Washington State Health Care Authority

Sacroiliac joint fusion

Clinical Expert

Conor P. Kleweno, MD

Assistant Professor, Department of Orthopaedics and Sports Medicine
University of Washington School of Medicine

Orthopaedic Trauma Surgeon
Harborview Medical Center

Applicant Name	Conor Kleweno
Address	325 9th ave
	Seattle wa 98104
	Department of Orthopaedics and Sports Medicine

1. Business Activities

(a) If you or a member of your household was ***an officer or director of a business*** during the immediately preceding calendar year and the current year to date, provide the following:

Title	Business Name & Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) If you or a member of your household ***did business under an assumed business name*** during the immediately preceding calendar year or the current year to date, provide the following information:

Business Name	Business Address	Business Type
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

2. Honorarium

If you ***received an honorarium of more than $100*** during the immediately preceding calendar year and the current year to date, list all such honoraria:

Received From	Organization Address	Service Performed
AO North America	435 Devon Park Drive Building 800, Suite 820 Wayne, PA 19087	Educational lecturer
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

3. Sources of Income

(a) Identify ***income source(s) that contributed 10% or more of the combined total gross household income*** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

Source Name & Address	Received By	Source Type
University of Washington	Myself	Salary
UW Physicians	Myself	Salary

Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☒ Yes ☒ No

If "yes", describe: Click here to enter text.
Sometimes I treat SI joint injuries
Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes ☒ No

If "yes", describe: Click here to enter text.
Click here to enter text.
Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household ***shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist***, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

Lobbyist Name	Business Name	Type Business Shared
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (***not amounts***) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

Income Source	Address	Description of Income Source
Globus Medical	2560 General Armistead Avenue Audubon, PA 19403 *phone:* (610) 930-1800	Consultant for design of tibia fracture nail
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

6. Business Investments of More Than $1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

Business Name	Business Address	Description of Business
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.

7. Service Fee of More Than $1,000

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each ***person for whom you performed a service for a fee of more than $1,000*** in the immediate preceding calendar year or the current year to date.

Name	Description of Service
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

Print Name Conor Kleweno

Check One: ☒ Committee Member ☐ Subgroup Member ☐ Contractor → Clinical Expert

[redacted]

Signature 1/9/19 Date

Curriculum Vitae

Conor Patrick Kleweno, MD
Assistant Professor
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Fax: 206.744.3227
[redacted]
ckleweno@uw.edu

EDUCATION

MD	**Harvard Medical School**, Boston, MA Doctor of Medicine (MD) Cum Laude	8/28/2002 – 6/7/2007
Undergraduate	**University of Washington**, Seattle, WA BSE Bioengineering Magna Cum Laude	9/30/1996 – 6/8/2001

POSTGRADUATE TRAINING

Fellowship	Orthopaedic Trauma Fellowship R Adams Cowley Shock Trauma Center University of Maryland Medical Center Baltimore, MD Program Director: Robert O'Toole	8/1/2012 – 7/31/2013
Residency	Combined Orthopaedic Residency Program Harvard University Boston, MA	6/17/2008 – 6/30/2012
Internship	General Surgery Internship Program Beth Israel Deaconess Hospital Harvard University Boston, MA	6/18/2007 – 6/17/2008

FACULTY POSITIONS HELD

Assistant Professor — Seattle, Washington
Department of Orthopaedics and Sports Medicine — 9/5/2013 – Present
Harborview Medical Center
University of Washington School of Medicine

HOSPITAL POSITIONS HELD

Attending Orthopaedic Surgeon — Seattle, Washington
University of Washington — 11/15/13 – Present
Department of Orthopaedics
Northwest Hospital and Medical Center

Attending Orthopaedic Surgeon — Seattle, Washington
University of Washington — 9/5/2013 – Present
Department of Orthopaedics
Harborview Medical Center

Attending Orthopaedic Surgeon — Seattle, Washington
University of Washington — 9/5/2013 – Present
Department of Orthopaedics
University of Washington Medical Center

HONORS AND AWARDS

2018 AOA Traveling Fellowship Recipent — 5/2018
In association with Japanese Orthopaedic Association

Orthopaedic Trauma Association — 3/10/18 - Present
Nominated to Membership Committee

Western Orthopaedic Association — 6/5/17 - Present
Nominated as Board Member

AO Trauma North America — 6/2017 - Present
Nominated to Fellowship Committee Member

2016 Washington State Orthopaedic Association
Nominated as Board Member — 9/18/16 - Present

2016 Washington State Medical Association
Nominated to Young Physician Section Council Member — 9/12/16 – 10/28/17

2016 Washington State Medical Association
Leadership Development Conference Scholarship Recipient — 2/19/16

UW Medicine Fall Cares Award — 9/2014
Harborview Medical Center
Seattle, WA.

Best Trauma Poster Award, AAOS 2014 Meeting — 3/11/14
New Orleans, LA

William Thomas Award, Overall Outstanding Resident — 2012

Harvard Combined Orthopaedic Residency Program

Chief Resident 2011
Harvard Combined Orthopaedic Residency Program

Resident Leadership Forum Nominee 2011
American Orthopaedic Association (AOA)

Candidate, Health Policy Center of Expertise Certificate Program 2011
Massachusetts General Hospital

Partners in Excellence Award for Quality Treatment and Service 2010
Massachusetts General Hospital

Participant, Value-based Health Care Delivery Intensive Seminar 2010
Harvard Business School

1st Place, Top Research Award in Orthopaedics 2006
National Student Research Forum

1st Place, Best Overall Clinical Science Presentation 2006
Eastern-Atlantic Student Research Forum

Doris Duke Clinical Research Fellowship 2005
Columbia University College of Physicians & Surgeons

Rhodes Scholarship Competition 2001
Washington State Finalist

Howard Wahl Endowed Scholarship: Top bioengineering student 2000

Bioengineering Education Technologies Summer Program Scholar 2000
Northwestern University

Barry M. Goldwater National Research Scholarship 1999

Howard Hughes Medical Research Summer Scholarship 1998-1999

NSF Research Experience for Undergraduates (REU) 1999
University of Washington

CERTIFICATIONS

American Board of Orthopaedic Surgery: Board Certified

Part I (Written):	Passed 7/12/2012
Part II (Oral)	Passed 7/23/2015

CURRENT LICENSE

Washington	60378333	6/27/2013 – Present

PREVIOUS LICENSE(S)

Massachusetts	247217	4/6/2011 – 10/28/2015

PROFESSIONAL ORGANIZATIONS

National

American Academy of Orthopaedic Surgeons, Fellow and Active Member

AOTrauma, Faculty

AOTrauma North America, Board Member
Trauma Fellowship Board Member (2017 – Present)

Orthopaedic Trauma Association, Active Member
Membership Committee Member (9/2018 – 9/2021)

Regional

Western Orthopaedic Association 6/5/17 - Present
- Board Member

Washington State Orthopaedic Association
- Board Member 9/18/16 - Present

Washington State Medical Association
- Young Physician Section Council Member 9/12/16 – 10/28/17

RESEARCH

Actively Funded

Validation of PROMs in Trauma Patients with Pelvic and Acetabular Fractures. OREF Prospective Clinical Research Grant. Cizik AM (PI), **Kleweno CP (Co-PI).** $150,000. 7/1/18 – 6/30/21.

PREVENTion of CLot in Orthopaedic Trauma (PREVENT CLOT): A Randomized Pragmatic Trial Comparing the Complications and Safety of Blood Clot Prevention Medicines Used in Orthopaedic Trauma Patients (As part of the Major Extremity Trauma Research Consortium (METRC)). **Kleweno CP (Site administrative Co-PI).** $11.2million (multicenter), 2016

An imaging framework for clinically testing new treatments to prevent post-traumatic arthritis (multi-center study). **Kleweno CP (Site PI).** $79,000 OTA Grant, 2017

Patient Reported Outcome Measures in Pelvis and Acetabular Fracture Patients Using the PROMIS Physical Function Test. **Kleweno CP (PI).** $15,500. 5/2015

Johns Hopkins University. *Streamlining Trauma Research Evaluation with Advanced Measurement: STREAM Study.* **Kleweno CP (Site PI).** 4/24/14

University of Washington New Faculty Research Grant. *A Novel Teaching Simulator for Percutaneous Placement of Iliosacral Screws*. **Kleweno CP (PI).** $12000. 3/2014

Johns Hopkins University. *Supplemental Perioperative Oxygen to Reduce Surgical Site Infection After High Energy Fracture Surgery.* **Kleweno CP (Site CO-Investigator).** 12/11/13

Previously Funded

Johns Hopkins University. *A Prospective Randomized Trail to Assess PO versus IV Antibiotics for the Treatment of Early Post-op Wound Infection after Extremity Fractures.* **Kleweno CP (CO-PI).** 11/13/13

BIBLIOGRAPHY

Part A: Peer Reviewed Journal Articles

1. **Kleweno CP**, Murr K, Refaat M, Githens M, Thayer MK, Davies J. Are retrograde nails better for distal femur fractures in obese patients? (In submission)

2. Refaat M, Thayer MK, Firoozabadi R, **Kleweno CP**, Githens M. Nail or Plate? Supracondylar Distal Femur Fractures in the Elderly. (In submission)

3. Tannoury C, **Kleweno C**, Gary J, Kamath A. Comparison of opioid use and prescribing patterns in orthopedic surgery in Japan and the United States: A JOA-AOA Traveling Fellowship Investigation. 2018 October 3;100(19): e126.

4. Thayer MK, **Kleweno CP**, Lyons VH, Taitsman LM. Concomitant upper extremity fracture worsens outcomes in elderly patients with hip fracture. Geriatric Orthopaedic Surgery Rehabilitation. 2018 June. Doi: 1077/2151459318776101

5. Tarabadkar N, Alton T, Gorbaty J, Nork S, Taitsman L, **Kleweno CP**. Are the fractures we treat becoming more complex? Trends in orthopaedic fracture and injury severity, a Level-I trauma center experience. *Orthopedics.* 2018 Mar 1;41(2):e211-e216.

6. Rodrigues-Pinto R, Kurd MF, Schroeder GD, Kepler CK, Krieg JC, Holstein JH, Bellabarba C, Firoozabadi R, Oner FC, Kandziora F, Dvorak MF, **Kleweno CP**, Vialle LR, Rajasekaran S, Schnake KJ, Vaccaro AR. Sacral Fractures and Associated Injuries. *Global Spine J*. 2017 Oct;7(7):609-616.

7. McDonald C, Firoozabadi R, Routt ML, **Kleweno CP**. Incidence and risks in the development of pin-site infections after pelvic external fixation. *Orthopedics*. 2017 Nov 1;40(6):e959-e963.

8. Schroeder GD, Vaccaro AR, Kepler CK, Kurd MF, Krieg JC, **Kleweno CP**, et al. The Development of a Universally Accepted Sacral Fracture Classification: A Survey of AOSpine and AOTrauma Members. *Global Spine Journal*. 2016 November; 6(7): 686-694.

9. **Kleweno CP**, Bellabarba C. Lumbo-Pelvic Fixation for Pelvic Fractures. Operative Techniques in Orthopaedics. *Journal of Operative Techniques in Orthopaedics.* 2015 December; 25 (4): 270-281.

10. Firoozabadi R, Swenson A, **Kleweno C,** Routt MC. Cell Saver Use in Acetabular Surgery: Does Approach Matter? *J Orthop Trauma*. 2015 Aug;29(8):349-53.

11. **Kleweno CP,** O'Toole RV, Ballreich J, Pollak AN. Does Fracture Care Make Money for the Hospital? An Anyalsis of Hospital Revenues and Costs for Treatment of Common Fractures. *J Orthop Trauma*. 2015 Jul;29(7):e219-24.

12. **Kleweno CP,** Morgan J, Redshaw J, Harris M, Rodriguez E, Zurakowski D, Vrahas M, Appleton P. Short versus Long Cephalomedullary Nails for the Treatment of Intertrochanteric Hip Fractures in Patients over 65 Years. J Orthop Trauma. 2014 July 28 (7): 391-7

13. **Kleweno CP,** Jawa A, Wells JH, O'Brien TG, Harris MB, Higgins LD, Warner JP. Midshaft Clavicle Fractures: Comparison of Intramedullary Pin and Plate Fixation. *J Shoulder Elbow Surg.* 2011 Oct;20(7):1114-7.

14. McCormick F, **Kleweno CP,** Kim YJ, Martin SD. Vascular safe zones in hip arthroscopy. *Am J Sports Med*. 2011 Jul;39 Suppl:64S-71S.

15. **Kleweno CP**, Jacir AM, Gardner TR, Ahmad CS, Levine WN. Biomechanical evaluation of ACL femoral fixation techniques. *Am J Sports Med.* 2009 Feb;37(2):339-45.

16. **Kleweno CP,** Bryant WK, Jacir AM, Levine WN, Ahmad CS. Discrepancies and rates of publication in orthopaedic sports medicine abstracts. *Am J Sports Med*. 2008;Oct:36(10):1875-9.

17. **Kleweno CP**, Zampini JM, White AP, Kasper EM, McGuire KJ. Survival after concurrent traumatic dislocation of the atlanto-occipital and atlanto-axial joints: a case report and review of the literature. *Spine.* 2008 Aug;15;33(18).

18. Carter CW, **Kleweno CP,** Levine WN. Assessment of shoulder range of motion: introduction of a novel patient self-assessment tool. *Arthroscopy.* 2008 Jun;24(6):712-7.

19. Ahmad CS, **Kleweno CP**, Jacir AM, Bell JE, Gardner TR, Levine WN, Bigliani LU. Biomechanical performance of rotator cuff repairs with humeral rotation: a new rotator cuff repair failure model. *Am J Sports Med.* 2008 May;36(5):888-92.

20. Vitale MA, **Kleweno CP**, Jacir AM, Levine WN, Bigliani LU, Ahmad CS. Training resources in arthroscopic rotator cuff repair. *J Bone Joint Surgery.* 2007;89:1393-1398.

21. Kleweno CP. Seibel EJ. Viirre ES. Kelly JP. Furness TA 3rd. The virtual retinal display as a low-vision computer interface: a pilot study. *Journal of Rehabilitation Research & Development*. 38(4):431-42, 2001.

22. Walsh JT, McKenna A, **Kleweno CP**, Wu P (2001). Teaching engineering bio-optics with a challenge-based approach. *Annals of Biomedical Engineering*. Vol. 29 supplement 1 page S-106. Durham, NC

Part B: Non-Peer Reviewed Articles

1. **Kleweno CP.** Case Report: Acute total hip arthroplasty as treatment for intertrochanteric hip fracture in the setting of end-stage arthritis. University of Washington Department of Orthopaedics and Sports Medicine Discoveries 2014. pp. 63-64.

Part C: Book Chapters

1. Hebert-Davies J, **Kleweno CP**. Tibia and Fibula Shaft Fractures. In: Synopsis of Orthopaedic Trauma Management. 2017 (In Press)

2. **Kleweno CP**, Sagi HC. Treatment of Sacral Fractures. In: *Fractures of the Pelvis and Acetabulum.* 2017 (In submission)

3. Sullivan M, **Kleweno CP.** Lateral femoral nailing. In: Harborview Tips and Tricks, 2nd Ed. 2018 (In Press)

4. **Kleweno CP,** Rodriguez EK. Trimalleolar Ankle Fractures. In: Sethi M, Jahangir A, Obremskey W, eds. *Orthopedic Traumatology: An Evidence Based Approach. 2nd Edition.* Philadelphia, PA: Springer Science+Business Media LLC. 2018 (In Press)

5. Yuan B, **Kleweno CP.** Fractures of the Femur. In: *AAOS Let's Discuss Series.* 2016

6. Firoozabadi R, **Kleweno CP.** Acetabular Fractures: Evaluation and Management. *Orthopaedic Knowledge Update: Trauma 5.* William M. Ricci, MD, and Robert F. Ostrum, MD, Eds. 2016

7. **Kleweno CP,** Rodriguez EK. Trimalleolar Ankle Fractures. In: Sethi M, Jahangir A, Obremskey W, eds. *Orthopedic Traumatology: An Evidence Based Approach.* Philadelphia, PA: Springer Science+Business Media LLC, 2012, Chapter 23, pp. 345-350.

Part D: Recent Abstracts

1. Murr K, Refaat M, Githens M, Thayer MK, Hebert-Davies J, **Kleweno CP.** Are retrograde nails better for distal femur fractures in obese patients? Podium Presentation. American Academy of Orthopaedic Surgeons Annual Meeting, New Orleans, LA, March 6-10, 2018.

2. Cizik A, **Kleweno CP**. Measuring Patient-Reported Outcomes (PROs) in a High Volume Trauma Clinic in Pelvis and Acetabular Fracture Patients Using PROMIS® CAT: A Preliminary Study. Poster presented at the 3rd Annual Meeting of the PROMIS® Health Organization (PHO), Philadelphia, PA. October 17, 2017.

3. Murr K, Refaat M, Githens M, Thayer MK, Hebert-Davies J, **Kleweno CP.** Are retrograde nails better for distal femur fractures in obese patients? Poster Presentation. Orthopaedic Trauma Association Annual Meeting, Vancouver, BC, October 11-14, 2017.

4. Murr K, Refaat M, Githens M, Thayer MK, Hebert-Davies J, **Kleweno CP.** Are retrograde nails better for distal femur fractures in obese patients? Podium Presentation. Western Orthopaedic Association Annual Meeting. Kauai, Hi. 8/3/2017.

5. Gregory D. Schroeder MD, Alexander R. Vaccaro MD, MBA, PhD, Christopher K. Kepler MD, MBA, Mark F. Kurd MD, James C. Krieg MD, **Conor P. Kleweno MD**, Reza Firoozabadi MD, Frank Kandizoria MD, Klause J. Schnake MD, S. Rajesekaran, Jorg H. Holstein MD, Henry C. Sagi. MD, Marcel F. Dvorak MD, Luiz R. Vialle MD, F.C. Oner MD, Carlo Bellabarba MD, Jens R. Chapman, MD. The Development of a Universally Accepted Sacral Fracture Classification: A Survey of AOSpine and AOTrauma Members. Podium Presentation. Global Spine Congress. Dubai, UAE. 4/13/16 – 4/16/16

6. Gregory D. Schroeder MD, Alexander R. Vaccaro MD, MBA, PhD, Christopher K. Kepler MD, MBA, Mark F. Kurd MD, James C. Krieg MD, **Conor P. Kleweno MD**, Reza Firoozabadi MD, Frank Kandizoria MD, Klause J. Schnake MD, S. Rajesekaran, Jorg H. Holstein MD, Henry C. Sagi. MD, Marcel F. Dvorak MD, Luiz R. Vialle MD, F.C. Oner MD, Carlo Bellabarba MD, Jens R. Chapman, MD. The role of CT and MRI in the classification and assessment of thoracolumbar fractures. Poster Presentation. Global Spine Congress. Dubai, UAE. 4/13/16 – 4/16/16

7. McDonald C, Firoozabadi R, Agel J, **Kleweno CP**. Incidence and risks in the development of pin-site infections after pelvic external fixation. 2016 Western Regional Meeting. Carmel, CA. 1/28/16 – 1/30/16.

8. Tarabadkar N, Alton T, Gorbaty J, Taitsman L, Nork S, **Kleweno CP**. Are the fractures we treat becoming more complex? Trends in orthopaedic fracture and injury severity – a level-I trauma center experience. Scientific Poster. Orthopaedic Trauma Association Annual Meeting. Tampa, FL. 10/14/14 – 10/18/14

9. Alton T, Tarabadkar NS, Nork S, Taitsman L, **Kleweno CP.** Are the fractures we treat becoming more complex? Trends in orthopaedic fracture and injury severity, a level-I trauma center experience. Podium Presentation. Western Orthopaedic Association Annual Meeting. Big Island, HI. 8/1/2014

TEACHING RESPONSIBILITIES

Part A: Invited Lectures, Courses and Grand Rounds

1. AAOS Annual Meeting Instuctional Course Lecture (ICL): Management of Pelvic Fractures. ***Moderator.*** New Orleans, LA. 3/6/18.

2. AAOS/OTA Fractures of the Pelvis and Acetabulum: Case Controversies and Avoiding Complications. ***Invited Course Instructor****.* OLC Education and Conference Center, Rosemont, IL. Nov 2-4, 2017.

3. AOTrauma Course Basic Principles of Fracture Management. ***Invited Lecturer and Table Instructor****.* Phoenix, AZ. 9/14/17 – 9/17/17.

4. AOTrauma Course Basic Principles of Fracture Management. ***Invited Lecturer and Table Instructor****.* Bellevue, WA. 8/17/17 – 8/20/17.

5. AOTrauma Pelvic and Acetabular Fracture Management Course. ***Invited Lecturer and Table Instructor***. Chicago, IL. 6/1/17 – 6/4/17.

6. University of Cincinnati Trauma 101 Fracture Care. ***Invited Course Faculty***. Clearwater, FL. 5/11/17 – 5/13/17.

7. Pelvic Ring Injuries: A Novel Sacral Fracture Classification and the Seattle Experience. ***Invited Lecturer***, UCLA-Harbor Orthopaedic Grand Rounds. Los Angeles, CA. 4/19/17.

8. AOTrauma Course Basic Principles of Fracture Management. ***Invited Lecturer and Table Instructor***. Dallas, TX. 3/8/17 – 3/12/17.

9. AOTrauma Course Advanced Principles of Fracture management. ***Invited Lecturer and Table Instructor***. Phoenix, AZ. 11/17/16 – 11/20/16.

10. AOTrauma Course Advanced Principles of Fracture Management. ***International Invited Course Faculty***. Queenstown, New Zealand. 8/30/16 – 9/2/16

11. AOTrauma Basic Principles of Fracture Management. ***Invited Lecturer and Table Instructor***. Minneapolis, MN. 8/17/16 – 8/21/16

12. AAOS/OTA Orthopaedic Trauma Update. ***Invited Lecturer and Table Instructor***. La Jolla, CA. 3/31/16 – 4/2/16

13. Pelvic Ring Injuries: A Novel Sacral Fracture Classification and the Seattle Experience. ***Invited Lecturer***, Harvard Orthopaedic Grand Rounds. Boston, MA. 1/27/16.

14. AOTrauma Advanced Principles of Fracture Management. ***Invited Lecturer and Table Instructor***. New Orleans, LA. 2/25/15 – 3/1/15

15. AO Basic Principles of Fracture Management Course for Residents. ***Invited Lecturer and Table Instructor***. Atlanta, GA. 10/23/14 – 10/26/14

Part B: National Meeting Invited Panel Discussions

1. Stover MD, Mayo KA, **Kleweno CP,** Sems SH. "Current Standards of Pelvic Ring Injury Evaluation, Acute Management, Decision Making, Surgical Techniques, and Complication Avoidance." AAOS Annual Meeting ICL. San Diego, CA. 3/16/17.

2. Sassoon A, **Kleweno CP**, Schemitsch E. Mini Symposium: Lower Extremity Arthroplasty: Unreconstructable Articular Fractures Periprosthetic Fractures, and Failed Fixation. Orthopaedic Trauma Association Annual Meeting. National Harbor, MD. *Faculty*. 10/8/16.

3. Gary JL, Guy P, **Kleweno CP**, Sagi HC, Starr AJ. Pelvic ring disruption decision making: assessment of stability, strategies of fixation, and determining what needs to be fixed. Orthopaedic Trauma Association Annual Meeting. San Diego, CA. 10/9/15

4. Sciadini M, Chesser T, **Kleweno CP**, Reilly M, Starr AJ. Mini Symposium: Techniques and Controversies in Treatment of Acetabular Fractures. Orthopaedic Trauma Association Annual Meeting. National Harbor, MD. *Faculty.* 10/7/16

5. Nascone J, Gary JL, Guy P, **Kleweno CP**, Sagi HC, Starr AJ. Pelvic Ring Disruption Decision Making: Assessment of Stability, Strategies of Fixation, and Determining What Needs To Be Fixed. Mini Symposia. Orthopaedic Trauma Association Annual Meeting. San Diego, CA. Oct. 9, 2015

6. Doro C, Gardner MJ, **Kleweno CP**, Summers H. Nascone J. Distal Femur Cases. Case Presentations. Orthopaedic Trauma Association Annual Meeting. Tampa, FL. Oct. 14, 2014

Part C: National Teaching Responsibilities

1. Residents Comprehensive Fracture Course. Polytrauma, Pelvis, and Acetabulum. 2017 Orthopaedic Trauma Association Annual Meeting. Vancouver, B.C. ***Module Leader***. October 11-14, 2017

2. Institute for Global Orthopaedics and Traumatology (*IGOT)* 2017 SMART Course. San Francisco, CA. ***Invited Course Instructor***. September 17-19, 2017.

3. Residents Comprehensive Fracture Course. Polytrauma, Pelvis, and Acetabulum. 2016 Orthopaedic Trauma Association Annual Meeting. National Harbor, MD. ***Module Leader***. October 5-7 2016

4. 1st Annual Pre-SIGN Fracture Care Hands-On Cadaveric Course. ***Course Co-Chair***. Seattle Science Foundation. Seattle, WA. 9/19/16 – 9/20/16

5. Scientific Paper Session IV: Pelvis and Acetabulum. Orthopaedic Trauma Association Annual Meeting. San Diego, CA. *E-Moderator.* 10/9/15

6. 2015 Orthopaedic Trauma Association. Pelvic and Acetabular Fractures. 2015 Annual OTA Meeting. San Diego, CA. *Lecturer*. 10/9/15

7. 2015 Orthopaedic Trauma Association Boot Camp Skills Lab. Nailing Proximal Tibia. 2015 Annual OTA Meeting. San Diego, CA. *Lab Table Instructor*. 10/8/15

8. Scientific Paper Session IV: Pelvis and Acetabulum. Orthopaedic Trauma Association Annual Meeting. Tampa, FL. *E-Moderator.* 10/17/14

Part D: Other Local Teaching Responsibilities

1. Continuing Paramedic Education Series. Pelvis Fractures: From Field to Operating Room. Program put on by the Michael K. Copass, MD Paramedic Training Program to further the ongoing education of Paramedics. (More than 100 paramedics attended in person, and the program was broadcasted throughout the WWAMI States. *Invited Lecturer*. 11/7/17

2. Resident Conference: Acetabular Fracture Management. Harborview Medical Center. Seattle, WA. *Lecturer*. 5/9/16

3. Resident Conference: Pelvic Ring. Seattle, WA. Harborview Medical Center. *Lecturer.* 4/25/16

4. Pelvic Fractures. Physical Therapy All Staff Meeting. Seattle, WA. *Lecturer.* 1/13/16

5. DePuy Synthes Lower Extremity SMART Lab. Seattle, WA. *Table Instructor, Lecturer.* 9/12/15

6. Resident Cadaver Session: Acetabular Surgical Approaches. Harborview Medical Center, Seattle, WA. *Lecturer.* 6/22/15

7. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. "Hip and Thigh/Sacral Plexus, Gluteal and posterior Thigh Living and Gross Sessions." *Table Instructor and Lecturer.* 2/19/15

8. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. "Lumbar Plexus and Thigh Living and Gross Sessions." *Table Instructor and Lecturer.* 2/12/15

9. Resident Case Presentations: Damage Control Orthopaedics and Coordinated Multispecialty Care. 2015 LeCocq Lectureship. Seattle, WA. *Moderator*. 1/29/15

10. Resident Case Presentations: Pelvic and Acetabular Fractures. 2015 LeCocq Lectureship. Seattle, WA. *Moderator*. 1/29/15

11. Clinical Preceptorship in Orthopaedic Surgery (Class ORTHP 505 P). Shoaib Fakhri (UW Medical Student). *Preceptor and Mentor*. 1/2015 – 3/2015

12. Clinical Preceptorship in Orthopaedic Surgery (Class ORTHP 505 P). David Yu (UW Medical Student). *Preceptor and Mentor*. 9/2014 – 12/2014

13. University of Washington Junior Resident Friday Morning Teaching Session (Harborview Medical Center), Seattle, WA. "Femoral Shaft Fractures." *Group Discussion Leader.* 4/25/14

14. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA." Knee Joint and Leg Gross Session." *Table Instructor and Lecturer.* 2/27/14

15. Musculoskeletal Systems HuBio Course 553 (University of Washington Medical Center), Seattle, WA. "Hip and Thigh Living and Gross Sessions." *Table Instructor and Lecturer.* 2/20/14

16. Pelvis/Acetabulum Fellow Session (Harborview Medical Center), Seattle, WA. "Recent Acetabular Fractures Case Presentations." *Group Discussion Leader*. 2/6/14

17. Clinical Preceptorship in Orthopaedic Surgery (Class ORTHP 505 P). Sawley Wilde (UW Medical Student). *Preceptor and Mentor*. 1/2014 – 3/2014.

18. Pelvis/Acetabulum Fellow Session (Harborview Medical Center), Seattle, WA. "Pelvic Ring Disruptions." *Group Discussion Leader*. 12/19/13

19. University of Washington Junior Resident Friday Morning Teaching Session (Harborview Medical Center), Seattle, WA. "Pathologic Fractures." *Group Discussion Leader.* 9/27/2013

Presentations

Part A: International Presentations

1. Routt ML, **Kleweno CP,** Eastman JG, Krieg JC. Modern and Reliable Techniques for the Urgent Treatment of Unstable Pelvic Ring Injuries. OTA Webinar, March 20, 2018.

2. McCormick FM, **Kleweno CP**, Kim YJ, Martin SD. Vascular safe zones during hip arthroscopy. Podium Presentation. 8th Biennial International Society of Arthroscopy, Knee Surgery, and Orthopaedic Sports Medicine Congress, Rio de Janeiro, Brazil May 15-19, 2011.

3. McCormick FM, **Kleweno CP**, Kim YJ, Martin SD. Vascular safe zones during hip arthroscopy. Podium Presentation. International Society for Hip Arthroscopy Annual Scientific Meeting. Cancun, Mexico, Oct. 2010.

Part B: National Presentations

1. Murr K, Refaat M, Githens M, Thayer MK, Hebert-Davies J, **Kleweno CP.** Are retrograde nails better for distal femur fractures in obese patients? Podium Presentation. American Academy of Orthopaedic Surgeons Annual Meeting, New Orleans, LA, March 6-10, 2018.

2. Cizik A, **Kleweno CP**. Measuring Patient-Reported Outcomes (PROs) in a High Volume Trauma Clinic in Pelvis and Acetabular Fracture Patients Using PROMIS® CAT: A Preliminary Study. Poster presented at the 3rd Annual Meeting of the PROMIS® Health Organization (PHO), Philadelphia, PA. October 17, 2017.

3. Murr K, Refaat M, Githens M, Thayer MK, Hebert-Davies J, **Kleweno CP.** Are retrograde nails better for distal femur fractures in obese patients? Poster Presentation. Orthopaedic Trauma Association Annual Meeting, Vancouver, BC, October 11-14, 2017.

4. **Kleweno CP,** O'Toole RV, Ballreich J, Pollak AN. Does fracture care make money for the hospital? An analysis of hospital revenue and cost for treatment of common fractures. Poster Presentation. American Academy of Orthopaedic Surgeons Annual Meeting. New Orleans, LA, March 11-15, 2014.

5. **Kleweno CP,** O'Toole RV, Ballreich J, Pollak AN. Does fracture care make money for the hospital? An analysis of hospital revenue and cost for treatment of common fractures. Podium Presentation. Orthopaedic Trauma Association Annual Meeting, Phoenix, AZ, October 9-12, 2013.

6. McCormick FM, **Kleweno CP**, Kim YJ, Martin SD. Vascular safe zones during hip arthroscopy. Poster Presentation. Arthroscopy Association of North America Annual Meeting, San Francisco, CA, April 14-16, 2011.

7. McCormick FM, **Kleweno CP**, Kim YJ, Martin SD. Vascular safe zones during hip arthroscopy. Podium Presentation. American Academy of Orthopaedic Surgeons 2011 Annual Meeting, San Diego, CA, Feb. 15-19, 2011.

8. **Kleweno CP**, Jawa A, Wells J, O'Brian T, Higgins LD, Harris MB, Warner JJ. Middle-third diaphyseal clavicle fractures: comparison of intramedullary pin and plate fixation. Poster Presentation. Eastern Orthopaedic Association's Annual Meeting, Naples, FL, Oct. 2010.

9. Levine WN, **Kleweno CP**, Bigliani LU, Ahmad CS, Carter CW. Shoulder range of motion: introduction of a novel self-assessment tool. Poster Presentation. American Academy of Orthopaedic Surgeons 2008 Annual Meeting, San Francisco, CA. Mar. 2008.

10. Levine WN, **Kleweno CP**, Vitale MA, Jacir AM, Ahmad CS, Bryant W. Comparison of publication rates and inconsistencies of abstracts presented at national meetings. Podium Presentation. American Academy of Orthopaedic Surgeons 2007 Annual Meeting, San Diego, CA. Feb. 2007.

11. Jain SH and **Kleweno CP**. Health system literacy as a core competency in medical education. Invited Presentation, Gold Humanism Honor Society Biennial Conference. The Arnold P. Gold Foundation, Chicago, IL, Sept. 2006.

12. Ahmad CS, **Kleweno CP**, Jacir AM, Bell JE, Gardner TR, Levine WN, Bigliani LU. Biomechanical performance of rotator cuff repairs with humeral rotation: a new rotator cuff repair failure model. Podium Presentation. Annual American Orthopaedic Society for Sports Medicine Meeting, Hershey, PA, July 1, 2006.

13. **Kleweno CP**, Jacir AM, Gardner TR, Ahmad CS, Levine WN, Bigliani LU. Clinical and biomechanical analysis of rotator cuff repair. Podium Presentation. National Student Research Forum 47th Annual Meeting, Galveston, Texas, April 27-28, 2006.

14. **Kleweno CP**. Spanish language program in Guatemala: an opportunity in service learning. 64th Annual Soma Weiss Student Research Day, Harvard Medical School, April 2004.

15. Walsh, JT, McKenna A, **Kleweno CP**, and Wu P. (2001). Teaching engineering bio-optics with a challenge-based approach. Biomedical Engineering Society Annual Conference, BMES Durham, NC, Oct. 4-7, 2001.

16. **Kleweno C.**, Seibel E., Kloeckner K., Viirre E., and Furness TA. Evaluation of a scanned laser display as an alternative low vision computer interface. Technical Digest of Vision Science and Its Applications Topical Meeting, Santa Fe, NM, Feb 19-22, 1999.

Part C: Regional Presentations

1. Murr K, Refaat M, Githens M, Thayer MK, Hebert-Davies J, **Kleweno CP.** Are retrograde nails better for distal femur fractures in obese patients? Podium Presentation. Western Orthopaedic Association Annual Meeting. Kauai, Hi. 8/3/2017.

2. **Kleweno CP, Taitsman LA.** Overnight emergencies (pulseless limbs, pulse-ox on limbs, ABIs), PEs, Compartment Syndrome. University of Washington Orthopaedic Residency Bootcamp. University of Washington. Seattle, WA. 6/17/16

3. **Kleweno CP.** Orthopaedic Emergencies. University of Washington Orthopaedic Residency Bootcamp. University of Washington. Seattle, WA. 6/26/15

4. **Kleweno CP.** Orthopaedic Emergencies. Orthopedic Trauma Panel, Paramedic Training Program. Harborview Medical Center. Seattle, WA. 5/5/15

5. **Kleweno CP.** Orthopaedic Emergencies. West Region EMS Conference. Ocean Shores, WA. 2/22/15

6. **Kleweno CP.** Pelvic Surgery. Harborview Medical Center Clinical Education In-Service Presentations. Seattle, WA. 7/30/14

7. **Kleweno CP.** Orthopaedic Surgery Emergencies. Orthopaedic Resident Bootcamp. Washington Faculty Club. Seattle, WA. 6/25/14

8. **Kleweno CP.** Pelvic Injuries: Field to Operating Room. Harborview Medical Center Paramedic Lecture Series. Seattle, WA. 5/6/14

9. **Kleweno, CP.** Proximal Femur Fractures. Harborview Medical Center Paramedic Lecture Series. Seattle, WA. 5/6/14

10. **Kleweno CP.** Orthopaedic Trauma: What We Do and How We Fix Things. Seattle Central Community College SURG 123 Course, Seattle, WA. 3/17/14

11. **Kleweno C**, Walsh J, Olds S, Kanter D, Miller M. Development of a web-based teaching module for light propagation in turbid media. Conference Proceedings of the Biomedical Engineering Society Annual Meeting, Seattle, WA October 12-14, 2000

EDITORIAL RESPONSIBILITIES

Journal of the American Academy of Orthopaedic Surgeons 6/2017 - Present
Reviewer

Healthcare: The Journal of Delivery Science and Innovation 6/2015 - Present
Reviewer

SPECIAL INTERNATIONAL RESPONSIBILITES

AOSpine Sacral Classification Working Group 5/14/15 – Present
Invited panelist and member for the international expert committee creating the AO Sacral Fracture Classification System

SPECIAL NATIONAL RESPONSIBILITIES

AO Trauma Fellowship Committee Member 6/2017 - Present

Orthopaedic Trauma Association 3/10/18 - Present
Nominated to Membership Committee

Major Extremity Trauma Research Consortium (METRC) 10/2013 - Present
Local Principle and Co-Principle Investigator

SPECIAL LOCAL RESPONSIBILITIES

Departmental

Director Quality Improvement Orthopaedic Trauma 1/1/2017 – Present
Department of Orthopaedic Surgery
Harborview Medical Center

Orthopaedic Resident Clinical Competency Committee 10/2015 - Present
Department of Orthopaedics and Sports Medicine

University of Washington

Resident Selection Committee *2013* – Present
Department of Orthopaedics and Sports Medicine
University of Washington

Trauma Fellow ACE Selection Committee *2013* – Present
Harborview Medical Center
University of Washington

SERVICE ACTIVITIES

Summer Health Professions Education Program (SHPEP) 6/1/16 – Present
Faculty Mentor/Supervisor
University of Washington
Seattle, WA

- Supervise and mentor undergraduate students, including overseeing their shadowing/observation expierence in a clinical/OR setting, to help foster the development of underrepresented student's interest in professions in the medical field.

Northwest Healthcare Network's Disaster Clinical Advisory Committee 3/16/18 – Present
Disaster Clinical Advisory Committee Surgical Subcommittee
Harborborview Medical Center

- Help hospitals throughout the region and the state prepare for mass casualty incidents, disasters, and pandemics. Create best practice guidelines for hospitals to follow in the event of limited resources, mass casualty events, or natural disasters.

Washington State Health Care Authority

Agency medical director comments

Sacroiliac Joint Fusion

Emily Transue, MD, MHA
Associate Medical Director, WA Health Care Authority

January 18, 2019

Washington State Health Care Authority

Background

- Low back pain: High burden of disease and disability (4-25% prevalence in adults)
- SI joint has been implicated as a pain source (some studies suggest 10-30% of low back pain may be from SI)
- Strong desire by patients and providers for effective treatments
- History of procedural overuse (spinal fusion, etc) with high costs and harm to patients highlights need for rigor in assessing evidence for treatment options

2

Sacroiliac joint fusion

- Theorizes that pain in the sacroiliac (SI) region is related to instability in the SI joint, and that mechanically stabilizing the joint with a screw or specialized device will decrease pain
- Candidates include surgically naïve patients, and also a significant number of patients with sacroiliac pain after lumbar fusion
- A variety of devices as well as surgical screws have been used, but trial data is almost exclusively about a specific device (iFuse), consisting of 2-4 triangular rods placed across the joint via minimally invasive surgery

3

Designated CPT/HCPCS

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

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

4

Current state agency policy

Agency	27279	27280
PEBB/UMP	**Covered** * Prior Auth required after 2/28/2019	Prior Auth
MEDICAID	**Not Covered**	Not Covered
LABOR AND INDUSTRIES	**Covered** With substantial trauma and demonstrated SI joint disruption	Prior Auth

5

Current utilization

2014 – 2017 Claims for Sacroiliac Joint Fusion

Fewer than 11 procedures paid by state-covered programs (threshold for public reporting of data)

6

Cost experience (HCA)

- Minimally invasive/closed fusion
  - Median billed charges: $19,000
  - Median allowed amount: $10,500

7

Agency medical director concerns

Safety = High
Efficacy = High
Cost = High

8

Key questions

- What is the evidence of efficacy and effectiveness for SI fusion compared to other active interventions, placebos, sham procedures, or no treatment?
- What direct harms are associated with SI fusion?
- Do important patient efficacy/effectiveness outcomes or direct harms from SI fusion vary by:
  - Indication, and
  - Patient characteristics
- What are the cost-effectiveness and other economic outcomes of SI fusion?

9

FDA approval limitations

- All devices were approved using 510(k) approval ("substantial equivalence" to other treatment or device on the market prior to 1976); none have had premarket approval (PMA) studies.

10

Limitations: lack of diagnostic gold standard

- Inclusion criteria vary: typically a combination of physical exam tests (3 out of 5 tests positive) and reduction of pain (variable degree, often 50% or 80%) with SI anesthetic injection (imaging-guided requirement variable)
- Poor reliability of physical exam: Kappa values for pooled parameters of inter-rater reliability for physical exam for SI joint pain <0.20
  - **Van Tilburg et al. J Back Musculoskel Rehabil 2017; 30: 551-557**
- An analysis using combined data from 2 trials (1 RCT [INSITE] and 1 uncontrolled trial [SIFI], total N = 320) found no relationship between level of immediate response to SI joint block (average percent decrease in pain after injection from 40% to 100%) and 6- and 12-month pain and disability scores among patients undergoing SI joint fusion.
  - **Polly D et al. Int J Spine Surg 2016; 10:4**

Data limitations

- Every study evaluated (except cost studies) had "serious" or "very serious" risk of bias:

Comparator:

- "Conservative management" comparator defined at providers' discretion, not an evidence-based multidisciplinary management program

Lack of blinding:

- No sham studies performed
- Providers, patients, and evaluators unblinded to study arm

Controls:

- Most available data comes from uncontrolled studies

Funding:

- All trials reviewed were funded by device manufacturer

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Effectiveness: key studies

- 2 RCTs, both comparing iFuse to conservative mgt (CM)
  - Both studies are ongoing prospective, open-label, multicenter randomized controlled trials
  - Unblinded (patient and evaluator); no independent assessment of outcome
  - Manufacturer funded
  - Crossovers allowed after 6 months
  - Conservative management at provider discretion, not standardized

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INSITE trial (2015, US)

- iFuse vs. non-operative treatment
- 19 centers, 148 patients,~38% with prior lumbar fusion
- Dx: Hx SI joint pain, 3 of 5 provocative joint findings, 50% reduction in pain with block
- Crossover allowed at 6 months
  - 88.6% crossover at 2 years, i.e. 142/148 eligible got eventually surgery
  - **Conservative mgt:** CBT-based treatments were not used as they were deemed "unstandardizable, impracticable and unrepresentative of modern US healthcare"

Polly et al, Int. J. Spine Surg. 2016 Aug 23; 10:28.

14

iMIA trial (2017, mult European sites)

- iFuse vs. non-operative treatment
- 9 centers, 101 patients,~35% with prior lumbar fusion
- Dx: Fortin finger test, 3 of 5 provocative joint findings, 50% reduction in pain with block
- Crossover allowed at 6 months; 43% crossover at 1 yr

Cher et al, Pain Physician Journal, 2017;20;537-550.

15

RCT results: iFuse vs non-operative management

INSITE	Pain (VAS)	Disability (ODI)	Quality of Life (SF-36)	Opioid use
1 mo	-35.9	-13.7		
3 mo	-38.0	-19.2		
6 mo	-40.5	-25.4	11.5 physical 5.6 mental	-9% vs +7.5% CM
iMIA			EQ-5D	
1 mo	-35.3			
3 mo	-38.6			
6 mo	-38.1	-19.8	-.21	
1 yr	-27.6	-20.1	-.22	

Minimal clinically important differences:
VAS:8-11 ; ODI: 8-11; SF-36 3

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Safety

- No common protocols for data assessment or standardized definitions
- Range of adverse events for iFuse: 0 to 30%
- One study based on CPT codes post minimally invasive SI fusion found 13% complications at 90 days, 16.4% at 6 months
- Most common complications: neuritis or radiculitis
- Post-market surveillance: 2.8% revisions over median 4 year f/u

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FDA MAUDE Adverse Event data on the SI-BONE IFuse implant system

Sample of cases reported in Nov, 2018

- MDR key 8081562-In 2012 left SI joint arthrodesis with 3 implants 2012; patient later reported no pain relief; In 2018 new surgeon “removed all three implants using chisels as they were all solidly fixed in bone”
- MDR key 8081596-2017 Left side SI joint arthrodesis with 3 implants-pain 6 weeks after procedure. CT showed cranial positioned implant impinging on neural foramen. “In 2018, the surgeon performed a revision procedure where he removed the cranial positioned implant using osteotomes as it was solidly fixed in bone”

Differential impact by population

- No data available

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Cost effectiveness

- Very low quality of evidence
- 1 study on cost (Ackerman): iFuse vs. non-operative commercial population:
  - iFuse $15,545 more over 3 years,
  - $6, 137 more over 5 years
  - Medicare: iFuse costs $3,358 less over lifetime
- 1 study on cost-effectiveness: iFuse vs. non-operative
  - $13,313 per QALY
  - Break even at 13 years

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Coverage comparisons for minimally invasive SI fusion

- Medicare:
  - No national coverage determination
  - Local coverage decision: Covered when all of these met:
    a) Failed 6 months intensive non-operative treatment (meds, activity mod., and active PT);
    b) Classical symptoms of SI pain
    c) Localized SI tenderness without tenderness elsewhere or other sources of pain
    d) Provocative signs/symptoms
    e) Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia)
    f) Imaging excludes infection, tumor, inflammatory process, hip OA, l-spine compression
    g) 75% reduction of pain with imaging-guided anesthetic

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Coverage comparisons for minimally invasive SI fusion

- **Aetna, Cigna, Kaiser, Premera:**
  Covered only for instability associated with major trauma (pelvic ring fracture, etc.), as adjunctive therapy for infection/sepsis, or malignancy; not covered for mechanical low back pain, SI joint syndrome, radiculopathy
- **Regence:**
  Covers when all of the following: ADLs impacted, 6 months non-operative treatment, 75% pain reduction with imaging-guided anesthetic, at least 1 steroid injection, lack of generalized pain syndrome, and a list of clinical findings to indicate likely SI pain

22

Guidelines: minimally invasive SI fusion

- **National Institute for Health and Care Excellent (NICE):**
  Current evidence is adequate to support this procedure; should only be done by experienced surgeons.
- **AIM Specialty Health Musculoskeletal Program Clinical Appropriateness Guidelines**
  May be considered medically necessary when: persistent pain interfering with function; failure 6 months conservative mgt; confirmatory physical exam; at least 75% pain reduction following image-guided SI injection on 2 separate occasions

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AGENCY MEDICAL DIRECTOR WORKGROUP

Recommendation: Sacroiliac Joint Fusion (p. 1 of 2)

Sacroiliac joint fusion is covered with conditions

SI joint fusion with iFuse or open fusion is medically necessary when **all** of the following are met:

- Appropriate imaging studies demonstrate localized SI joint pathology; AND
- **ONE** of the following:
  - Post-traumatic injury of the SI joint (e.g. following pelvic ring fracture) with radiological evidence of joint disruption
  - As an adjunctive treatment for SI joint infection or sepsis
  - Management of sacral tumor
  - When performed as part of multi-segmental long fusions for correction of spinal deformity

AGENCY MEDICAL DIRECTOR WORKGROUP

Recommendation: Sacroiliac Joint Fusion (p. 2 of 2)

- SI joint fusion is not covered for any other indication, including the following, because it is considered experimental and investigational
  - Mechanical low back pain
  - SI joint syndrome
  - Degenerative SI joint
  - Radicular pain syndrome
- Rationale:
  - Evidence for efficacy in these conditions is based on unblinded, manufacturer-funded trials with high risk of bias and lack of objective data. Serious adverse events may be underreported in trials.

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Washington State Health Care Authority

Questions?

More Information:

Emily Transue, MD, MHA
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Washington State Health Care Authority

Order of scheduled presentations:

Sacroiliac joint fusion

	Name
1	David W. Polly, Jr., MD
2	

Disclosure

Any unmarked topic will be considered a "Yes".

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		**X**
2.	Equity interests such as stocks, stock options or other ownership interests.		**X**
3.	Status or position as an officer, board member, trustee, owner.		**X**
4.	Loan or intellectual property rights.		**X**
5.	Research funding.		**X**
6.	Any other relationship, including travel arrangements.		**X**

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

There is a PhD graduate student who receives funding from SI Bone for a basic science project. I am on his advisory committee.

	Potential Conflict Type	Yes	No
7.	Representing a person or organization.	**X**	

If yes, provide the name and funding source(s) (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).:

American Academy of Orthopaedic Surgeons- funded by member dues, industry advertising and educational grants

International Society for the Advancement of Spinal Surgery- funded by member dues, industry advertising and educational grants

American Association of Neurological Surgeons and Congress of Neurological Surgeons- funded by member dues, industry advertising and educational grants

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

[redacted] 12/31/2018 _____

Signature *Date* *Print Name*

So we may contact you regarding this information, please provide the following:

Email Address: **pollydw@umn.edu**

Phone Number: **(612) 273-8095**

Comments on Washington State HTA on SI Joint Fusion

David W. Polly, Jr., MD
James W. Ogilvie Professor and Chief of Spine Surgery
Catherine Mills Davis endowed chair
Department of Orthopaedic Surgery
Professor of Neurosurgery (W)
University of Minnesota

Also representing:
American Academy of Orthopaedic Surgeons 34,000 members
American Association of Neurological Surgeons and Congress of Neurological Surgeons 4,000 members
International Society for the Advancement of Spine Surgery 2,100 members
Washington State Association of Neurological Surgeons

Disclosures

- Springer textbook royalties

Summary Comments

- Rigorous methodology reviewing existing published peer reviewed data
- Conclusions are supported by the data
  - The highest quality clinical data are about the trans-iliac trans-sacral approach using triangular titanium rods
  - Unclear if this is generalizable to other devices or approaches

Criteria for surgical treatment

- We agree with the criteria listed of:
  - Positive Fortin finger test
  - Positive 3 out of 5 or greater physical exam maneuvers
  - Positive 50% or greater pain relief with injection

Concerns

- While the data is good for patients who meet the inclusion criteria from the RCT's, there are patients who do not meet those specific criteria who may also benefit.
- The data to support continued non-surgical management of those who have failed an initial course is perhaps of lower quality than the surgical data.
- What treatment will be allowed for these patients?
- Perhaps the state of Washington might consider a strategy of coverage with evidence development to generate meaningful real world data on this cohort

RTI INTERNATIONAL

UNC | THE CECIL G. SHEPS CENTER FOR HEALTH SERVICES RESEARCH

RTI-University of North Carolina Evidence-based Practice Center

Sacroiliac Joint Fusion

Health Technology Assessment
State of Washington Health Care Authority

Contributors:
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Presented by:
Leila Kahwati, MD, MPH

January 18, 2019
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Overview of Presentation

- Background
- Methods
- Results
  - Primary research synthesis
  - Clinical practice guideline synthesis
- Discussion

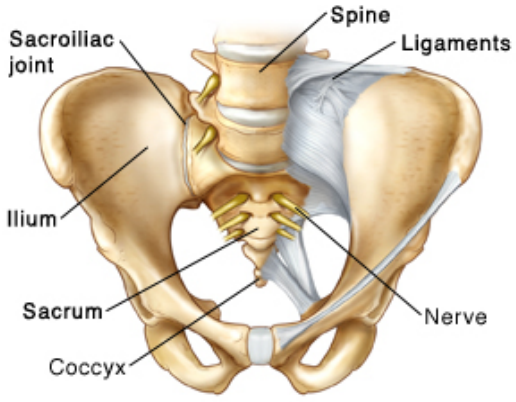
2

Background

3

Sacroiliac (SI) Joint Pain

- Estimated to be the primary source of pain in 10%-30% of patients with mechanical low back pain
- Originates from one or both surfaces of the SI joint and/or the SI joint complex
- Clinical presentation of pain varies
  - Buttock pain extending into posterolateral thigh is most common



Front view of pelvis (hip bone)

Image source: https://www.saintlukeskc.org/health-library/anatomy-sacroiliac-joint

4 Page 1

Etiology

- Thought to be caused by degenerative sacroiliitis or joint dysfunction from repeated axial loading and rotation

- Several predisposing factors:
  - History of serious pelvic trauma
  - Leg length discrepancies
  - Gait abnormalities
  - Persistent strain/low-grade trauma (i.e., running)
  - Scoliosis
  - Pregnancy
  - Prior spine surgery (especially spinal fusion)

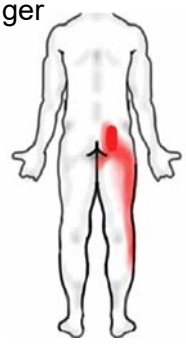
5 Page 1

Contextual Question 1: SI joint pain diagnosis and test accuracy

- Currently, no universally accepted gold standard for diagnosis

- Clinical practice guidelines and experts recommend:
  - History of pain in appropriate distribution
  - Physical exam provocation tests
    - Gaenslen maneuver
    - Distraction test
    - Compression test
    - Sacral thrust test
    - Thigh thrust or femoral shear test
    - FABER (flexion, abduction, external rotation)

Fortin Finger Test



Gaenslen maneuver

6 Pages 1, 36-37

Images source: Ou-Yang DC, York PJ, Kleck CJ, et al. 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.

Diagnostic SI Joint Injection

- SI joint injection is the current reference standard for diagnosis
  - Intraarticular placement under imaging guidance
  - Volume of injectate used varies
  - Pain relief threshold required for positive test varies from 50% to 80% but, appears to have minimal impact on prevalence estimates
  - Double or confirmatory injections reduces the false positive rate
- Patients who varied in the % of pain relief after diagnostic injection had similar outcomes after SI joint fusion
  - Implication: using a very high threshold for pain relief after diagnostic injection may exclude some patients that might benefit from surgery

7 Pages 36-37

Physical exam test accuracy

- Accuracy of physical exam elements compared to reference standard of diagnostic SI joint injection

Clinical Test	Sensitivity (95% CI)	Specificity (95% CI)
Fortin finger test (1 study; n=88)	76% (65 to 85)	47% (35 to 57)
Thigh thrust test (3 studies pooled; n=242)	91% (79 to 97)	66% (53 to 77)
Compression test (2 studies pooled; n=202)	63% (47 to 77)	69% (57 to 80)
3 or more positive tests (4 studies pooled; n=304)	85% (75 to 92)	76% (68 to 84)

Studies varied in threshold of pain relief required for a positive reference test (range 50% to 80% pain relief).

8 Pages 36-37

Abbreviations: CI = confidence interval

Contextual Question 2: Diagnosis in usual practice

- We found no data describing typical patterns in clinical practice for diagnosing SI joint pain

SI Joint Pain Management

- Nonsurgical options for management
  - Analgesics and anti-inflammatory medications
  - Physical therapy
  - Pelvic belts and girdles
  - Therapeutic joint injection
  - Prolotherapy
  - Radiofrequency denervation
- Fusion of SI joint
  - Typically reserved for people who fail less invasive treatment
  - Open procedure
  - Minimally invasive procedure
    - Represents 39% of all SI fusions in 2009 increasing to 88% in 2012

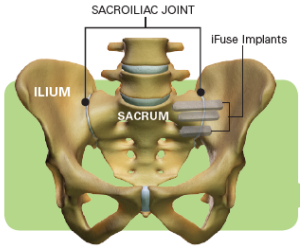
Surgical Systems for SI Joint Fusion

Numerous proprietary surgical systems exist:

- Typically consist of 2-3 specialized implants or screws to span SI joint and create immediate fixation, with specialized designs or coatings to promote bone growth and bony fusion
- Some combine immediate fixation with decortication and bone graft insertion to promote bone growth and bony fusion

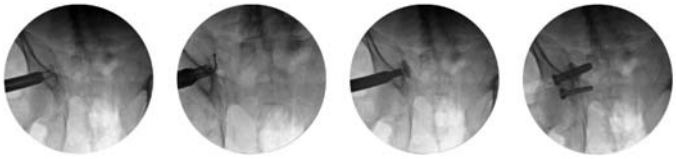
Example: iFuse Implant System (SI-BONE)

Image source: https://si-bone.com/providers/, Smith (2018)



Example: SImmetry (Zyga)

Image source: https://zyga.com/providers-doctors/simmetry-solution-sacroiliac-joint-dysfunction/true-si-joint-arthrodesis/



11 Page 2

Regulatory Status

- 15 devices with FDA 510k clearance* currently on the market in the U.S.
- 5 devices with Title 21 CFR Part 1271 FDA approval** currently on the market in the U.S.
- 2 devices not currently on the market: SI-DESIS (has FDA 510k approval, but unavailable) and DIANA (available for use in Europe)
- Open procedures could be performed with cleared or approved devices, but they may also be performed with orthopedic plates, screws, and instruments that are already cleared by FDA but which may not be designed specifically for SI Joint Fusion

* 510(k) approval is based on evidence that the device is 'substantially equivalent' to a device that the FDA has already cleared or that was marketed before 1976
** Title 21 CFR Part 1271 applies to devices that are designed to be used with allografts or other biologic materials

12 Pages 2-5, Table 1

Policy Context for Washington

- This topic was selected for review by the state because of:
  - High concerns for safety
  - High concerns for efficacy
  - High concerns for cost

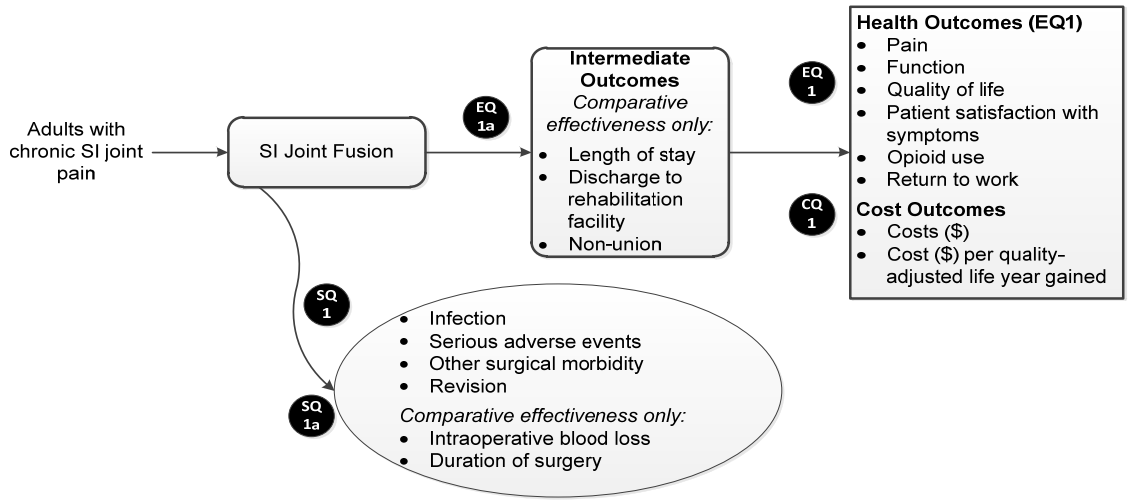
13 Page 5

Methods

1. Primary Research Synthesis
2. Synthesis of Relevant Clinical Practice Guidelines

14

Analytic Framework



15 Page 6, Figure 1

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

Study Selection for Primary Research Synthesis

Population	Adults with ≥ 3 months SI joint pain diagnosed using a standard approach
Intervention	Open SI joint fusion; minimally invasive SI joint fusion
Comparator	Active treatment; placebo; no treatment
Outcomes	*EQ1*: Pain; function; quality of life; patient satisfaction; opioid use; return to work *SQ1*: Adverse events, revision surgery *CQ*: Cost; cost per quality-adjusted life year gained; cost per disability-adjusted life year gained
Study Design	*EQ*: Controlled trials, controlled cohort studies *SQ*: All of the designs listed for EQ plus studies without a comparator group *CQ*: Cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis
Setting	Countries categorized as “very high” on United Nations Human Development Index

16 Pages 7-10, Table 2

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

Risk of Bias Assessment

- Risk of bias is assessed at the individual study level
  - Cochrane Risk of Bias version 2.0 instrument for RCTs
  - ROBINS-I tool for non-randomized comparative studies
  - Quality of Health Economic Studies instrument for cost analyses
- Each study assessed as having one of the following risks:
  - High risk of bias
  - Some concerns for bias
  - Low risk of bias

17 Page 10

Abbreviation: RCT = randomized controlled trial

Quality of the Evidence – GRADE approach

- **Domains assessed:**
  - Risk of bias
  - Consistency
  - Directness
  - Precision
  - Publication bias
- **Quality of evidence**
  - ⊕◯◯◯ VERY LOW
  - ⊕⊕◯◯ LOW
  - ⊕⊕⊕◯ MODERATE
  - ⊕⊕⊕⊕ HIGH

- Bodies of RCT evidence start at ***HIGH***
- Observational studies start at ***LOW*** because of limitations with this study design
- Quality level may be downgraded based on domain assessments:
  - No concerns
  - Serious concerns (↓ one level)
  - Very serious concerns (↓ two levels)
- Observational evidence may be upgraded based on:
  - Large effect (↑ one level)
  - Dose response (↑ one level)
  - Plausible confounding and bias accounted for (↑ one level)

18 Pages 10-12

GRADE interpretation

Grade	Definition
High	**We are very confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has few or no deficiencies. We believe that the findings are stable, that is, another study would not change the conclusions.
Moderate	**We are moderately confident that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	**We have limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Very Low	**We have very limited confidence that the estimate of effect lies close to the true effect for this outcome.** The body of evidence has numerous major deficiencies. We believe that substantial additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.

19 Page 11

Clinical Practice Guideline Quality Appraisal

- Appraisal of Guidelines for Research & Evaluation (AGREE-II)
  - Overall score of 1 (lowest possible quality) to 7 (highest possible quality)

20 Page 12

Results

1. Primary Research Synthesis
2. Synthesis of Relevant Clinical Practice Guidelines

21

Search Results

- Primary Research Synthesis
  - Titles/abstracts screened: **662**
  - Full text articles screened: **113**
  - Full text studies included: **43 studies (50 articles)**

EQ:	*SQ:*	*CQ:*
2 RCTs 5 CCS	2 RCTs 5 CCS 32 Uncontrolled studies	3 cost analyses

- Clinical Practice Guidelines: **2***

22 Pages 12-13

*Publicly available guidelines
Abbreviations: CCS = controlled cohort study; CQ = cost question; EQ = efficacy question; RCT = randomized controlled trial; SQ = safety question

Comparisons evaluated

SI joint fusion compared to conservative management or no surgery

- Minimally invasive fusion compared to CM (EQ, SQ, CQ)
- Open fusion compared to no surgery (EQ and SQ)

Minimally invasive SI joint fusion compared to open fusion

- EQ and SQ

Minimally invasive SI joint fusion with implants compared to screws

- SQ

23 Abbreviations: CM = conservative management; CQ = cost question; EQ = efficacy question; SQ = safety question

SI Joint Fusion compared to Conservative Management (CM)

Study (Year) Risk of Bias Funding	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
INSITE (Whang, 2015) Some concerns SI Bone, Inc.	RCT	19 U.S. centers, 2013 to 2014	iFuse (102) CM (46 at 6 mos.) Crossovers from CM to iFuse allowed after 6 mos.
iMIA (Dengler, 2016) Some concerns SI Bone, Inc.	RCT	9 European centers, 2013 to 2015	iFuse (52) CM (49 at 6 mos.) Crossovers from CM to iFuse allowed after 6 mos.
Vanaclocha (2018) High Not reported	CCS (retrospective)	Single center in Spain, 2007 to 2015	iFuse (27) Radiofrequency denervation (47) CM (63)

24 Pages 16-19; Table 6 Abbreviations: CCS = controlled cohort study; CM = conservative management; RCT = randomized controlled trial

Characteristics of Enrolled Participants

- Diagnosis/study entry criteria
  - Chronic symptoms
  - Positive Fortin finger test
  - At least 3 positive provocative physical exam findings
  - At least 50% reduction in pain after diagnostic SI joint block
  - Other sources of back pain ruled out
- Mean duration of pain 3 to 7 years
- Mean pain score (Visual Analog Scale) was 82 mm in both groups on a scale of 0 mm [no pain] to 100 mm [worse pain ever]
- About 1/3 of participants had a history of prior lumbar fusion

25 Pages 16-17; Appendix C-2, C-3, C-16

MI SI Joint Fusion compared to CM [Pain]

Change in pain at 6 mos. (Visual Analog Scale, 0 mm [no pain] to 100 mm [worse pain], MID = 7 to 11)

2 RCT: INSITE, iMIA ⊕⊕⊕◯ MODERATE Favors iFuse	• Significantly larger improvements with iFuse; between-group difference o -40.5 mm (95% CI, -50.1 to -30.9) in 1 study o -38.1 mm (95% CI NR, P < 0.0001) in other study

Change in pain at 6 mos. to 3.5 yrs. (Visual Analog Scale, 0 to 10 cm)

1 CCS: Vanaclocha ⊕◯◯◯ VERY LOW Favors iFuse	• Significantly larger improvement with iFuse o Compared to conservative management (between-group difference: -6 cm, P < 0.001) o Compared to denervation (between-group difference: -4.5 cm, P < 0.001)

26 Pages 14,20-22; Tables 4, 7

Abbreviations: CI = confidence interval; CM = conservative management; cm = centimeters; MI = minimally invasive; MID = minimally important difference; mm = millimeters; mos = months; NR = not reported; yrs = years

MI SI Joint Fusion compared to CM [Physical Function]

Change in physical function at 6 mos. (Oswestry Disability Index, 0 [no disability] to 100 [complete disability], MID 8 to 11)

2 RCT: INSITE, iMIA ⊕⊕⊕◯ MODERATE Favors iFuse	• Significantly larger improvement with iFuse, between-group difference o -25.4 points (95% CI, -32.5 to -18.3, P < 0.0001) in 1 study o -19.8 points (95% CI NR, P < 0.0001) in other study

Change in physical function at 6 mos. to 3.5 yrs. (Oswestry Disability Index)

1 CCS: Vanaclocha ⊕◯◯◯ VERY LOW Favors iFuse	• Significantly larger improvement with iFuse o Compared to conservative management (between-group difference: -24 points [P < 0.001]) o Compared to denervation (between-group difference: -17 points [P < 0.001])

27 Pages 14, 20-22; Tables 4, 7

Abbreviations: CI = confidence interval; CM = conservative management; MI = minimally invasive; MID= minimally important difference; mos = months; NR = not reported; yrs = years

MI SI Joint Fusion compared to CM [QOL]

Change in quality of life at 6 mos. (EQ-5D, <0 [worse than death] to 1 [perfect health]; SF-36, 0 [lowest QOL] to 100 [best QOL], MID 3)

2 RCT: INSITE, iMIA ⊕⊕⊕◯ MODERATE Favors iFuse	• Significantly larger improvement with iFuse o EQ-5D between-group difference ▪ 0.24 (95% CI, 0.16 to 0.32) in 1 study ▪ 0.21 (95% CI NR, P < 0.0001) in other study o SF-36 between group difference in 1 study ▪ PCS 11.5 (95% CI, 8.1 to 14.9) • MCS 5.6 (95% CI, 1.8 to 9.4)

28 Pages 15, 20-22; Tables 4, 7

Abbreviations: CI = confidence interval; CM = conservative management; EQ-5D = EuroQOL utility measure; MCS = mental health component score; MI = minimally invasive; mos = months; NR = not reported; PCS = physical health component score; QOL = quality of life; SF-36 = short form survey

MI SI Joint Fusion compared to CM [Opioid Use]

Opioid use at 6 mos.

1 RCT: INSITE ⊕⊕◯◯ LOW No difference	• No significant difference in percentage of participants using opioids o ARD -12.0% (95% CI, -28.6% to 4.5%) o RR 0.83 (95% CI, 0.64 to 1.07)

Opioid use at 6 mos. to 3.5 yrs.

1 CCS: Vanaclocha ⊕◯◯◯ VERY LOW Favors iFuse	• Significant difference (P < 0.001) between groups in oral morphine equivalents used at the time of last follow-up o iFuse (3.1 mg/day) o CM (38.5 mg/day) o Denervation (32.2 mg/day),

29 Pages 15, 20-22; Tables 4, 7

Abbreviations: ARD = absolute risk difference; CI = confidence interval; CM = conservative management; mg = milligrams; MI = minimally invasive; mos = months; RR = relative risk; yrs = years

MI SI Joint Fusion compared to CM [Adverse Events]

Serious Adverse Events

2 RCT: INSITE, iMIA ⊕⊕◯◯ LOW No difference	• In one study, 21 serious events among 102 iFuse participants and 6 serious events among 46 conservative management participants (p=0.3241) • In other study, 8 events among 52 iFuse participants and 10 events among 49 conservative management participants

1 CCS: Vanaclocha ⊕◯◯◯ VERY LOW No difference	• No serious adverse events reported in either group

30 Pages 15, 23-24; Tables 4, 8

Abbreviations: CCS = controlled cohort study; CM = conservative management; MI = minimally invasive

MI SI Joint Fusion compared to CM [Revision Surgery]

Revision Surgery

2 RCT: INSITE, iMIA ⊕⊕⊕◯ MODERATE	• In one study o Incidence 3.4% at 2 yrs. among 89 iFuse participants with follow-up data o Incidence 2.6% among 30 CM participants that crossed over to surgery • In other study o No revisions among 52 iFuse participants o1 revision among 21 CM participants that crossed over to surgery
1 CCS: Vanaclocha ⊕◯◯◯ VERY LOW	• No revision surgery reported among participants who received iFuse

31 Pages 15, 23-24; Tables 4, 8

Abbreviations: CCS = controlled cohort study; CM = conservative management; MI = minimally invasive

MI SI Joint Fusion compared to CM- Trial outcomes after 6 mos.

- Crossovers from CM to surgery allowed after 6 months in both RCTs
  - Participants who crossed over had higher mean VAS pain and ODI scores at 6 months compared to participants who did not cross over
- Changes in VAS low back pain scores observed at 6 months persisted at 1 year among those allocated to fusion
- At least 20 mm improvement on VAS pain scale at 1 year
  - iMIA: 69% of those allocated to fusion vs. 27% of those allocated to CM who did not cross over
  - INSITE: 81.6% of those allocated to fusion vs. 12.5% of those allocated to CM (all crossovers considered failures for this analysis)
- Similar pattern observed for physical function as measured by ODI

32 Page 23

Abbreviations: CM = conservative management; ODI = Oswestry Disability Index; VAS = visual analog scale

Open SI Joint Fusion compared to No Surgery

Study (Year) Risk of Bias Funding	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
Kibsgard (2013) High Various[1]	CCS (retrospective)	Single center in Norway, 1977 to 1998	Open fusion with dorsal approach (50) No surgery (28)

33 Page 17; Table 6

[1] Norwegian Foundation for Health and Rehabilitation and Sophies Minde Ortopedi AA.
Abbreviations: CCS = controlled cohort study

Open Fusion compared to No Surgery (continued)

Pain at 11 to 23 yrs. (Visual Analog Scale, 0 mm [no pain] to 100 mm [worse pain], MID = 7 to 11)

1 CCS: Kibsgard ⨁◯◯◯ VERY LOW No difference	• No significant between-group difference: -6 mm (95% CI, -10.2 to 22.2).

Physical Function at 11 to 23 yrs. (Oswestry Disability Index 0 [no disability] to 100 [complete disability], MID 8 to 11)

1 CCS: Kibsgard ⨁◯◯◯ VERY LOW No difference	• No significant between-group difference; -4 points (95% CI, -9.1 to 17.1).

Quality of Life at 11 to 23 yrs. (SF-36)

1 CCS: Kibsgard ⨁◯◯◯ VERY LOW No difference	• No significant between-group differences in any of the 8 subscale scores.

34 Page 16, Table 5

Abbreviations: CCS = controlled cohort study; CI = confidence interval; MID = minimally important difference; SF-36 = short form survey

MI SI Joint Fusion compared to Open Fusion

Study (Year) Risk of Bias Funding	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
Ledonio (2014) High Not reported	CCS (retrospective)	Single U.S. center, 2006 to 2011	iFuse (22) Open anterior ilioinguinal approach (22)
Ledonio (2014) High Not reported	CCS (retrospective)	2 U.S. centers, 2006 to 2012	iFuse (17) Open anterior ilioinguinal approach (22)
Smith (2013) High SI Bone, Inc.	CCS (retrospective)	7 U.S. centers, 1994 to 2012	iFuse (114) Open posterior approach (149)

35 Page 25-26; Table 10

Abbreviations: CCS = controlled cohort study; MI = minimally invasive

MI SI Joint Fusion compared to Open Fusion [Pain & Function]

Change in pain over 2 yrs. (Visual Analog Scale, 0 cm [no pain] to 10 cm [worse pain], MID = 0.7 to 1.1)

1 CCS: Smith ⨁◯◯◯ VERY LOW Favors iFuse	• Significantly larger improvement for iFuse; repeated measures between-group difference -3.0 cm (95% CI, -2.1 to -4.0)

Change in physical function at 13 to 15 months (Oswestry Disability Index 0 [no disability] to 100 [complete disability], MID 8 to 11)

2 CCS: Ledonio, Ledonio ⨁◯◯◯ VERY LOW Mixed Findings	• Significantly larger improvements for iFuse in 1 study (between-group difference -33 points, P < 0.0008) • Similar improvements in other study (between-group difference 4.9 points, P = 0.272)

36 Page 25; Table 9

Abbreviations: CCS = controlled cohort study; CI = confidence interval; cm = centimeters; MI = minimally invasive

MI SI Joint Fusion compared to Open Fusion [Length of Stay]

Length of Hospital Stay

3 CCS: Smith, Ledonio, Ledonio ⨁◯◯◯ VERY LOW Favors iFuse	• Significantly shorter length of stay for iFuse participants o Range of differences was 1.3 to 3.8 days across studies

37 Page 25; Table 9

Abbreviations: CCS = controlled cohort study; MI = minimally invasive

MI SI Joint Fusion compared to Open Fusion [Safety]

Adverse Events

3 CCS: Smith, Ledonio, Ledonio ⨁◯◯◯ VERY LOW No difference	• No intraoperative complications reported in any study • Frequency of postoperative complications similar between groups and ranged from 2.3% to 35% across groups and studies

Revision Surgery

3 CCS: Smith, Ledonio, Ledonio ⨁◯◯◯ VERY LOW Mixed findings	• Infrequent revision in both groups in two studies (1 to 2 per group) • Significantly fewer revisions with iFuse in third study o ARD -51.3% (95% CI, -60.1% to -42.4%) o RR 0.10 (95% CI, 0.04 to 0.26)

38 Page 25; Table 9

Abbreviations: ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; RR = relative risk

MI SI Joint Fusion with Implants Compared to Screw Fixation

Study (Year) Risk of Bias Funding	Study Design	Setting/ Time Period	Intervention (N analyzed) Comparator (N analyzed)
Spain (2017) Some concerns SI Bone, Inc.	CCS	Single U.S. center, NR	iFuse (263) Percutaneous fixation with screws (29)

39 Page 29; Table 14

Abbreviations: CCS = controlled cohort study; NR = not reported

MI SI Joint Fusion with Implants Compared to Screw Fixation [Safety]

Revision Surgery at 2.8 to 4.6 yrs.

1 CCS: Spain ⨁◯◯◯ VERY LOW Favors iFuse	• Significantly fewer revisions with iFuse (4.6%) compared to screws (65.5%) o ARD -57.5% (95% CI, -74.8% to -40.2%) o RR 0.40 (95% CI, 0.26 to 0.63)

40 Page 29; Table 15

Abbreviations: ARD = adjusted risk difference; CCS = controlled cohort study; CI = confidence interval; MI = minimally invasive; RR = relative risk

Safety Outcomes from Uncontrolled Studies

41

Procedures Evaluated in Uncontrolled Studies

Procedure	Number of Studies
Open fusion	8 studies total: 2 studies using posterior approach 2 studies using anterior approach 1 study using anterior approach with symphysiodesis 1 study using Verral and Pitkin technique(bilateral) 1 study using modified Smith-Petersen technique 1 study using distraction interference arthrodesis
iFuse Implant System (triangular, titanium coated implants)	13 studies total: 12 studies using iFuse only; 1 study using iFuse or Samba
SImmetry System (titanium cannulated and antirotational implants with surface roughness)	3 studies
Percutaneous fusion using hollow modular anchorage screw	3 studies
SI-LOK Sacroiliac Joint Fusion System	1 study
INTERFIX system (single-threaded titanium cage filled with rhBMP-2)	1 study
Fusion using dual fibular dowel allografts	1 study
Fusion using threaded fusion cages	1 study
Various minimally invasive procedures based on CPT code 27279	1 study

42 Pages 30-31; Table 16

Abbreviations: CPT = current procedural terminology

Safety Outcomes from Uncontrolled Studies

- Heterogenous adverse event ascertainment methods and reporting a major limitation of this body of evidence
- Using insurance claims from 469 beneficiaries who underwent MI SI fusion (based on CPT code) from 2007 to 2014
  - Incidence of complications 13.2% at 90 days and 16.4% at 6 months
    - Most common complication: neuritis or radiculitis

43 Page 32

Abbreviations: CPT = Current Procedural Terminology; MI = minimally invasive

Safety Outcomes from Uncontrolled Studies (continued)

- Among the 13 studies using iFuse
  - Incidence of device or procedure-related adverse events ranged from 0% to 30%
  - Incidence of revision surgery ranged from 0% to 8%
    - Post-market surveillance database of 11,388 participants that received iFuse
      - Incidence of revision 2.8% over 4 years follow-up
      - 63% of revisions occurring within the first year

44 Page 31

Cost Question

45

SI Joint Fusion compared to Nonoperative care [CQ]

Study (Year) Risk of Bias Funding	Study Design	Key Parameters	Intervention Comparator
Ackerman (2014) Low SI Bone, Inc.	Comparative cost analysis	Payer perspective, 2012 USD Time horizon: 3 to 5 years Commercially insured, mean age 45.2 years	MI SI Joint Fusion (iFuse inputs) Nonoperative care
Ackerman (2014) Low SI Bone, Inc.	Comparative cost analysis	Payer perspective, 2012 USD Time horizon: lifetime Medicare, starting age 70 with life expectancy age 84	MI SI Joint Fusion (iFuse inputs) Nonoperative care
Cher (2016) Low SI Bone, Inc.	Cost-effectiveness analysis	Payer perspective, 2015 USD Time horizon: 5 years Utility measure: EQ-5D	iFuse Nonoperative care

46 Page 32-34, Table 18

Abbreviations: CQ = cost question; EQ-5D = EuroQOL measure of generic health status; MI = minimally invasive; USD = United States dollars

MI SI Joint Fusion compared to Nonoperative care [Cost]

Costs over 3 to 5 years in a commercially-insured population

1 CCA: Ackerman ⊕◯◯◯ VERY LOW	• Minimally invasive SI joint fusion with iFuse costs $14,545 more over 3 years and $6,137 more over 5 years.

Lifetime costs in a Medicare population

1 CCA: Ackerman ⊕◯◯◯ VERY LOW	• Minimally invasive SI joint fusion with iFuse costs $3,358 less than nonoperative care.

47 Page 32-34, Table 17

Abbreviations: CCA = comparative cost analysis; MI = minimally invasive

MI SI Joint Fusion compared to Nonoperative care [Cost-effectiveness]

Cost-effectiveness over 5 years

1 CEA: Cher ⊕◯◯◯ VERY LOW	• Minimally invasive SI joint fusion with iFuse costs $13,313 per QALY gained • Breakeven costs at 13 years

48 Page 32-34; Table 17

Abbreviations: CEA = cost-effectiveness analysis; MI = minimally invasive; QALY = quality-adjusted life year

Clinical Practice Guideline Synthesis

- National Institute for Health and Care Excellence (U.K.)
  - Intervention Procedure Guidance 578: Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain
    - Quality Rating 4 out of 7 on AGREE-II (7 = highest quality)
    - "Current evidence is adequate to support this procedure"

49 Pages 34-35

Abbreviations: AGREE-II = Appraisal of Guidelines for Research & Evaluation II; U.K. = United Kingdom

Clinical Practice Guideline Synthesis (continued)

- AIM Specialty Health
  - "Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion"
    - Quality Rating 3 out of 7 on AGREE-II (7 = highest quality)
    - "Percutaneous/minimally invasive SI joint fusion with iFuse may be considered medically necessary when clinical criteria are met"
      - Persistent pain more than 6 months that interferes with function and has documented VAS pain score of 5 cm or greater and ODI of 30 or greater
      - Failure of 6 months of conservative management
      - Confirmation of pain (typical pattern, positive Fortin test, at least 3 positive provocative physical exam tests, and other causes excluded)
      - Imaging indicates evidence of injury/degeneration and excludes other sources
      - At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions

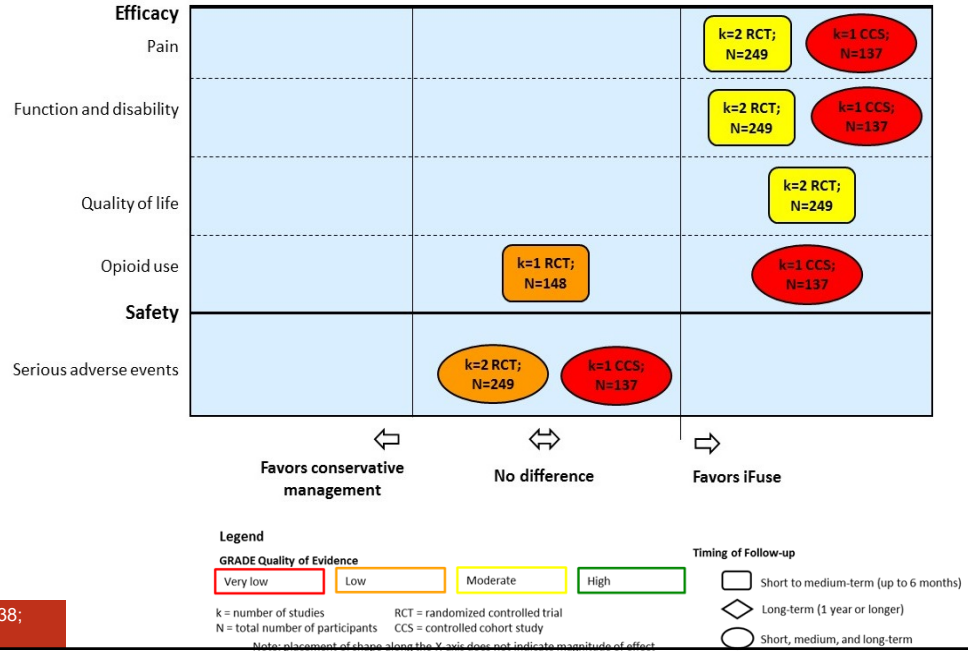
50 Pages 34-35

Abbreviations: AGREE-II = Appraisal of Guidelines for Research & Evaluation II; ODI = Oswestry Disability Index; VAS = visual analog scale

Discussion

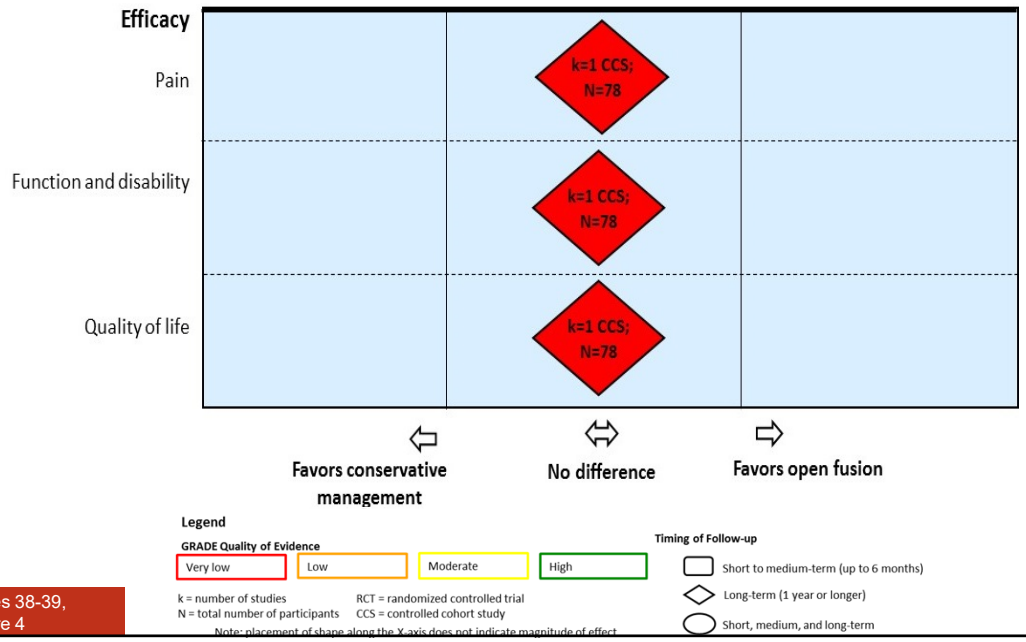
51

Evidence Map – SI joint fusion with iFuse compared to conservative management



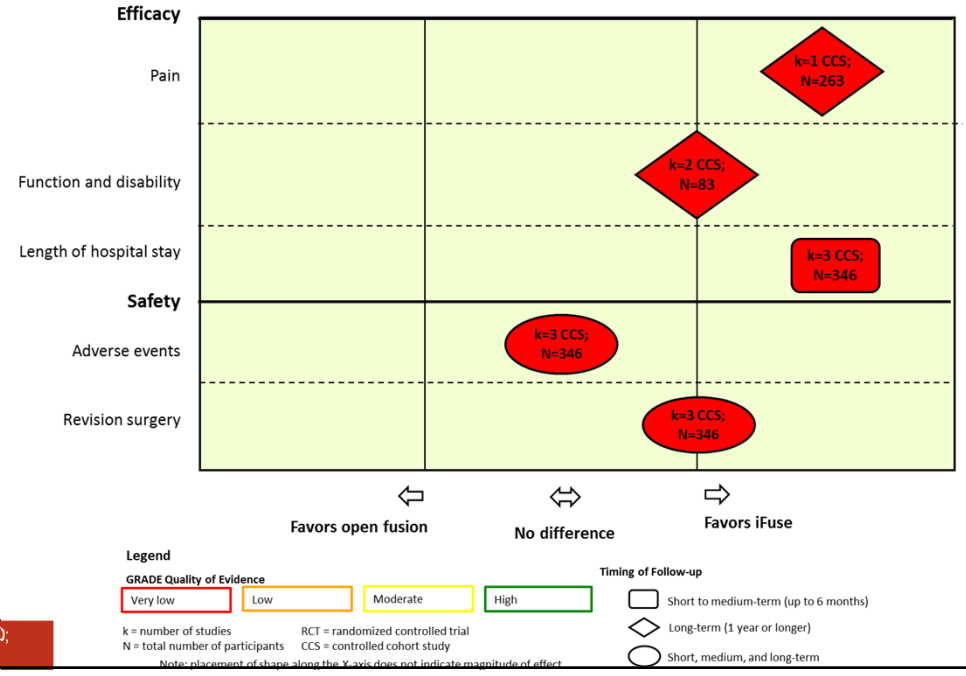
52 Pages 37-38; Figure 3

Evidence Map – Open SI joint fusion compared to conservative management



53 Pages 38-39, Figure 4

Evidence Map – SI joint fusion with iFuse compared to open fusion



54 Pages 39-40; Figure 5

Limitations of the Evidence Base

- Most studies were uncontrolled
  - Small sample sizes, heterogeneity in ascertainment and reporting of adverse events and revision surgery
- All controlled studies of minimally invasive fusion evaluated the iFuse implant system, unclear generalizability to other devices/techniques
- Limited outcomes reported by studies of open fusion
- Risk of bias limitations:
  - RCT evidence
    - Lack of blinding
    - Crossovers after 6 months
  - Controlled observational studies
    - Confounding and selection bias
- No prespecified subgroup analyses

55 Page 41

Payer Coverage (through October 1, 2018)

- CMS: No national coverage determination, but several Medicare Administrative Contractors (MAC) do cover this procedure
  - Including 1 in the State of Washington (Noridian Healthcare Solutions)
- Two payers cover minimally invasive fusion when certain clinical criteria are met

Payor	Coverage status
Medicare	_
Medicaid	Covered in 44 states
Aetna	X
Cigna	X
Humana	X
Kaiser	X
Noridian Healthcare Solutions (MAC)	✓
Premera	X
Regence	✓
TRICARE	✓
UnitedHealthcare (Commercial)	_
United Healthcare (Medicare Advantage)	X

Notes: ✓ = covered; ✕ = not covered; — = no policy identified

56 Pages 42-45

Ongoing Studies

Sponsor	Description	Number of Participants	Estimated Completion Date
Globus Medical, Inc.	Uncontrolled trial of SI-LOK joint fixation system	55	11/2018
SI-BONE, Inc.	Extended follow-up from 2 ongoing multicenter prospective U.S. clinical trials to evaluate long-term safety and effectiveness of iFuse Implant System	103	12/2019
Zyga Technology, Inc.	Prospective, non-randomized postmarket study to collect data following implant of the SImmetry device	250	8/2020

57 Pages 46-47

Limitations of this Health Technology Assessment

- Scope
  - English-language articles only
  - Did not seek unpublished data or data presented only in conference abstracts
  - Excluded efficacy outcomes from uncontrolled studies
- Process
  - Search limited to 3 databases
- Analysis
  - Did not GRADE the body of evidence from uncontrolled studies
  - Limitations of AGREE-II tool for appraising clinical practice guidelines

58 Page 46

Abbreviations: AGREE-II = Appraisal of Guidelines for Research & Evaluation II; GRADE = Grading of Recommendations, Assessment, Development, and Evaluation

Conclusion

Among patients meeting diagnostic criteria for SI joint pain who have not responded to conservative management:

Minimally invasive SI joint fusion with iFuse (vs. conservative management)

- Reduces pain more ⊕⊕⊕◯
- Improves function/disability more ⊕⊕⊕◯
- Improves quality of life more ⊕⊕⊕◯
- Has uncertain effects on opioid use ⊕⊕◯◯
- Results in no difference in serious adverse events ⊕⊕◯◯
- Is likely cost-effective ⊕◯◯◯

Open fusion (vs. conservative management)

- Results in no long-term difference in
  - Pain ⊕◯◯◯
  - Function/disability ⊕◯◯◯
  - Quality of life ⊕◯◯◯

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GRADE Quality of Evidence: Very low | Low | Moderate | High

Conclusion (continued)

Among patients meeting diagnostic criteria for SI joint pain who have not responded to conservative management:

Minimally invasive SI joint fusion with iFuse (vs. open fusion)

- Reduces pain more ⊕◯◯◯
- Has uncertain impact on function/disability ⊕◯◯◯
- Has shorter hospital length of stay ⊕◯◯◯
- Results in no difference in adverse events ⊕◯◯◯
- Has uncertain impact on incidence of revision surgery ⊕◯◯◯

Minimally invasive SI joint fusion with iFuse (vs. percutaneous screw fixation)

- Reduces incidence of revision surgery ⊕◯◯◯

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GRADE Quality of Evidence: Very low | Low | Moderate | High

HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

Clinical committee findings and decisions

Efficacy considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next step: Cover or no cover

If not covered, or covered unconditionally, the chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next step: Cover with conditions

If covered with conditions, the committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical committee evidence votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Discussion document: What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety outcomes	Importance of outcome	Safety evidence/ confidence in evidence
Infection		
Serious adverse events		
Other surgical morbidity		
Revision surgery		
Blood loss		
Duration		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Pain		
Function		
QOL		
Patient satisfaction		
Opioid use		
Return to work		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

For cost outcomes/ cost-effectiveness:

Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all (yes)

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not covered _____ Covered unconditionally _____ Covered under certain conditions

Discussion item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

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 an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.

Medicare Coverage

From page 23 of the final evidence report:

The Center for Medicare & Medicaid Services does not have a national coverage determination for SI joint fusion procedures though several Medicare Administrative Contractors (MAC) do cover this procedure, including 1 that operates in the State of Washington (Noridian Healthcare Solutions).

Guidelines

From page 58 of the final evidence report:

Table 1. Clinical practice guidelines related to sacroiliac joint fusion

Title/Organization Guideline Quality	Year Published	Excerpts of Findings	Rating/Quality of Evidence Narrative Assessment
Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain - Intervention Procedure Guidance 578[38] National Institute for Health and Care Excellence (United Kingdom) Quality Rating: 4 out of 7	2017	"Current evidence on safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support use of this procedure, provided that standard arrangements are in place for clinical governance, consent, and audit. Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption. This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and NICE expertise in minimally invasive SI joint fusion surgery for chronic SI pain." NICE expects to release a guidance document focuses specifically on iFuse in October 2018.[87]	Based on 2 RCTs, 2 SRs, 3 prospective cohort studies, and 2 retrospective case series; quality of evidence assessment not performed.
Musculoskeletal Program Clinical Appropriateness Guidelines: Sacroiliac Joint Fusion AIM Specialty Health[39] Quality Rating: 3 out of 7	2018	Percutaneous/minimally invasive SI joint fusion with iFuse system may be considered medically necessary when all of the following criteria are met: • Persistent pain more than 6 months that interferes with function and has documented VAS of 5 cm or greater and ODI of 30 or greater • Failure of 6 months of conservative management • Confirmation of pain (typical pattern, positive Fortin test, at least 3 positive provocative physical exam tests, and other causes excluded) • Imaging indicates evidence of injury/degeneration and excludes other sources • At least 75% pain reduction following image-guided SI joint injection on 2 separate occasions	Not reported

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