80) at 12 mo Surgical time: 128 (73-180) min Hospital Stay: 3 (2-6) days	

Author, Year	Study design	N	Implant	Technique	Demographics <i>Mean (±SD) or (range), unless otherwise specified</i>	Results <i>Mean (±SD) or (range) unless otherwise specified</i>	Complications (n)
Graham-Smith 2013 ²⁶	Multicenter, retrospective comparative cohort study	114	iFuse Implant System	Lateral approach	<u>MIS Cohort</u> Age: 57.4 (14.0) years Sex: 82F/32M Prior lumbar fusion: 47.4% Follow-up: 24 mo	VAS: 8.3 (1.6) pre-op, 2.3 (2.6) at 12mo, 1.7 (2.9) at 24mo MCID: 86% reached at 12mo, 82% at 24mo Surgical time: 70 (24) min EBL: 33 (27) mL Hospital stay: 1.3 (0.5) Days	No intraoperative. Postop repositioning of implants (4), 3.5% (4/114).
		149	Screws, plates	Open posterior approach	<u>Open Cohort</u> Age: 45.8 (11.3) years Sex: 103F/46M Prior lumbar fusion: 23.5% Follow-up: 24 mo	VAS: 7.1 (1.9) pre-op, 4.6 (3.0) at 12mo, 5.6 (2.9) at 24mo MCID: 61% reached at 12mo, 50% at 24mo Surgical time: 163 (25) min EBL: 288 (182) mL Hospital stay: 5.1 (1.9) Days	No intraoperative. Postop removal of implants (66), 44% (66/149).

NOTE: The table excludes 3 systematic reviews:

- Zaidi – *J Neurosurg Spine* 2015⁴⁹: systematic review of studies on SIJ fusion, includes open and MIS.
- Heiney – *Int J Spine Surg* 2015⁴⁸: systematic review and meta-analysis of MIS SIJ fusion utilizing a lateral transarticular technique.
- Lingutla – *Eur Spine J* 2016⁵⁶: Systematic review and meta-analysis of observational studies describing outcome of SIJ fusion in patients with LBP.

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

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February 20, 2019

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Via e-mail: shtap@hca.wa.gov

Subject: Washington State Health Care Authority Non-coverage for Sacroiliac Joint Fusion Surgery

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN) and the Washington State Association of Neurological Surgeons (WSANS), we wish to express our deep disappointment regarding the decision of the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) program Health Technology Clinical Committee (HTCC) not to cover sacroiliac (SI) joint fusion surgery.

We are particularly disappointed by the outcome given the fact that the *Evidence Report on Sacroiliac (SI) Joint Fusion Surgery*, prepared by RTI International–University of North Carolina Evidence-based Practice Center for consideration by the HTCC, concluded that minimally invasive SI joint fusion procedures provide significant benefit to carefully selected patients. The evidence clearly supported minimally invasive SI joint fusion procedures as safe and cost-effective for pain management and improved quality of life for patients with chronic SI joint dysfunction. Furthermore, we found the literature search and data extraction in the report to be up to date and comprehensive.

Rather than a thorough examination of the clinical evidence report prepared for the meeting, it appears that the HTCC digressed into a discussion of revision surgery and durability, which were not part of the evidence review. We share the concern expressed by David W. Polly, Jr., MD — who made a presentation at the January 18, 2019, HTCC meeting on behalf of the American Academy of Orthopaedic Surgeons (AAOS), AANS, CNS, DSPN and WSANS — that anecdotal discussion of non-operative management for SI Joint pain was not supported by valid clinical evidence of enduring efficacy for those treatments. Dr. Polly and the AAOS have submitted letters objecting to the decision for non-coverage, and we agree with their comments.

We share a common dedication to safe and effective treatments, and nothing is more important to our members than the well-being of their patients. Organized neurosurgery has been active in reviewing, commenting on and attending meetings regarding procedures under consideration by the HTA program for over a decade. For patients, clinicians and other stakeholders to have confidence in this process, it is essential that the HCA focus the HTCC review and discussion on the clinical data provided for a given topic and insist on rigorous adherence to evidence-based medicine. While this sometimes occurs, we

have observed that on occasion, opinion or anecdote regarding operative spine care has led to a bias that is not based on the best available clinical data.

Thank you for the opportunity to express our views. We urge you to reconsider the non-coverage decision for SI Joint fusion procedures, as we believe that the scientific evidence supports coverage for the procedure in appropriately selected patients who have not found relief from non-operative treatment.

If you have any questions or need additional information, please feel free to contact us.

Sincerely,



Shelly D. Timmons, MD, PhD, FAANS, President
American Association of Neurological Surgeons



Ganesh Rao, MD, FAANS, President
Congress of Neurological Surgeons



Michael Y. Wang, MD, FAANS, Chair
AANS/CNS Section on Disorders of the Spine
And Peripheral Nerves



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Washington State Association of Neurological
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Sacroiliac joint fusion

HTCC final approval of coverage decision

(From page 7 of decision aid)

Next step: Proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- 1) Based on public comment was evidence overlooked in the process that should be considered?
- 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: Final determination

Following review of the proposed findings and decision document and public comments:

Final vote

- Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or unclear outcome (i.e., tie), chair will lead discussion to determine next steps.

Key questions and background

Peripheral nerve ablation for the treatment of limb pain

Background

Clinical need and target population

Severe limb pain can markedly limit quality of life if it is not effectively managed. Chronic Limb pain can occur in a joint, such as the hip, shoulder or knee and is most often due to osteoarthritis.¹ Other causes of chronic limb pain include traumatic injury, rheumatoid arthritis, postoperative pain syndromes, or soft tissue (e.g., muscles, tendons, ligaments) dysfunction.² Standard treatments for chronic limb pain include physical activity, weight loss, medications (prescription drugs and over-the-counter pain relievers), physical therapy, complementary and alternative therapies (e.g., massage, acupuncture), and surgery.³ Treatments for osteoarthritis aim to reduce symptoms and improve function, although most treatments do not modify the natural history or progression of the disease.²

Technology of interest

Nerve ablation can be accomplished in several ways, including radiofrequency ablation, chemical ablation, and surgical ablation. There are three different types of radiofrequency ablation that have been developed. Standard thermal radiofrequency nerve ablation is a minimally invasive procedure that uses heat and coagulation necrosis to damage or destroy nerve tissue.² A high frequency electrical current is applied to the target tissue, using a needle electrode that is inserted through the skin.² The electrode generates heat (80 to 90°C) which coagulates a small volume of tissue.² The goal is to destroy peripheral sensory nerve endings, resulting in alleviation of pain.² However, the affected nerves may regenerate, causing the pain to return.⁴

Cooled radiofrequency is a newer technology that uses a water cooled radiofrequency probe to create a larger lesion size and therefore treat a larger area than standard thermal radiofrequency ablation.⁵ Cooled radiofrequency devices apply more energy at the desired location, but use water cooling to prevent as much heat diffusing beyond the target area.⁵ COOLIEF, produced by Haylard Health, Inc., is a cooled radiofrequency treatment that was cleared for marketing by the FDA in 2017.⁶ It is used to treat hip and knee osteoarthritis pain and is performed as an outpatient procedure.⁵

Pulsed radiofrequency treatment uses short bursts of radiofrequency current, rather than continuous current of standard radiofrequency ablation.² The heat from pulsed radiofrequency ablation (not exceeding 45°C) may cause less damage than standard thermal radiofrequency ablation.² Pulsed radiofrequency has been proposed as a possibly safer alternative to continuous radiofrequency ablation in the treatment of variety pain syndromes.²

Final

Policy context

Peripheral nerve ablation is one of many available treatments for patients with limb pain. This topic was selected for a health technology assessment because of high concerns for the safety and efficacy of the procedure and medium/high concern for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding peripheral nerve ablation for patients with limb pain.

Key questions

1. What is the evidence of efficacy and effectiveness for peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
2. What direct harms are associated with peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?
3. Do important patient efficacy/effectiveness outcomes or direct harms from peripheral nerve ablation for limb pain vary by:
 - a. Indication
 - b. Patient characteristics
4. What are the cost-effectiveness and other economic outcomes of peripheral nerve ablation for limb pain compared to other active interventions, placebo, sham procedures, or no treatment?

Scope

Study component	Inclusion	Exclusion
Populations	Adults and children with chronic limb pain due to osteoarthritis or other conditions	Pain that does not arise from an extremity joint or soft tissue
Interventions	Peripheral nerve ablation using any technique	Ablation as part of another surgical intervention Procedures involving the central nervous system
Comparators	Other treatments for limb pain, including: <ul style="list-style-type: none"> • Medication • Surgery • Behavioral or psychological interventions • Physical therapy or other non-invasive non-medication therapies • Placebo 	Studies without a comparator intervention Studies with indirect comparisons Studies with an outdated comparator or a comparator

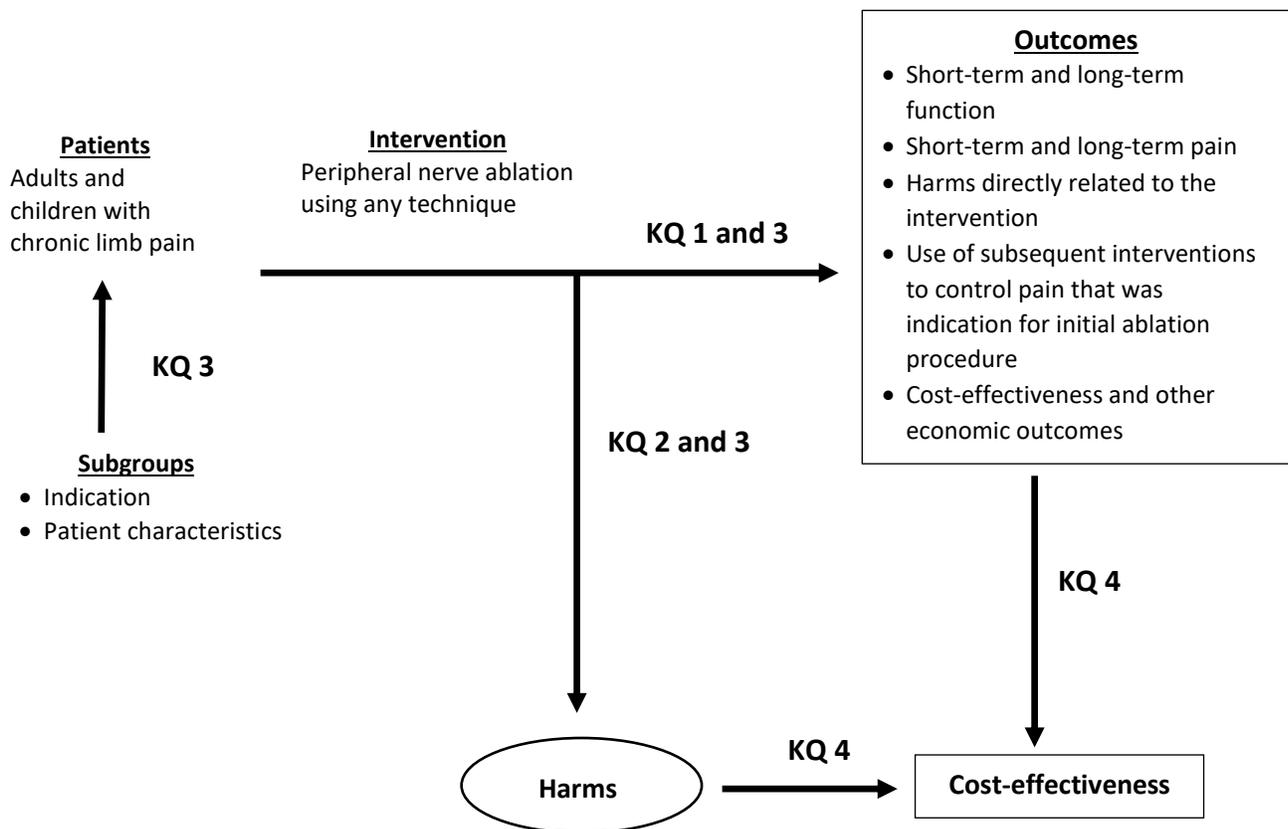
Final

Study component	Inclusion	Exclusion
	<ul style="list-style-type: none"> • Sham procedures • No treatment 	intervention that is not available in the U.S.
Outcomes	<ul style="list-style-type: none"> • Primary outcomes: short-term and long-term function measured by a validated method • Secondary outcomes: short-term and long-term pain measured by a validated method • Safety: harms directly related to the intervention • Indirect outcomes: use of subsequent interventions to control pain that was the original indication for the initial peripheral nerve ablation procedure • Economic: cost-effectiveness outcomes (e.g., cost per improved outcome) or cost-utility outcomes (e.g., cost per quality adjusted life year [QALY], incremental cost effectiveness ratio [ICER]) 	Other outcomes
Study design	<ul style="list-style-type: none"> • KQ 1–4 <ul style="list-style-type: none"> ○ Randomized controlled trials ○ Systematic reviews of randomized controlled trials • Additional studies/data for KQ 2–3 (harms) <ul style="list-style-type: none"> ○ Non-randomized comparative studies ○ Non-randomized studies without a comparator will be assessed for harms only, if evidence for the intervention is included in KQ1 ○ Governmental or other registries and databases containing reports of procedure-related harms or device recalls (e.g., FDA MAUDE database, FDA Medical Device Recall database) • Additional studies/data for KQ 4 <ul style="list-style-type: none"> ○ Cost-effectiveness studies and other formal comparative economic evaluations ○ Systematic reviews of cost-effectiveness studies and other formal comparative economic evaluations 	Abstracts, conference proceedings, posters, editorials, letters, case reports and case series with fewer than 10 subjects (for harms only), studies with harms outcomes for an intervention that is not included in KQ1

Study component	Inclusion	Exclusion
Publication	<ul style="list-style-type: none"> • Studies in peer reviewed journals, technology assessments or publically available FDA or other federal government reports • Published in English • Published from database inception through September 2018 	<p>Studies whose abstracts do not allow study characteristics to be determined</p> <p>Studies that cannot be located</p> <p>Duplicate publications of the same study that do not report different outcomes or follow-up times, or single site reports from multicenter studies</p> <ul style="list-style-type: none"> • Studies in languages other than English

Analytic framework

The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.



Final

References

1. Centers for Disease Control and Prevention. Osteoarthritis (OA). 2017; <https://www.cdc.gov/arthritis/basics/osteoarthritis.htm>. Accessed 7/9/2018.
2. Bhatia A, Peng P, Cohen SP. Radiofrequency procedures to relieve chronic knee pain: an evidence-based narrative review. *Reg Anesth Pain Med*. 2016;41(4):501-510.
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Public comment and response

See **Draft key questions: Comment and response** document published separately.

**Health Technology Clinical Committee
Findings and Decision**

Topic: Peripheral nerve ablation for limb pain

Meeting date: January 18, 2019

Final adoption: Pending

Meeting materials and transcript are available on the [HTA website](#).

Number and coverage topic:

20190118B – Peripheral nerve ablation for limb pain

HTCC coverage determination:

Peripheral nerve ablation, using any technique, to treat limb pain including for knee, hip, foot, or shoulder due to osteoarthritis or other conditions, is **not a covered benefit** for adults and children.

HTCC reimbursement determination:

Limitations of coverage: N/A

Non-covered indicators: N/A

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Draft

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on peripheral nerve ablation for limb pain due to osteoarthritis is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of peripheral nerve ablation. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to not cover peripheral nerve ablation, using any technique, for limb pain due to osteoarthritis or other conditions for adults and children

	Not Covered	Covered under certain conditions	Covered unconditionally
Peripheral nerve ablation, using any technique, for chronic limb pain due to osteoarthritis or other conditions for adults and children.			
Foot, Shoulder, Hip	10	0	0
Knee	6	4	0

Discussion

The committee reviewed and discussed the available studies for use of peripheral nerve ablation for limb pain. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of peripheral nerve ablation for the foot, shoulder or hip, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer, more effective, or more cost-effective than comparators. The committee found that peripheral nerve ablation of the knee, using any technique, for limb pain for osteoarthritis or other conditions was unproven for being safer or more cost-effective than comparators. The committee did find that in some cases, peripheral knee ablation of the knee, using any technique, for limb pain due to osteoarthritis or other conditions is more efficient.

Additional Considerations

The Committee recognizes, from information provided in the review process, that ongoing studies could impact the evidence-based determination: they will re-review this topic following publications of new research findings that could change the determination.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Medicare does not have a NCD for peripheral nerve ablation for limb pain.

The committee discussed clinical guidelines, however, none of identified clinical practice guidelines made a recommendation for the use of nerve ablation procedures for limb pain. Organizational guidelines:

- Association of Extremity Nerve Surgeons (2014)
- American College of Occupational and Environmental Medicine (2013)
- American College of Foot and Ankle Surgeons (ACFAS) (2018)
- American Academy of Orthopaedic Surgeons (2013)
- National Institute for Health and Care Excellence (NICE) (2014)
- Veterans Administration/Department of Defense (2014)

The committee's determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on use of peripheral nerve ablation for limb pain for public comment to be followed by consideration for final approval at the next public meeting.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

Peripheral nerve ablation

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Sacroiliac joint fusion.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	March 5, 2018	
Public comments	March 5 to 19, 2018	15
Selected technologies published	March 23, 2018	
Public comments	March 23 to April 23, 2018	32
Draft key questions published	July 24, 2018	
Public comments	July 27 to August 9, 2018	14
Final key questions published	September 6, 2018	
Draft report published	November 1, 2018	
Public comments	November 1 to 30, 2018	30
Final report published	December 18, 2018	
Public meeting	January 18, 2019	
Draft findings & decision published	February 6, 2019	
Public comments	February 7 to 20, 2019	14
Total		105

Overview

Category	Comment Period	
	June 15, to 28, 2018	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	2	1
Professional society & advocacy organization	1	1
Total	3	2

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Timothy Maus, MD	Chair, Spine Intervention Society	Yes
<input type="checkbox"/>	2. Lisa Spafford-Huston	Regence	No
<input type="checkbox"/>	3. Diane Weaver, MS	Avanos Medical	Yes



February 7, 2019

Josh Morse, MPH
Health Technology Assessment Program Director
Washington State Health Care Authority
626 8th Avenue SE
P.O. Box 45502
Olympia, WA 98504-5502

via e-mail: shtap@hca.wa.gov

Re: Findings and Decision on Peripheral Nerve Ablation for Knee Pain

Dear Mr. Morse:

The Spine Intervention Society, a multi-specialty association of over 2,800 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on the Washington State Health Care Authority Health Technology Clinical Committee's decision to exclude coverage of peripheral nerve ablation for knee pain.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care, as well as interventional pain management for musculoskeletal care, is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

While we are pleased to see that nearly half of the committee members acknowledged the value of the procedure, we are disappointed that the decision was not made to support coverage. We wish to reiterate our comments, previously submitted on November 16, 2018, in **support of the efficacy and effectiveness of radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with knee osteoarthritis (OA)**. Current evidence shows that for patients suffering with chronic knee pain (≥ 3 months) due to knee OA and/or after total knee arthroplasty not improved with standard conservative management, RFA of the corresponding genicular nerves is an effective, non-surgical treatment that will improve patient's function and quality of life. Patients treated with RFA experience decreased dependence on oral pain medications, reduced physical therapy utilization, and many are spared future costly and unnecessary surgical interventions.

Choi *et al*, in a 2010 double-blinded, randomized controlled trial (RCT) investigated the efficacy of thermal RFA in patients greater than 50 years old with persistent arthritic knee pain (≥ 3 months) not improved with physical therapy, oral analgesics, and intra-articular knee injections (either corticosteroid or hyaluronic acid) [1]. Nineteen patients who had positive diagnostic, fluoroscopically-guided genicular nerve blocks underwent subsequent standard, thermal RFA. The patients in this group reported significant decreased joint pain on the Visual Analog scale (VAS) and Oxford knee scores at 1-, 3-, and 6-month follow-up intervals compared with 19 patients with similar demographics and knee OA severity, who underwent the sham procedure.

Similar results were found in a 2016 RCT by Qudsi-Sinclair *et al*; however, this study assessed the effectiveness of RFA in a population of patients with continued knee pain at least 6 months after knee replacement [2]. Prior to RFA, patients underwent fluoroscopically-guided genicular nerve blocks with lidocaine. Of the 28 patients included in the study, 14 were randomized to thermal RFA and 14 to therapeutic peripheral nerve injection with corticosteroid. Both groups' pain and function improved, with decreased use of pain medications at months 3 and 6, with similar results approaching 1 year for both groups. Besides some localized post-injection discomfort, no major adverse events were noted with the above studies.

The 2018 trial by Davis *et al* is the largest study and was also the first to employ cooled radiofrequency ablation (CRFA) [3]. Patients meeting inclusion criteria had at least grade 2 Kellgren–Lawrence radiographic OA, refractory knee pain of ≥ 6 month duration, pain of at least 6 of 10 on a Numeric Rating Scale (NRS), an Oxford Knee Score (OKS) of at least 35, and at least 50% improvement with genicular nerve blocks. The 151 patients who met the inclusion criteria were randomized to receive either CRFA or intra-articular steroid (IAS) injection. CRFA was performed under fluoroscopic guidance with 17-gauge introducers at 60°C for 150 seconds. The primary outcome measure was the percentage of patients achieving at least 50% pain reduction at 6 month follow-up as measured by the NRS. Secondary outcome measures included function measured on OKS, patient's overall perception of the treatment, and analgesic usage. Pain relief with CRFA was superior to that obtained with IAS at all time periods, and at 6 month follow-up, 74% of the CRFA group had at least 50% relief compared with just 16% of the IAS group. Function and global perception were also superior in the CRFA cohort, although there was no statistically significant difference between the groups in terms of oral opioid use. The longer duration of relief noted in this study, compared with duration of relief reported for traditional RFA, provides evidence for the theoretical increased benefit of CRFA -- namely the creation of larger lesions to reduce the technical failure rate of the procedure (*i.e.*, failure to effectively ablate the target nerves).

The most recent 2018 RCT by El-Hakeim *et al* compared RFA to conservative management consisting of oral acetaminophen, diclofenac, and physical therapy, as needed [4]. Sixty patients with grade 3 or 4 Kellgren–Lawrence OA were randomized to receive either RFA or conservative treatment. RFA was accomplished with three 90 seconds cycles at 90°C per site, which is a substantially longer duration of RFA than that employed by any other RCT. Patients were evaluated at baseline, 2 weeks, 3 months, and 6 months. Results showed

statistically significant, superior pain relief with RFA at all follow-up intervals. Function, as assessed by the WOMAC Index, was improved in both groups at 6 months, but was superior with RFA. Lastly, patient satisfaction as measured on a Likert scale was significantly higher at 3- and 6-month follow-up in the RFA group. However, the study is limited by the failure to select patients based on response to diagnostic blocks and the absence of patient blinding.

The 2017 RCT by McCormick *et al* also employed CRFA, but the study was designed to determine the predictive value of prognostic nerve blocks, not to compare RFA to other modalities [5]. Fifty-four patients with chronic knee pain due to OA received CRFA. The study included patients between 30 and 80 years of age, with >6 months of refractory knee pain, NRS pain score of at least four, and at least grade 2 radiographic OA. Prior to RFA, the 32 patients in the nerve block group received prognostic blocks, of which 29 had positive blocks and proceeded to RFA. Notably, only three of 32 (9.3%) patients had a negative block, defined as <50% pain relief. Twenty-five patients were randomized to the non-nerve block RFA group. Follow-up was conducted at 1, 3, and 6 months, but the primary outcome measure was attainment of at least 50% pain relief at the 6-month mark. Results showed significant improvements in both groups at 6 months, with 58.6% of the nerve block group and 64% of the non-nerve block group achieving at least 50% relief at 6 months. There were no significant differences between groups in terms of pain and function at any of the time periods.

Prospective observational evidence outside of RCTs can also be used to demonstrate the effectiveness of a procedure. In fact, when the outcomes of well-performed, prospective trials demonstrate dramatic and sustainable results that are reproducible across studies, one could argue that the need to demonstrate that the effects of the procedure are not due to placebo effects alone are seriously minimized.

One such prospective cohort study published by Iannaccone *et al* presents results of 31 patients treated with genicular RFA [6]. The patients were assessed at both 3 and 6 months after RFA. At 3 months the average pain relief was 67% improvement from baseline and at 6 months those that received pain relief at 3 months continued to have durable pain relief of 95%.

Another study by Pineda *et al* in 2017 presented evidence that RFA of the genicular nerves significantly reduced perceived pain and disability in the majority of participants, without adverse events [7]. This single-center, prospective, observational study included patients with grade 3 to 4 arthrosis suffering from intractable knee pain of at least 6 months and scoring 5 or more on the visual analog scale (VAS). The proportion of participants with improvement of at least 50% in pretreatment VAS scores at 1, 6, and 12 months following intervention were 88% (22/25), 64% (16/25), and 32% (8/25), respectively.

Due to the robust nature of the evidence, RFA of the genicular nerves is a valuable treatment for patients suffering from chronic knee pain and for patients with residual pain after total knee arthroplasty. Further, the procedure is indicated and may be the only option for patients that are not surgical candidates or who choose not to have surgical

treatment. Acknowledging the strength and quality of the evidence in support of the safety and effectiveness of genicular nerve RFA, **the American Medical Association's Current Procedural Terminology (CPT®) Editorial Panel has approved a Category I code that will go into effect on January 1, 2020.**

We hope that this information, as well as any dialogue and collaboration between the Washington State Health Care Authority's Health Technology Clinical Committee and the Spine Intervention Society, will lead to the establishment of a reasonable coverage policy that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@SpineIntervention.org.

Sincerely,



Timothy P. Maus, MD
President
Spine Intervention Society

References:

1. Choi WJ, Hwang SJ, Song JG, et al. Radiofrequency treatment relieves chronic knee osteoarthritis pain: a double-blind randomized controlled trial. *Pain* 2011;152:481-487.
2. Qudsi-Sinclair S, Borrás-Rubio E, Abellan-Guillén JF, Padilla del Rey ML, Ruiz-Merino G. A comparison of genicular nerve treatment using either radiofrequency or analgesic block with corticosteroid for pain after a total knee arthroplasty: a double-blind, randomized clinical study. *Pain Pract* 2017;17(5):578-588.
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6. Iannaccone F, Dixon S, Kaufman A. A review of long-term pain relief after genicular nerve radiofrequency ablation in chronic knee osteoarthritis. *Pain Physician* 2017;20:E437-44.

7. Pineda S, Vanlinthout L, et al. Analgesic effect and functional improvement caused by radiofrequency treatment of genicular nerves in patients with advanced osteoarthritis of the knee until 1 year following treatment. *Reg Anesth Pain Med* 2017;42:62-68.

From: Spafford-Huston, Lisa
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To: 'Morse, Josiah (HCA)' <josh.morse@hca.wa.gov>; Transue, Emily R (HCA) <emily.transue@hca.wa.gov>; Spafford-Huston, Lisa <Lisa.Spafford-Huston@regence.com>; Oliveira, Drew <Drew.Oliveira@regence.com>; Whitlock, Stephanie <Stephanie.Hammond@regence.com>
Subject: HTCC clarification

Hi Josh,

The HTCC for Peripheral Nerve Ablation for limb pain is still pending for final committee vote however, we had a question around clarification on HTCC coverage determination that indicates “due to Osteoarthritis or *other conditions*”. Could you advise is other conditions, ALL other conditions or relates to specific conditions or is there examples of “other conditions the committee was referring to.

Thanks for your assistance.

Lisa Huston
Clinical Services
Manager, Care Management
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(360) 755-2050

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If you no longer wish to receive these e-mails or participate in the care management program please let me know and we will update our records to reflect this.

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From: Weaver, Diane <Diane.Weaver@avanos.com>
Sent: Tuesday, March 12, 2019 8:22 AM
To: HCA ST Health Tech Assessment Prog
Cc: Weaver, Diane; dweaver3122@cox.net
Subject: Washington State Health Care Authority - Peripheral nerve ablation for the treatment of limb pain
Attachments: Davis T Twelve-month analgesia and rescue, by cooled.pdf

Dear WA State Health Care Authority;

I am writing to you in response to the January 2019 committee meeting on the topic of Peripheral nerve ablation for the treatment of limb pain. As promised, I will continue to provide new high level evidence as it becomes available.

Please see for your review the **12 month follow up data that was just published**. The Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial. Published in Regional Anesthesia and Pain Medicine, 2019.

Cooled Radiofrequency induced Pain Relief, Improved Joint Function and Global Perceived Effect improvement were sustained through 12 months:

- NRS: 65.4% of CRFA patients received $\geq 50\%$ Pain Reduction
- Oxford Knee Score: At baseline, 67.1% reported severe arthritis, only 11.5% at 12 months.
- 46.2% reported satisfactory joint function
- Patient Global Perceived Effect: $\geq 50\%$ reported improvement
- Safety (Adverse Events): No serious AEs reported
- Opioid Medical Usage: No differences between groups

Thank you for your time and consideration.

Best regards,

Diane

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Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial

Tim Davis,¹ Eric Loudermilk,² Michael DePalma,³ Corey Hunter,⁴ David A Lindley,⁵ Nileshkumar Patel,⁶ Daniel Choi,⁷ Marc Soloman,⁸ Anita Gupta,⁹ Mehul Desai,¹⁰ Elizabeth Cook,⁶ Leonardo Kapural¹¹

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Received 19 August 2018
 Revised 15 December 2018
 Accepted 21 January 2019



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To cite: Davis T, Loudermilk E, DePalma M, et al. *Reg Anesth Pain Med* Epub ahead of print: [please include Day Month Year]. doi:10.1136/rapm-2018-100051

ABSTRACT

Background and objectives As a follow-up to the 6-month report,¹² this study investigated the analgesic effect of cooled radiofrequency ablation (CRFA) in patients with knee osteoarthritis (OA) 12 months postintervention and its ability to provide pain relief in patients who experienced unsatisfactory effects of intra-articular steroid injection (IAS).

Methods Seventy-eight per cent (52/67) of patients originally treated with CRFA were evaluated at 12 months, while at 6 months post-IAS, 82% (58/71) of those patients crossed over to CRFA and assessed 6 months later.

Results At 12 months, 65% of the original CRFA group had pain reduction $\geq 50\%$, and the mean overall drop was 4.3 points ($p < 0.0001$) on the numeric rating scale. Seventy-five per cent reported 'improved' effects. The cross-over group demonstrated improvements in pain and functional capacity ($p < 0.0001$). No unanticipated adverse events occurred.

Conclusions This study demonstrates that analgesia following CRFA for OA knee pain could last for at least 12 months and could rescue patients who continue to experience intolerable discomfort following IAS.

Clinical trial registration The ClinicalTrials.gov registration number for this study is NCT02343003.

INTRODUCTION

Total knee arthroplasty (TKA) is an effective therapeutic option of last resort for individuals afflicted with significant osteoarthritis (OA)-related knee pain and dysfunction. While the outcomes of TKA are consistent and well established,^{1,2} the procedure may not be indicated in patients who have comorbidities,³ or those who otherwise may not be appropriate candidates for TKA.⁴ Therefore, providing a therapeutic option with long-term duration of effect may enable such patients to have a more satisfactory quality-of-life.

The minimally invasive, outpatient nature of radiofrequency ablation (RFA) of targeted nociceptive nerves is becoming an increasingly well known and timely option for patients in whom conservative therapies have failed and/or those who are not candidates for TKA.⁵⁻⁸ In particular, the 'cooled' form of RFA (CRFA) has afforded patients

with knee OA with pain relief⁹⁻¹² and functional improvement.^{9-11,12} Most recently, we reported that 74% of patients treated with CRFA had pain reduction of 50% or more compared with 16% of demographically matched patients who received an intra-articular steroid injection (IAS) at 6 months postintervention.¹² In addition, through secondary measures, significantly more patients at 6 months reported 'satisfactory joint function' via the Oxford Knee Score and a perception that their treatment effect had 'improved' their condition than those who received an IAS per the Patient Global Perceived Effect. Although the beneficial effectiveness of CRFA for treating OA of the knee was evident from the 6-month analyses of this study,¹² a paucity of data has been published regarding longer term durability of these effects.

This analysis explored the sustainability of analgesic effects realized at 6 months in patients with knee OA who were treated with CRFA. We hypothesized that significant ($\geq 50\%$) analgesia would remain among the majority ($> 50\%$) of patients in the original CRFA group 12 months postintervention and that patients who still had intolerable discomfort 6 months following IAS would experience significant ($\geq 50\%$) pain relief after CRFA. As such, this current study primarily evaluated the proportion of patients whose knee pain was reduced by $\geq 50\%$ from baseline 12 months post-treatment within the initial cohort of patients with OA who were enrolled in the 6-month clinical trial at 11 different sites.¹² Additionally, clinical features of subjects who elected to cross-over to receive CRFA after 6 months ('cross-over' (XO) group) were evaluated.

METHODS

All patients were properly consented prior to initiating screening activities. The study is registered in ClinicalTrials.gov: registration number, NCT02343003; initial release date, 15 January 2015.

Study design

This prospective, randomized, open-label, multicenter (11 sites) clinical study with a parallel-group design initially included the test treatment,

CRFA (N=76), utilizing the Coolief System (Halyard Health, Alpharetta, Georgia, USA), or IAS (N=75), in a 1:1 randomization scheme. The methodological differences between the active treatment comparators in this study did not permit blinding of investigators or patients to the interventions. The initial results from this study presented data through study follow-up visits at 1, 3, and 6 months compared with the two study groups primarily by the proportion of subjects whose knee pain was reduced by $\geq 50\%$ from baseline at 6 months post-treatment. Additional secondary measures noted improvements in function, and nearly all patients in the CRFA group (91%) reported perceptions of 'improvement' regarding their knee pain.¹² The focus of this report is to describe the patient's experience through 12 months. Additionally, to further evaluate CRFA, patients who were dissatisfied with their IAS treatment after 6 months could cross-over to the ablation treatment. The substantial migration of original IAS study group members to the XO group left only four patients in the former cohort, which was considered too small to conduct any meaningful analytical statistical comparisons between CRFA and IAS treatments at 12 months post-interventions. Patients in the IAS cohort who elected to receive CRFA treatment at the 6-month follow-up visit were followed for an additional 6 months and are herein referred to as XO group members. Methodology, patient demographics, and 6-month results for the original CRFA and IAS study groups have been published.¹²

Study population

Patients who had radiographic evidence of OA within 12 months prior to study screening, with no other etiology demonstrated as the source of knee pain, were eligible for the study. While individuals with bilateral knee OA were not excluded; only one knee was screened and enrolled as the 'index knee' for treatment. Management of contralateral knee pain in bilateral patients was left up to the discretion of the investigators and patients as part of standard of care. Selection criteria included: knee pain ≥ 6 months that was unresponsive to conservative treatments (physical therapy, oral analgesics: ≤ 60 mg morphine equivalence, stable for 2 months; intra-articular injections with steroids and/or viscosupplementation), body mass index (BMI) < 40 , and reporting $\geq 50\%$ response to blocks as described previously¹² and below. On confirmation that a patient was eligible, randomization was completed utilizing prepopulated, sequentially numbered, sealed envelopes generated by the statistician using a computerized randomization programme. Sites opened a single envelope per patient and chose the lowest available number to maintain sequential ordering of randomization. Additional treatments for the index knee were prohibited during the study.

The block paradigm was as follows: patients who indicated a score reduction on the numeric rating scale (NRS) $\geq 50\%$ ⁵ at least 15 min following fluoroscopically guided blockade of the superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve¹³ using 0.60–0.75 mL/site of local anesthetic (preferably Marcaine (bupivacaine) Hospira, Lake Forest, Illinois, USA, 0.5% or similar) at each site were eligible for the study.¹²

Study intervention

Cooled RFA of the index knee was administered to patients in the CRFA study cohort, as facilitated by fluoroscopic visualization of anatomical landmarks.¹³ A 75 or 100 mm 17-gage CRF introducer was placed at the appropriate locations after 1–3 mL of 1% lidocaine was infiltrated. An 18-gage internally cooled 4

mm active tip electrode was placed into the introducer needle, and 50 Hz sensory stimulation at < 0.5 V in all three locations reproduced concordant knee pain that ensured proximity of the probe to each of the target nerves (superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve)¹³ prior to lesioning. Next, motor stimulation at 2 Hz was carried on up to 1 V without muscular contractions to ensure proper distance of final radiofrequency (RF) needle active tip position from any motor nerve fibers.

The CRFA intervention produces thermal energy with average maximum tissue temperatures greater than 80°C,¹⁴ while the probe tip temperature is maintained at 60°C by the cooling water circulating within the probe. Each lesion was created over 150 s. Following the procedure and patient recovery, each patient was discharged to home with instructions to limit strenuous activity for at least 24 hours postprocedure.

Study outcomes

The proportion of subjects whose knee pain was reduced by $\geq 50\%$ compared with baseline was calculated at 12 months post-treatment,¹⁵ as measured by the NRS. Secondary endpoints included: (1) change in knee function detected by the Oxford Knee Score (OKS)—a validated outcomes instrument that is routinely used to evaluate the overall condition of subjects with knee OA,¹⁶ (2) subjects' perception of treatment effect as reflected by the Global Perceived Effect score, and (3) opioid analgesic use, as measured by subject self-reported average daily dosage used. Reported assessments of these study endpoints were based on patients' impressions made during the week preceding data collection at each study visit for the original CRFA group (baseline and 12 months) and XO group (baseline and 6 months). The baseline values utilized for XO analysis were those at the time of cross-over for all outcome measures. All subjects were evaluated for adverse events (AEs) and serious AEs (SAEs) at each visit.

To investigate a theoretical concern that CRFA could inadvertently progress knee OA relative to evidence provided at study baseline, an amendment was created late in the study to allow for the collection of radiographs at 12 months. Fifty-one images were considered, and the disease state displayed by each was quantified by independent radiologists (generally) per the Kellergan-Lawrence Scale. Twenty-four images were from the originally treated CRFA group and 27 were from the XO group.

Statistical analysis

A non-inferiority evaluation was used to estimate the study sample size. The sample size was based on the estimated success rates of 59%⁸ (success $\geq 50\%$ NRS score reduction) and 47%¹⁷ (success $\geq 30\%$ NRS score reduction) in the CRFA and standard groups, respectively, and a non-inferiority margin of 15%. Assuming an attrition rate of 20% and a two-sided significance level of 5%, 144 subjects enrolled into the study would yield 114 subjects at the primary endpoint.

As was previously reported on 6-month outcomes of this study,¹² the 12-month data are derived from the full-analysis study population set, while the XO results are from the per-protocol set. The protocol defined the full analysis set as: all randomized subjects will be analyzed following the principle of intention-to-treat (ITT) provided they received Coolief or corticosteroid injection treatment and had at least one effectiveness observation, thereby, the results presented can be considered a modified ITT. Percentages are reported with 95% CI. Within-group comparisons were expressed as mean and an associated SD, with significant differences indicated by $p \leq 0.05$. Such

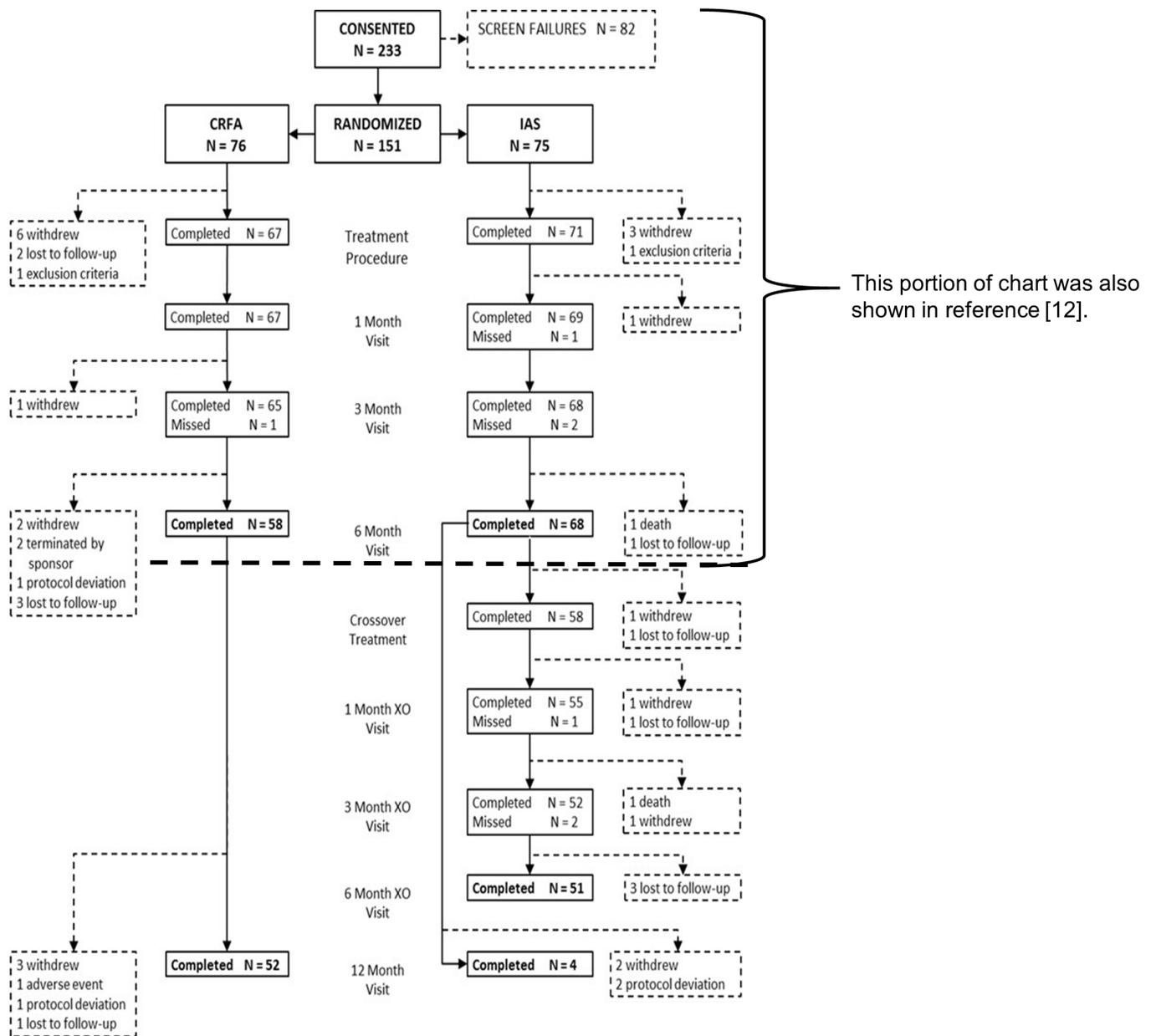


Figure 1 Consolidated Standards of Reporting Trials diagram displaying patients through study stages. *Two subjects were terminated by the sponsor, because the principal investigator changed jobs and a suitable replacement could not be identified. The site was closed, and subjects were dropped. **Adverse event—subject had return of index knee pain and chose a surgical alternative.

analyses were not prespecified, and so no type I error adjustment for multiplicity was made to preserve the overall 5% level of significance. Assessment determinations were made from aggregates of data collections from all available patients at each study time point.

RESULTS

Disposition of study patients

Out of the 233 patients screened, 151 were enrolled into the initial study,¹² with 76 and 75 randomized to the CRFA and IAS study groups, respectively¹² (figure 1). Of those randomized, 67 patients in the CRFA and 71 patients in the IAS group were treated.¹² At 6 months, 58 (87%) and 68 (96%) of treated patients in the CRFA and IAS cohorts contributed data to the primary endpoint,¹² and 58 (82%) patients of the IAS group crossed over to receive CRFA. At 12 months, 52 (78%) patients

in the originally treated CRFA group contributed data to the primary endpoint, while at 6 months post-CRFA, 51 (88%) patients in the XO group did the same. Four patients (6%) of the IAS group completed the 12-month visit. At the time of crossover eligibility, three of these four patients were not in severe enough pain to warrant intervention and one did not want the procedure due to comorbid conditions.

Study population

Baseline demographic variables, including age, gender and race distributions, mean BMI, mean duration of knee pain, analgesic medication utilization, knee OA severity, mean index knee pain levels (NRS scores) before diagnostic block, and the extent of index knee pain reduction postdiagnostic block were made available previously.¹²

Table 1 Study outcomes: original CRFA group versus IAS group up to 12 months†

	Numeric Rating Scale									
	Baseline		1 Month		3 Months		6 Months		12 Months	
	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS
N	76	75	67	69	65	68	58	68	52	4
Mean	7.3	7.2	3.0	3.9	2.8	5.2	2.5	5.9	3.1	3.3
SD	1.2	1.0	2.3	2.2	2.2	2.0	2.3	2.2	2.7	3.3
P value for difference between groups*	0.55		0.025		<0.0001		<0.0001		0.99	

	Oxford Knee Score									
	Baseline		1 Month		3 Months		6 Months		12 Months	
	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS
N	76	75	67	69	65	68	58	67	52	3
Mean	16.7	16.9	33.3	29.4	34.6	24.6	35.7	22.4	34.3	22
SD	4.4	5.1	9.2	8.5	8.3	7.6	8.8	8.5	11.1	16.6
P value for difference between groups*	0.83		0.004		<0.0001		<0.0001		0.11	

	Global perceived effect									
	Baseline		1 Month		3 Months		6 Months		12 Months	
	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS	CRFA	IAS
Number of subjects improved/total number of subjects (percentage of group improved)	12/72 (16.7)	7/71 (9.9)	53/67 (79.1)	46/69 (66.7)	52/65 (80.0)	21/68 (30.9)	53/58 (91.4)	16/67 (23.9)	39/52 (75)	2/4 (50)
P value for difference between groups†	0.23		0.1		<0.0001		<0.0001		0.29	

*P≤0.05 indicates a significant difference.

†Full-analysis study set data are presented.

CRFA, cooled radiofrequency ablation; IAS, intra-articular steroid; N, number of study subjects.

Pain assessment in the original CRFA group at 12 months

Raw data are presented in table 1. The mean 4.3 ± 2.7 (SD)-point decrease in NRS from baseline at 12 months in the original CRFA group was statistically significant (N=52, $p < 0.0001$, paired Student's t-test). The mean alteration in the NRS score at the 12-month time point was similar with that reported at 6 months, where a mean improvement of 4.9 ± 2.4 points was identified.¹² Further evidence for this sustained response to CRFA is shown

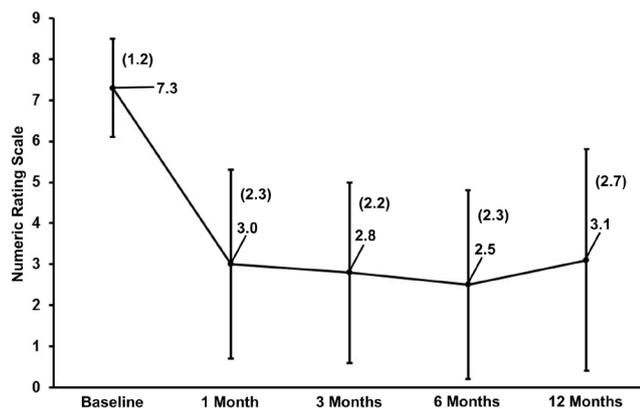


Figure 2 Mean pain scores (Numerical Rating Scale) in the cooled radiofrequency ablation cohort over time. SD are indicated in parentheses. Baseline, N=76; 1 month, N=67; 3 months, N=65; 6 months, N=58; 12 months, N=52. Baseline through 6-month values were previously reported.¹²

in figure 2, where the mean NRS scores following CRFA are similar from 1 to 12 months. And whereas 70% (47/67) (95% CI 59.2 to 81.1), 72% (47/65) (95% CI 61.4 to 83.2) and 74% (43/58) (95% CI 62.9 to 85.4) of the CRFA group experienced diminished pain relative to baseline that was $\geq 50\%$ at 1, 3, and 6 months, respectively¹²; 65% (34/52) (95% CI 52.5 to 78.3) of the group reported this clinically relevant¹⁵ outcome at 12 months.

Secondary study outcomes in the original CRFA group at 12 months

At 12 months, the OKS increase from baseline in the original CRFA cohort was 17.3 ± 12 points (N=52, $p < 0.0001$, Student's paired t-test), with an absolute mean of 34.3 ± 11.1 points. The fraction of patients in the CRFA group experiencing 'severe arthritis' and 'satisfactory knee function' (as defined by the OKS scale) with time post-treatment was inversely distributed (figure 3). Indeed, the percentage of patients reporting OKS 'severe arthritis' was progressively reduced from baseline to 6 months and was nearly sevenfold less at 12 months compared with baseline. In contrast, while there were no patients with OKS 'satisfactory joint function' in the CRFA group at baseline, the proportion of CRFA patients in this group consistently increased throughout the study, with nearly half reporting this outcome at 12 months. Patients who claimed 'moderate to severe arthritis' were approximately 25% at all time points, while those reporting 'mild to moderate' OKS were approximately 40% through 6 months, but then dropped to 17% at 12 months.

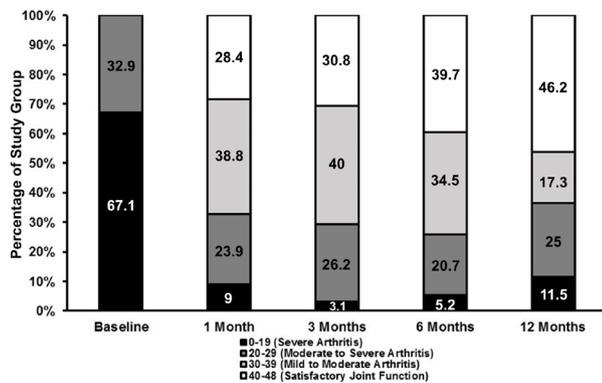


Figure 3 Knee function (Oxford Knee Scale) in the cooled radiofrequency ablation group over time. Baseline, N=76; 1 month, N=67; 3 months, N=65; 6 months, N=58; 12 months, N=52.

The proportion of patients in the CRFA group who had a perception of the treatment effect on their health as being 'improved' at 12 months was 75% (39/52) (95% CI 63.2 to 86.8), which was similar to values at 1 (79%, 53/67) (95% CI 69.4 to 88.8) and 3 months (80%, 52/65) (95% CI 70.3 to 89.7) post-treatment and substantially different than the baseline value of 17% (12/72) (95% CI 8.1 to 25.3).¹² Proportions for all of the aforementioned time points are less than that observed at 6 months (91%, 53/58) (95% CI 84.2 to 98.6).¹²

The mean total daily dose in opioid analgesic medication (morphine equivalents in mg) in the CRFA group at 12 months was 30.3 ± 27.4 mg (N=17), which was similar to the baseline value ($\Delta = -1 \pm 10.3$ mg, N=17, $p=0.68$, paired Student's *t*-test). As noted in the previous publication, 43% of patients in the CRFA group who were taking opioids as of the study's baseline assessment were using such medication for medical indications beyond OA related knee pain (ie, knee and back pain, back pain, etc). Additionally, a subgroup analysis was undertaken examining response to treatment of patients from the original CRFA group who were not taking opioids to manage their pain at study baseline. Fourteen of 67 (21%) patients fell into this category and of those, 11 (79%) patients indicated $\geq 50\%$ relief of their baseline reported index knee pain at 6 months. This subgroup reported greater pain relief (mean NRS point reduction=6.1 at 6 months) than what was observed for the entire originally treated CRFA group at 6 (mean improvement=4.9 points) or 12 months (mean improvement=4.3 points).¹²

Pain assessment in the XO group at 6 months

The XO group had significant reductions from baseline, reporting mean changes of 3.1 ± 2.5 points (N=40), 3.6 ± 2.4 points (N=38), and 3.2 ± 2.7 points (N=37) in the NRS at 1, 3, and 6 months, respectively ($p < 0.0001$, paired Student's *t*-test). These similar point reductions are reflected by the consistent NRS score means observed across the follow-up time points in this group (figure 4). Forty-nine per cent (18/37) (95% CI 32.5 to 64.8) of the XO group experienced clinically relevant¹⁵ pain relief compared with baseline that was $\geq 50\%$ at 6 months.

Secondary study outcomes in the XO group at 6 months

Improvements in function were also noted in the XO group, and the mean increase in the OKS from baseline in the XO group at 6 months was 11.6 ± 9.8 points (N=36, $p < 0.0001$, Student's paired *t*-test). The mean OKS at each study time point

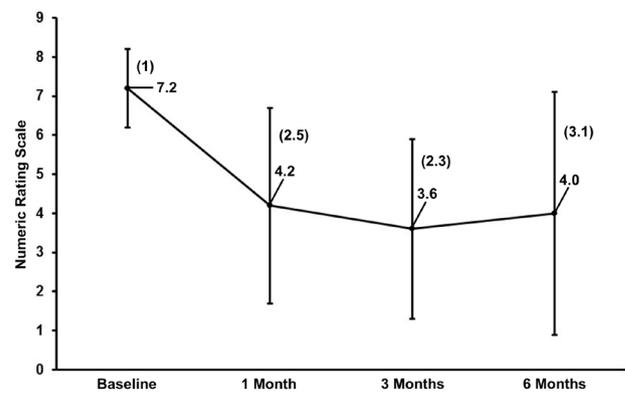


Figure 4 Mean pain scores (Numerical Rating Scale) in the cross-over group over time. SD are indicated in parentheses. Baseline, N=66; 1 month, N=40; 3 months, N=38; 6 months, N=37.

was 18.6 ± 6.6 (N=42), 30 ± 9.4 (N=40), 30.3 ± 10 (N=38), 29.8 ± 10.6 (N=37), at baseline, 1, 3, and 6 months, respectively. While none of the XO patients reported OKS 'satisfactory joint function' at baseline (6 months post-IAS), approximately two-thirds of XO cohort members reported OKS 'severe arthritis' at this time point (figure 5). However, nearly one-fifth of the XO group reported OKS 'satisfactory joint function' 1 month after CRFA, and this condition progressively increased to include approximately one-quarter of the cohort by 6 months. In contrast, the incidence of OKS 'severe arthritis' in the XO group fell more than fourfold at 1 month and included approximately one-fifth of the cohort at 6 months. The frequency of OKS 'moderate to severe arthritis' fell by more than 10% from 1 to 6 months post-CRFA, while the proportion of patients having OKS 'mild to moderate arthritis' consistently remained at approximately 34% during this time frame.

While at the baseline (6 months post-IAS), 7.1% (3/42) (95% CI 0.0 to 14.9) of XO group members described the effect of CRFA on their health as 'improved', 65% (26/40) (95% CI 50.2 to 79.8), 79% (30/38) (95% CI 66.0 to 91.9), and 57% (21/37) (95% CI 40.8 to 72.7) of the group reported this outcome at 1, 3, and 6 months post-CRFA, respectively.

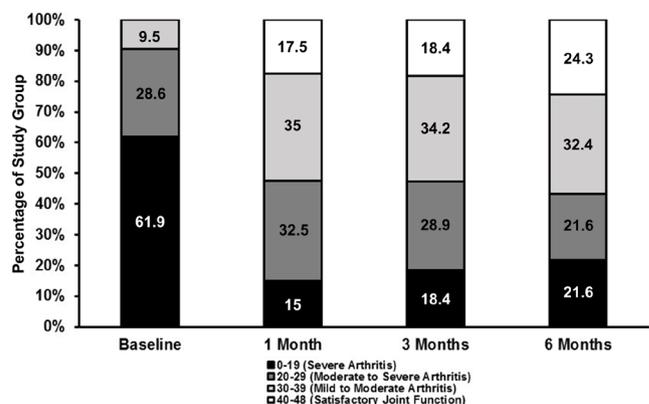


Figure 5 Knee function (Oxford Knee Score) in the cross-over group over time. Baseline, N=42; 1 month, N=40; 3 months, N=38; 6 months, N=37.

Radiographic evidence of knee OA

To understand the state of knee OA following CRFA, an amendment was added late in the study to collect x-rays at each subject's final visit allowing for comparison to baseline OA status. Fifty-one radiographs were collected, 24 of which were from patients originally treated with CRFA. While most of these patients (58.3%; 14/24) (95% CI 38.6 to 78.1) had no change in knee OA grade through 12 months, a worsening by one grade was detected in 8.3% (2/24) (95% CI 0.0 to 19.4) of the cohort. In the XO group, 27 radiographs were collected 6 months post-CRFA. These images revealed that 81.5% (22/27) (95% CI 66.8 to 96.1) of grades remained the same as reported at study entry, and worsening by one grade was identified in 7.4% (2/27) (95% CI 0.0 to 17.3) of this group. No patients worsened by more than one grade during the study.

Adverse events

There were 81 AEs that occurred among 42 CRFA patients between 6 and 12 months of the study. Non-SAEs included pain in the index knee (nine events—one of which led to subject discontinuation), with a decision to pursue a surgical alternative (1; [figure 1**](#)), pain in the non-index knee (3), musculoskeletal pain (9), and falls (5). SAEs occurred among four patients in the CRFA cohort from 6 to 12 months and included blood/lymphatic (3) and musculoskeletal (1) infections, cardiovascular (1), respiratory (3), gastrointestinal (1), and skin (1) events, and a non-CRFA procedure-related event that involved a musculoskeletal component. None of the SAEs were related to CRFA.

DISCUSSION

The effect of CRFA to reduce index knee pain by at least 50% in the majority of the originally treated CRFA study group was sustained at 12 months and validated a portion of the study hypothesis, as 65% of this cohort experienced this benefit. The mean 4.3-point decrease on the NRS at 12 months compared well with 4.9-point drop that was observed at 6 months.¹² Patients who elected to have CRFA after originally being treated with an IAS also reported analgesia, as the mean NRS pain score in the XO group fell at least 3.1 points up to 6 months post-procedure, and 49% of this population had at least 50% pain relief at 6 months, which confirmed the other portion of the study hypothesis. It is unknown why a difference in response was seen between the originally treated group and the XO group; however, the study was not powered or designed to draw specific conclusions from the XO group and this group should be considered observational given their participation and pathway in the trial. From a functional perspective, after CRFA, the incidence of patients having 'satisfactory joint function' was established and increased throughout the study in both cohorts, while the incidence of patients having 'severe arthritis' diminished with time in both groups. The majority of the originally treated and XO CRFA groups reported 'improved' perceptions of treatment effect on their health at 12 months and across all follow-up visits, respectively. Mean analgesic medication use was similar to baseline at 12 months in the originally treated CRFA group, and no unanticipated AEs occurred as a result of CRFA.

An effect of CRFA on opioid use in this investigation was not detected. As noted in the previous publication,¹² multiple factors affected our ability to detect a difference in this area, including the duration at which subjects were on opioids prior to the trial, the addictive nature of opioids and the fact that nearly half of the subjects in the CRFA group were taking opioids for reasons beyond their knee pain. However, opioid use stayed consistent

with baseline during the trial; therefore, the trial results noted are unlikely to be confounded by these medications.

Interestingly, for the patients described above who were not taking opioids to manage their pain at study baseline ((14/67) of the original CRFA group), 11 (79%) patients indicated $\geq 50\%$ relief of their baseline reported index knee pain at 6 months and their 6.1 mean NRS point reduction was larger than the study wide 4.9-point decrease. Adequately powered studies are warranted to explore the suggestion that CRFA treatment prior to opioid use may be most beneficial to mitigate OA-related knee pain.

As radiographic analysis was not completed through a central lab, assessment variability is to be expected. However, given that less than 9% of subjects in both CRFA groups experienced OA grade worsening during the study (in similar ratios), a concern that CRFA unreasonably accelerates joint degeneration seems unfounded.

The current treatment algorithm for knee OA has limited effectiveness, and patients often suffer for extended periods before they qualify for TKA. Chronic use of non-steroidal anti-inflammatory drugs can introduce gastrointestinal, cardiovascular, and renal complications¹⁸; opioids present the risk of tolerance and addiction with escalating dosage over time¹⁹; physical therapy requires routine visits that increase healthcare expenditures; corticosteroid injections have limited duration of efficacy^{20,21}; viscosupplementation efficacy is equivocal,^{22,23} as is platelet-rich plasma compared with viscosupplementation,^{24,25} and bracing may not be cost-effective.²⁶ A TKA is a well-established and successful procedure,^{1,2} but there are certain populations where one could argue for a more conservative option,²⁷ such as when patients are not yet considered 'operative', or have comorbid health issues that would preclude them from surgery or increase the risk profile for undergoing a TKA. A large subgroup of patients who may not be considered for TKA, such as those with poor glucose control and/or obesity, may become candidates following 6 months to 1 year of mobilization and weight loss afforded by undergoing CRFA first.

This study indicates that large percentages of patients can receive a durable analgesic effect from CRFA, which contrasts with other non-operative treatment options for patients with knee OA.²⁰⁻²⁵ Additionally, at the time of this publication, Santana *et al* produced the only standard RF knee OA series in the literature providing information to 12 months,⁷ with a mean NRS score reported of 5.8, compared with the mean NRS score of 3.1 in the current CRFA series. While few head-to-head studies exist comparing standard versus cooled radiofrequency directly, such observations are consistent with previous suggestions that the cooling characteristic of CRFA facilitates a larger lesion size than standard RF,²⁸ thus, making it more likely that target nerves will be ablated by the CRFA, and perhaps prolonging the time required to complete nerve regeneration.²⁹ Further study is needed to examine potential differences between the two technologies.

The beneficial outcomes observed in this current report with respect to CRFA treatment of knee OA extend the bibliography of publications having similar results using CRFA.⁹⁻¹¹ Our study is the largest prospective randomized comparison to date observing the changes in pain and disability in patients undergoing CRFA. Within this context, the results show that CRFA is safe and durable, thus providing patients who are ineligible for TKA with a seemingly more effective option than IAS,¹² and perhaps other conservative therapies, to gain relief from OA-related knee pain and disability. For those who are TKA candidates, but wish to postpone such a relatively more invasive intervention

in favor of CRFA first, evidence suggests benefits of RF-facilitated denervation in this scenario. Taverner *et al* demonstrated that pulsed RF, but not sham treatment, of patients with painful knees afforded them with a significant pain relief at rest and during exercise prior to total knee joint replacement.³⁰ Carli and co-workers used pulsed and thermal RFA to denervate nociceptive nerves of the knee¹³ of a 79-year-old woman with severe knee OA that required TKA.³¹ The patient had significant knee pain that was unrelieved by opioids, and severely impaired functional activity. The authors attributed significant improvement in the objective and self-reported outcome measures recorded during the 6 weeks of prehabilitation before surgery to the patient's denervation-facilitated preoperative analgesia. The successful prehabilitation was hypothesized to enable rehabilitation implementation post-TKA. The significant gains in functional improvement identified during this study warrant further exploration into this patient population, and large, adequately powered studies (ClinicalTrials.gov identifiers: NCT02746874 and NCT02925442) are in progress to investigate this seemingly purposeful synergistic clinical approach to knee OA between RF-mediated denervation and TKA.

A limitation of this study is the one-way XO option, from IAS to CRFA, but not vice versa. This paradigm is consistent with the intention of the study to test CRFA as a rescue intervention for knee OA, rather than long-standing, conservative IAS. The limitations of this portion of the study are that the remaining IAS group sample size was not large enough to perform statistical test-based comparisons between the originally treated CRFA patients and the IAS group members at 12 months, outcomes of the originally treated CRFA group and those of the XO cohort could not be directly compared at 6 months, because the groups were derived from two different study populations, and an effect of CRFA on opioid use could not be detected, perhaps due to alternate patient conditions that also utilized opioids as therapy. Further, the late addition of the amendment to collect X-rays at the final visit limited our ability to capture data on a large portion of the patients enrolled.

Statistically significant and clinically relevant pain relief and functional improvements were sustained 12 months following CRFA treatment of OA-related knee pain and dysfunction. These effects were reflected by patients' perceptions of their 'improved' health 12 months following CRFA. Moreover, CRFA may rescue patients who have been dissatisfied with results of prior IAS for OA knee pain and who are not candidates for TKA.

Contributors All authors equally contributed in completing this manuscript.

Funding Financial support was provided to each of the investigator's institutions by Halyard Health to cover the budgeted costs necessary to conduct this study protocol. Data management, study site monitoring and statistics services were performed by a third party, independently of Halyard Health.

Disclaimer This study and its 6-month results were presented as poster and platform abstracts at the American Society of Regional Anesthesia and Pain Medicine (ASRA) 2016 (November) Meeting in San Diego, California, USA, and the American Academy of Pain Medicine (AAPM) 2017 (March) Meeting in Orlando, Florida, USA, and have been published in manuscript form in Regional Anesthesia and Pain Medicine. The 12-month data in this report were presented at the European Society of Regional Anesthesia (ESRA) Congress 2017 in Lugano, Switzerland.

Competing interests TD, DePalma, MD, and LK are paid consultants (clinical advisory board) for Halyard Health.

Patient consent for publication Obtained.

Ethics approval This study was approved for engagement by the Western Institutional Review Board (IRB; Puyallup, Washington, USA) and Rush University Medical Center IRB (Chicago, Illinois, USA).

Provenance and peer review Not commissioned; externally peer reviewed.

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Next step: Proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- 1) Based on public comment was evidence overlooked in the process that should be considered?
- 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: Final determination

Following review of the proposed findings and decision document and public comments:

Final vote

- Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or unclear outcome (i.e., tie), chair will lead discussion to determine next steps.