Washington State Health Care Authority, HTA Program
Final Key Questions
Hip Surgery procedures for treatment of femoroacetabular impingement

Introduction

HTA has selected hip surgery procedures for the treatment of femoroacetabular impingement (FAI) to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA published the Draft Key Questions to gather public input about the key questions and any additional evidence to be considered in the evidence review. Key questions guide the development of the evidence report. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Femoroacetabular impingement is a condition where friction in the hip joint caused by the ball and socket rubbing causes wear or damage to the cartilage, which is thought to cause pain and contribute to the development of osteoarthritis. Hip surgery is a treatment aimed at correction of the abnormal hip biomechanics causing the friction in order to prevent or delay osteoarthritis and relieve pain.

Final Key Questions

When used in patients with Femoroacetabular Impingement (FAI):

1. What is the case definition of FAI, and are there measures of reliability and validity for case identification?
2. What are the expected treatment outcomes of hip surgery for FAI, and are there validated instruments and scores to measure clinically meaningful improvement?
3. What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) for FAI? Including consideration of short term and long term:
    a. Development or progression of Osteoarthritis
    b. Impact on Function, Pain, range of motion, quality of life, activities of daily living and return to work
    c. Need for continuing and/or subsequent intervention
    d. Other reported measures
4. What is the evidence of the safety of hip surgery for FAI? Including consideration of:
    a. Adverse events type and frequency (peri-operative, cartilage damage, fractures, nerve damage, mortality, other major morbidity)
    b. Revision/re-operation rates (if not addressed in efficacy)

5. What is the evidence that hip surgery for FAI has differential efficacy or safety issues in sub populations? Including consideration of:
    a. Gender
    b. Age
    c. Psychological or psychosocial co-morbidities
    d. Baseline functional status: e.g. type of deformity, extent of osteoarthritis or cartilage damage
    e. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI
    f. Provider type, setting or other provider characteristics
    g. Payor/ beneficiary type: including worker's compensation, Medicaid, state employees

6. What evidence of cost implications and cost-effectiveness of hip surgery for FAI? Including consideration of:
    a. Costs (direct and indirect) and cost effectiveness
    b. Short term and long term

Policy Context:

Osteoarthritis (OA) is very common, and affects some 27 million Americans; and is characterized by the breakdown of cartilage – the part of a joint that cushions the ends of the bones and allows easy movement. As cartilage deteriorates, bones begin to rub against one another. OA can also damage ligaments, menisci, and muscles and may cause bone outgrowths. Symptoms of OA vary greatly: some patients have minor to debilitating pain, swelling and stiffness. Other patients have few symptoms in spite of significant degeneration. The causes of hip pain and OA, and factors for progression and impact are not fully understood. OA is thought to be primarily related to aging (Primary OA) or severe congenital or developmental deformities (Secondary OA); though repetitive use; injury; weight; and heredity may play a role. There is no treatment to stop cartilage degeneration or repair damaged cartilage. The goal of treatment for patients with symptoms is to reduce joint pain and inflammation while improving and maintaining joint function.

Femoroacetabular impingement (FAI) syndrome is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint (orientation or morphology) are thought to cause friction/impingement and pain. It is theorized that FAI starts the breakdown of cartilage, leading to OA. There are two types of FAI: cam impingement (most common in young athletic males) and pincer impingement (most common in middle-aged women). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration.

Technology Description:

Hip surgery is an invasive procedure to correct FAI using either an open surgery or arthroscopic approach. The surgeon cuts off abnormal outgrowths of bone, removes damaged cartilage, and reshapes the femoral neck to ensure that there is sufficient clearance between the rim of the joint socket and the neck of the femur. After

corrective surgery, avoidance of weight bearing for several weeks to months and rehabilitation is required.

Issues:

The causes of hip pain, the natural history of FAI and its relationship to osteoarthritis are unclear; case definition and the selection criterion of patients for this procedure is uncertain.

Significant questions remain about the safety, efficacy and effectiveness and cost effectiveness of hip arthroplasty for FAI. Effectiveness questions particularly center on whether the potential beneficial outcomes of long term pain and functional improvement, and prevention of a total hip replacement due to OA deterioration occur with this surgical intervention; the risks of the intervention, and how often complications arise.

Paul A. Manner, M.D.

Associate Professor
University of Washington School of Medicine
Seattle, Washington

Specialty: Hip & Knee

College:	B.Sc. Tufts University
Medical School:	M.D. McGill University Faculty of Medicine
Internship:	St. Luke's/Roosevelt Hospital Center, New York, NY, 1991-1993
Residency:	McGill University, Montreal, QC, 1993-1996
Fellowship:	Shriners Fellow, Orthopedic Research, Joint Diseases Laboratory, Shriners Hospital for Children, Montreal Unit 1996-1997. Fellowship - Adult Reconstruction and Joint Replacement, University of Pittsburgh Medical Center, Pittsburgh, PA 1997-1998
Honors:	Resident Teaching Award, Department of Orthopedic Surgery The George Washington University Washington, DC, 2002-2003
	Fellow, Leadership Fellows Program American Academy of Orthopedic Surgeons, 2005-2006

Board Certification: Board Certified

Memberships:

- Leadership Fellows Program, American Academy of Orthopedic Surgeons, 2005-2006
- American Association of Hip and Knee Surgeons
- Fellow of the Royal College of Surgeons - Canada
- Fellow American Academy of Orthopedic Surgeons
- Orthopedic Research Society
- Washington Orthopedic Society
- Canadian Orthopedic Association

Common Surgeries Performed:

- Minimally invasive total hip replacement
- Total hip replacement
- Hemiresurfacing arthroplasty of the hip ("partial hip replacement")
- Open reduction internal fixation ("repair") of hip fractures
- Hemiarthroplasty for hip fracture
- Knee arthroscopy
- Knee osteotomy
- Minimally-invasive partial knee replacement (unicompartmental)
- Total knee replacement

Common Diagnoses Treated:

- Osteoarthritis (hip/knee)
- Rheumatoid arthritis (hip/knee)
- Avascular necrosis (osteonecrosis of the femoral head)
- Developmental dysplasia of the hip
- Metastatic disease to the hip/pelvis/knee
- Hip fracture
- Meniscus tears in the knee

Philosophy of care/General Information:

Many patients express interest in minimally invasive approaches to hip and knee surgery. I believe that this type of surgery, though technically challenging, offers many benefits to the patient, including less tissue injury, less post-operative pain, faster rehabilitation, and a shorter hospital stay.

My major interests relate to the care and treatment of osteoarthritis. My aim is to conduct clinical research that has a significant impact on the field while raising the clinical standards for optimal patient care. I want to reduce morbidity and improve outcomes in these patients not only through research but also by establishing a model of care that can be universally applied, easily adapted to both academic and community groups and led by outstanding trainees who can influence care throughout the world.

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Participant Conflict of Interest Guideline

Introduction

The HTCC Workgroup is a public service workgroup established to safeguard the public interest by identifying medical tests and treatments where evidence shows they are safe, effective, and cost-effective. Balance, independence, objectivity and scientific rigor are a basis for public trust and crucial to the credibility and integrity of decisions.

Guiding Principle

Conflict of Interest decisions must be disclosed and balanced to ensure the integrity of decisions while acknowledging the reality that interests, and sometimes even conflicting interests, do exist. Individuals that stand to gain or lose financially or professionally, or have a strong intellectual bias need to disclose such conflicts.

> *For example,* the fact that a member or stakeholder is a health care provider that may use a service under review creates a potential conflict. However, clinical and practical knowledge about a service is also useful, and may be needed in the decision making.

Procedure

Declaration of real or potential conflicts of interest, professional, intellectual, or financial is required prior to membership or provision of written or verbal commentary. Participants must sign a conflict of interest form; stakeholders providing comment must disclose conflicts.

The HTCC Chair or HCA Administrator shall make a decision, in his/her sole discretion, as to whether a conflict of interest rises to the level that participation by the conflicted participant could result in a loss of public trust or would significantly damage the integrity of the decision.

HCA defines conflict of interest as any situation in which a voting member or anyone who provides written or verbal testimony regarding products, services, or technologies discussed or voted on during the workgroup meeting, has a relationship with a manufacturer of any commercial products and / or provider of services discussed or voted on during the meeting. Relationship extends to include immediate family member(s) and / or any entity in which the member or person testifying may have an interest.

A relationship is considered as:

1. Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $10,000.
2. Equity interests such as stocks, stock options or other ownership interests in excess of $10,000 or 5% ownership, excluding mutual funds and blinded trusts.
3. Status of position as an officer, board member, trustee, owner or employee of a company or organization representing a company, association or interest group.
4. Loan or debt interest; or intellectual property rights such as patents, copyrights and royalties from such rights.
5. Manufacturer or industry support of research in which you are participating.
6. Any other relationship that could reasonably be considered a financial, intellectual, or professional conflict of interest.
7. Representation: if representing a person or organization, include the organization's name, purpose, and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).
8. Travel: if an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).

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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		✓
2.	Equity interests such as stocks, stock options or other ownership interests		✓
3.	Status of position as an officer, board member, trustee, owner		✓
4.	Loan or intellectual property rights		✓
5.	Research funding		✓
6.	Any other relationship		✓

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

_____

_____

_____

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

7. If yes, Provide Name and Funding Sources: _____

_____

_____

_____

	Potential Conflict Type	Yes	No
8.	Travel: if an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).		✓

8. If yes, Provide Name of Organization / Company and Disclose Travel Accommodations:

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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.

X _____ 8/12/20 Paul A Manner, MD

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

CURRICULUM VITAE

Name: Paul A. Manner, MD, FRCSC
Assistant Professor

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University of Washington School of Medicine
1959 Pacific Street NE
Box 356500
Seattle, WA 98195-6500

Office Phone: (206) 543-3690
Fax: (206) 685-3139
Email: pmanner@u.washington.edu

Education:

1986 B.Sc., Tufts University
Medford, MA (Biology)

For three years, I was enrolled in a five-year, double-degree (Bachelor of Music, Bachelor of Science) program at Tufts University and New England Conservatory of Music, in which I attended both schools simultaneously. In September 1985, I elected to withdraw from my studies as a clarinet performance major at NEC to concentrate on and complete my Tufts studies.

1991 M.D., McGill University Faculty of Medicine (Medicine)
Montreal, QC, Canada

Postdoctoral Training:

Internship and Residencies:

1991—1992 Intern in General Surgery, St. Luke's/Roosevelt Hospital Center, New York, NY
1992—1993 Resident in General Surgery, St. Luke's/Roosevelt Hospital Center, New York, NY
1993—1996 Resident in Orthopaedic Surgery, McGill University, Montreal, QC

Fellowships:

1996—1997	Shriners Fellow, Orthopaedic Research, Joint Diseases Laboratory, Shriners Hospital for Children, Montreal Unit
1997—1998	Fellowship - Adult Reconstruction and Joint Replacement, University of Pittsburgh Medical Center, Pittsburgh, PA

Academic Appointments:

1996—1997	Shriners Fellow, Orthopaedic Research, Joint Diseases Laboratory, Shriners Hospital for Children, Montreal Unit
1997—1998	Clinical Instructor, Department of Orthopaedic Surgery University Of Pittsburgh Medical Center. Pittsburgh, PA
2001—2006	Assistant Professor of Orthopaedic Surgery, The George Washington University, Washington, DC
2001	Visiting Faculty/Adjunct Investigator, Cartilage Biology and Orthopaedics Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS) National Institutes of Health, Bethesda, MD
2006—present	Assistant Professor of Orthopaedics and Sports Medicine, University of Washington, Seattle, WA

Hospital Appointments:

1998—2000	Holy Cross Hospital, Silver Spring, MD
1998—2000	Washington Hospital Center, Washington, DC
2000—2001	Overlook Hospital, Summit, NJ
2000—2001	Rahway Hospital, Rahway, NJ
2001—2006	The George Washington University Hospital, Washington, DC
2006—present	University of Washington Medical Center, Seattle, WA
2006—present	Harborview Medical Center, Seattle, WA

Certification and Licensure:

1991	FLEX (New York State) National Board of Medical Examiners
1991	LMCC (Licensure of the Medical Council of Canada)
1994	Principles of Surgery Examination - Royal College of Surgeons - Canada
1996	Specialty Examination in Orthopaedic Surgery - Royal College of Physicians and Surgeons – Canada
1998	American Board of Orthopaedic Surgery

	Part I Examination (written), July 14, 1998
	Part II Examination (oral), July 10, 2000
1993	Licensure in New York State (through 1998)
1996	Licensure in Pennsylvania (through 1998)
1997	Licensure in Maryland and District of Columbia (through present)
2000	Licensure in New Jersey (through 2002)
2006	Licensure in Washington State (MD 45978)
2009	American Board of Orthopaedic Surgery: Maintenance of Certification

Awards and Honors:

1997	Winner, Sherwood Davis & Geck Award for Excellence in Basic Science Research at McGill University.
2002—2003	Resident Teaching Award Department of Orthopaedic Surgery The George Washington University Washington, DC
2005—2006	Fellow, Leadership Fellows Program American Academy of Orthopaedic Surgeons

Hospital and Health Care Organization Service Responsibilities:

1998—2000	Clinical Leader, Arthroplasty Section, Centers of Excellence Strategy Planning Group, Mid-Atlantic Permanente Medical Group, PC Rockville, MD
2000—2001	Total Joint Replacement Sub-Committee, Orthopedic Service Line, Atlantic Health System Summit, NJ
2001—2006	Co-Director, The Total Joint Replacement Center The George Washington University Medical Center Washington, DC
2003—2006	Minimally Invasive Surgery Group The George Washington University Medical Center Washington, DC
2005—2008	Committee for Professional Liability American Academy of Orthopaedic Surgeons Rosemont, IL

2008—present Research Development Committee
American Academy of Orthopaedic Surgeons
Rosemont, IL

Other Major Committee Assignments:

2002—2006 Faculty Senate, The George Washington University, Washington, DC

2006—present Surgical Infections Committee, University of Washington Medical Center

2007—present Clinical Practice Committee, University of Washington Medical Center

2009—present Provider Satisfaction Committee, University of Washington Medical Center

Professional Societies:

National:
1996—present Fellow of the Royal College of Surgeons – Canada
1996—present Canadian Orthopaedic Association
1998—2000 Candidate Member, American Academy of Orthopaedic Surgeons
2000—present Fellow, American Academy of Orthopaedic Surgeons
2002—present Orthopaedic Research Society

Local:
2000—2001 New Jersey Orthopaedic Society
2001—2006 Washington Orthopaedic Society
2006—now Washington State Orthopaedic Association

Community Service Related to Professional Work:

2002 Lecturer, George Washington University Hospital Community Education Seminars – Replacing Worn Out Hips and Knees
Washington, DC

2002 Advisor on HIPAA regulations with respect to orthopaedic implant company representatives to Kathleen Fyffe, Senior Advisor, Office of the National Coordinator for Health Information Technology, Department of Health and Human Services, Washington, DC

2003 Lecturer, George Washington University Hospital Health Fair
Washington, DC

2004—2006	Lecturer, George Washington University Hospital Community Education Seminars – Minimally Invasive Knee Surgery, Minimally Invasive Hip Surgery Washington, DC
2005	National Orthopaedic Leadership Conference American Academy of Orthopaedic Surgeons Washington, DC
2006	National Orthopaedic Leadership Conference American Academy of Orthopaedic Surgeons Washington, DC
2006—present	Board Member, Arthritis Foundation Pacific Northwest Chapter Seattle, WA
2007	Featured Speaker, Journey for a Cure Arthritis Foundation Pacific Northwest Chapter Seattle, WA
2008	Featured Speaker, Journey for a Cure Arthritis Foundation Pacific Northwest Chapter Seattle, WA
2008	Arthritis Foundation Community Lecture Series Arthritis Foundation Pacific Northwest Chapter Lynnwood, WA

Teaching Responsibilities:

1. Local contributions
Medical School

2001—2006	"Introduction to Orthopaedics" "Common Orthopaedic Problems" "Examination of the Hip and Knee" Medical Student Surgical Clinical Core Teaching Program The George Washington University
2004—2006	"Introduction to Physical Examination of the Hip and Knee" Medical Student Introduction to Clinical Medicine The George Washington University

2008—2009 HuBio 553 Musculoskeletal System
University of Washington

Graduate Medical Education

2001—2006 Developed Adult Reconstruction and Arthroplasty Core Curriculum
GWU Orthopaedic Residency Program

2001—2006 Developed Basic Science Core Curriculum
GWU Orthopaedic Residency Program

2003—2006 Established research program for PGY-3 residents in Orthopaedic Surgery at Cartilage Biology and Orthopaedics Branch
National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, Bethesda, MD

2002—2006 Orthopaedic Resident Selection Committee
The George Washington University

2006—present Faculty Lecture Series
Department of Orthopaedics and Sports Medicine
University of Washington

2008 Orthopaedic Resident Selection Committee
Department of Orthopaedics and Sports Medicine
University of Washington

2008 - present Arthroscopy Boot Camp (Resident teaching)
Tracy, CA

Local Invited Teaching presentations (selected)

2002 Cartilage Biology and Orthopaedics Branch
NIAMS, NIH, Bethesda, MD

2002 Department of Rheumatology, The George Washington University, Washington, DC

2004 Featured Speaker, Association of Surgical Technologists
Annual Meeting, Washington, DC

2004 Featured Speaker, Orthopaedic Surgery Department Grand Rounds
National Naval Medical Center, Bethesda, MD

Continuing Medical Education

1997 Instructor, Revision Hip Surgery Course
American Academy of Orthopaedic Surgeons Orthopaedic Learning Center, Rosemont, IL

1998 Instructor, Lower Limb Anatomy
University of Pittsburgh Medical School
Pittsburgh, PA

1998 Lecturer, Continuing Medical Education
Mid-Atlantic Permanente Medical Group, PC
Maryland and Washington, DC.

2006 Faculty, Western Sphere of Influence September Meeting
"Embarking on the 2-incision MIS Total Hip Replacement"
"Trabecular Metal in Total Knee Replacement"
"The Mysteriously Painful Total Hip Arthroplasty"
Las Vegas, NV

2006 "What's New in Hip Replacement"
Department of Geriatrics
Harborview Medical Center
University of Washington

2007 "What's New in Hip Replacement"
Arthritis Foundation Pacific Northwest Chapter
Rheumatology Conference
Seattle, WA

2007 Faculty, Western Sphere of Influence Spring Meeting
"Trabecular Metal for hips and knees"
"The Painful Total Knee - Assessment and Treatment"
"Hip Resurfacing in 2007—Why Save the Neck?"
"The Mysteriously Painful THA"
Las Vegas, NV

2007 Faculty, Western Sphere of Influence September Meeting
"What's so great about big heads: Large Diameter Heads Should NOT be Used Most of the Time in THA"
"Two-Incision Minimally Invasive total Hip Arthroplasty in 2008"
"Hip Resurfacing in 2007—Why has it returned?"
Las Vegas, NV

2008 Faculty, The Hip and Pelvis in Function & Dysfunction: Biomechanical & Clinical Aspects of Hip & Pelvic Pain
"Recent Advances in Hip Replacement"
University of Washington
Seattle, WA

2009 Faculty, Idaho Orthopaedic Society Annual Meeting
"MIS THA/TKA: Pearls and Pitfalls"
"Bearing Surfaces and Large Femoral heads"
"Unicompartmental and Patellofemoral Arthroplasty: A New Hope?"
Boise, Idaho

2009 Faculty and Moderator, Modern Trends in Joint Replacement
"Diagnosis and Treatment of Infected Total Joint Arthroplasty"
"The AAOS Could Do a Lot Better!"
Indian Wells, CA

Advisory and Supervisory Responsibilities

2001 - 2006 Responsible for clinical supervision and educational component of adult reconstruction and arthroplasty for orthopaedic residency program
The George Washington University
Washington, DC

2002—present Mentor for 2-3 medical students/year with interest in orthopaedics
Class of 2003: 2 students
Class of 2004: 3 students
Class of 2005: 2 students
Class of 2006: 2 students

2001—2006 Shared responsibility for orthopaedic trauma education and clinical supervision while at George Washington University, Washington, DC

2006—present Shared responsibility for orthopaedic trauma and arthroplasty education and clinical supervision at the University of Washington
Seattle, WA

2007--present Faculty Research Adviser, University of Washington
Jason King, MD
Jason Wilcox, MD
Sean Amman, MD
Christopher Wolf, MD

2. Regional, National, And International Contributions

2003 "Basic Science of Cartilage—From the Machine Shop to the Greenhouse"
Visiting Faculty, Harvard Arthroplasty Course
Cambridge, MA

2003 "Two-incision Minimally Invasive Total Hip Arthroplasty"
Arthroplasty Instructional Course
Zimmer Institute; Warsaw, Indiana

2004 "Two-incision Minimally Invasive Total Hip Arthroplasty"
Arthroplasty Instructional Course
PAWS (Practical Anatomy Workshop)
St. Louis, Missouri

2004 "Two-incision Minimally Invasive Total Hip Arthroplasty"
Arthroplasty Instructional Course
Johns Hopkins Bayview Medical Center
Baltimore, MD

2005 Joint Replacement Video CME Course
Network for Continuing Medical Education
Secaucus, NJ

2005 "Embarking on the *Zimmer MIS 2-Incision* Hip Procedure"
Emerging Technologies & Techniques in Minimally Invasive Arthroplasty
Johns Hopkins Bayview Medical Center
Baltimore, MD

2006	"Computer-Assisted Total Knee Replacement" Arthroplasty Instructional Course Zimmer Institute, Warsaw, Indiana
2007	Moderator 6th Combined Meeting of the Orthopaedic Research Societies Honolulu, HI
2008	Moderator 54th Annual Meeting, Orthopaedic Research Society San Francisco, CA

Editorial Board/Reviewer:

2004—present	*Orthopedics* (Editorial Board)
2004—present	*Tissue Engineering*
2006—present	*Journal of Bone and Joint Surgery*
2005—present	*Journal of Orthopaedic Research*
2007	Orthopaedic Research Society 53rd Annual Meeting Program
2007	Orthopaedic Research Society 6th Combined Meeting
2008	Orthopaedic Research Society 54th Annual Meeting Program
2009	Canada Foundation for Innovation/Fondation canadienne pour I'innovation – Expert Committee on Musculoskeletal Research

Research, Teaching and Clinical Contributions:

A. Brief Narrative report of Research, Teaching and Clinical Contributions

My major interests relate to the care and treatment of osteoarthritis. My aim is to conduct clinical research that has a significant impact on the field while raising the clinical standards for optimal patient care. I want to reduce morbidity and improve outcomes in these patients not only through research but also by establishing a model of care that can be universally applied, easily adapted to both academic and community groups and led by outstanding trainees.

My research goals are to:
1) Improve our understanding of cartilage biology, in particular the role of artificial matrix constructs to replace or augment diseased cartilage, 2) Apply this understanding to development of new treatments relevant to joint diseases, and 3) Introduce new techniques into clinical use, thus translating laboratory findings into practical treatment for life-impairing joint disorders.

Upon my arrival at George Washington University, I initiated a formal research agreement with the Cartilage Biology and Orthopaedics Branch of the National Institute of Arthritis Musculoskeletal and Skin Diseases. After a year of collaboration with Dr. Rocky Tuan and his group, I subsequently broadened this arrangement to include resident involvement on a fulltime basis. Prior to my departure from George Washington University in 2006, I worked with Zimmer Holdings to continue salary support for this. Currently, all PGY-3 residents spend 6 months engaged in basic research in the Cartilage Biology and Orthopaedics Branch, with $145,000/annum provided by Zimmer.

In terms of clinical practice, I have been active in attempting to address perioperative morbidity and complications by the use of minimally invasive techniques for hip and knee replacement. In January 2003, I performed the first two-incision total hip arthroplasty in Washington, DC, after approximately one year of utilizing mini-incision approaches, which modified existing standard techniques. These techniques are now being applied in similar fashion to total knee arthroplasty. Clinical assessment studies are now ongoing for these techniques.

Since my arrival at the University of Washington, I have continued to collaborate with the Cartilage Biology and Orthopaedics Branch, and form new collaborations with groups at the University of Washington. My most active project of this type involves translational research in conjunction with Buddy Ratner, PhD of the University of Washington Engineered Biomaterials group.

B1. Funding Information at University of Washington

Wallace H. Coulter Foundation, $20,000 Seed Grant (August 2007-October 2007)

Wallace H. Coulter Foundation Translational Research Partnership, $100,000
(April 2008 – March 2009)

Wallace H. Coulter Foundation Translational Research Partnership, $96,000
(April 2009 – March 2010)

Details of Coulter-funded project:
A Cell-seeded Implant Scaffold For Articular Cartilage Resurfacing
Development of a scaffold device facilitating a tissue-engineering/surgical approach to articular cartilage resurfacing. The device has two faces – a face that heals to the bone as an anchor for new cartilage and a face that is seeded with mesenchymal stem cells that are directed down the cartilage lineage. The device is based on sphere–templating technology, a UW-owned development (patent applied for) and is licensed to Healionics, Inc. Initial proof-of-concept on stem cell differentiation has been successfully completed under our Coulter preliminary grant.

B2. Current Funding Proposals Submitted

1. In vitro vascular niche to improve culture-expansion of Mesenchymal Stem Cells

MSC are stem cells derived from multiple sources and have vast clinical applications for treatment of multiple diseases. However, their use for clinical application is hampered because the in vitro expansion capacity of MSC is very limited and long-term cultured MSC beyond passage 6-10 lose proliferation and differentiation capacity. In this proposal, we will study the functional need and interaction of MSC with sinusoids aimed at developing an *in vitro* vascular niche to improve culture-expansion of MSC.

PI: Morayma Reyes, PhD
Co-Investigators: Paul Manner, MD/Carol Ware, PhD
Grant number: 10348795
Grant Amount: $456,500.00
Mechanism: NIAMS R-21 (Exploratory/Developmental Research Grant Award)

2. Development of a porous scaffold of 3-D interpenetrating network of nio-ceramics and bio-polymers for skeletal reconstruction**.**

A research program to design and conduct *in vitro* and *in vivo* tests of a novel weight-bearing, patient-specific osteoinductive, osteoconductive and osseointegrative bone substitute for treatment of battlefield injuries to the upper and lower extremities.

PI: Paul Manner, MD
Co-Investigators: Christopher Allan MD/Rajendra Bordia, PhD/Peter Cavanagh, PhD/Cecilia Giachelli, PhD/Buddy Ratner, PhD
Grant Mechanism: Department of Defense (DOD) Congressionally Directed Medical Research Programs Peer Reviewed Orthopaedic Research Program (PRORP) Technology Development Award
Log number: OR090222

3. Development of novel Point-of-Care treatment for articular cartilage injury.

Use of a novel adipose-derived mesenchymal stem cell/biopolymer construct for acute and definitive osteochondral injury.

PI: Paul Manner, MD
Co-Investigator: Rocky Tuan, PhD
Grant Mechanism: Department of Defense (DOD) Congressionally Directed Medical Research Programs Peer Reviewed Orthopaedic Research Program (PRORP) Translational Research Award

Log number: OR090119P2

C. Report of Current Research Activities

My current basic science research topics include:

1. Development and use of a lapine model for osteoarthritis and cartilage injury. This builds on work I began at the NIH, as part of the Cartilage Biology Branch of NIAMS (National Institute of Arthritis, Musculoskeletal and Skin Diseases).

2. Use of artificial extracellular matrices as substrates for bone-derived adult mesenchymal stem cells. This forms the focus of my collaboration with Buddy Ratner from UWEB (University of Washington Engineered Biomaterials), along with the topic below.

3. Use of bone-derived mesenchymal stem cells for in vitro chondrogenesis

Planned: development of a bacterial DNA library for rapid diagnosis of joint infection.

Clinical research currently underway includes the following:

1. Radiologic analysis of fluoroscopically guided two-incision total hip arthroplasty (PI)

2. Economic comparison of standard and quad-sparing total knee arthroplasty (Co-PI)

3. Decision-tree analysis of staged versus direct exchange of infected total hip arthroplasty

Planned clinical research includes:

1. Use of a portable joint motion device to assess range of motion before and after hip and knee replacement (CO-PI)

2. Development of a hip anatomy simulator

3. Quantification of posterior cruciate ligament preservation in cruciate-retaining total knee arthroplasty (PI)

4. Use of memantine, an NMDA antagonist, for postoperative pain control in the setting of total knee arthroplasty (Co-PI)

D. Report of Clinical Activities

1. Description of Clinical Practice:
   My current practice focuses on hip and knee arthroplasty, with an emphasis on minimally invasive approaches to both. This comprises approximately 85% of my surgical volume, with the remainder distributed about equally between trauma and arthroscopy.

2. Patient load:
   My surgical volume has grown significantly over the last several years. Currently, on an annual basis, I perform about 300 arthroplasty procedures, divided about equally between hip and knee replacements. In addition, I take regular trauma call, which results in approximately 25 cases/year. Finally, I perform about 25 knee arthroscopies/year.

   In terms of patient visits, I average 40-60 patients/week, depending on the number of days per week spent in the clinic.

3. Clinical contributions:
   My primary contributions have been to increase the volume and scope of arthroplasty cases performed, and to further the development and study of minimally invasive procedures.

4. Other:
   Featured on local newscasts and in *Washington Post* for introducing minimally invasive hip and knee arthroplasty to the Washington, DC region.

   Featured on local newscasts and in *Seattle Times* for introducing minimally invasive hip and knee arthroplasty to the Seattle region.

FAI - Scheduled Public Comments (5 minutes per presenter)				
#	**Name**	**Representing**	**COI**	**PPT**
1	Paul Just, PharmD, BCPS	Smith & Nephew	Yes	Yes
2	Phil Downer, MD	Orthopedic Specialists of Seattle, Proliance Surgeons	Yes	Yes
3	Carlos Guanche, MD	Southern California Orthopedic Institute of Sports	Yes	No

Discussion of surgical treatment for Hip Impingement

Phil Downer MD
Orthopedic Specialists of Seattle
Proliance Surgeons

Hip preservation

- Identifying if a mechanical issue is the cause of patient hip pain
- Ruling out other non mechanical causes of hip pain
- Treating the painful hip that has failed non surgical treatment

Mechanical causes of hip pain

- Hip dysplasia and hip impingement emerging as the leading causes of damage to the hip joint
- Dysplasia well supported as mechanical cause of early hip joint failure
- Impingement becoming as clearly linked, as a cause of premature damage of the hip joint

Avoiding replacement of the hip the ultimate goal

- Clear shortcomings of hip replacement surgery
- Particular shortcomings in the young patient
  - Premature implant failure
- Productivity loss in the patient with disability due to hip pain and dysfunction

Hip damage caused by impingement a stage of arthritis

- Range of damage from mild labral fraying to full thickness articular cartilage loss
  - Association of articular cartilage damage and mechanical issues of hip impingement
- Rare to see labral damage without associated architecture issues
  - Evolving understanding of how a symptomatic hip deviates from the accepted ideal shape
- Goal is to intervene early and avoid advanced damage

Impingement surgery aimed at making a bad hip better

- Pain, physical dysfunction, and documented cartilage damage are how these patients are presenting
- The surgery to treat those who have failed non surgical treatment is aimed at slowing or possibly stopping damage progression
- Treating the mechanical issue in impingement is the primary step in symptom relief and joint preservation

Phil Downer MD

Orthopedic Specialists of Seattle

Proliance Surgeons

Washington State Health Care Authority

Participant Conflict Disclosure

Introduction

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Guiding Principle

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A relationship is considered as:

1. Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of $10,000.
2. Equity interests such as stocks, stock options or other ownership interests in excess of $10,000 or 5% ownership, excluding mutual funds and blinded trusts.
3. Status of position as an officer, board member, trustee, owner or employee of a company or organization representing a company, association or interest group.
4. Loan or debt interest; or intellectual property rights such as patents, copyrights and royalties from such rights.
5. Manufacturer or industry support of research in which you are participating.
6. Any other relationship that could reasonably be considered a financial, intellectual, or professional conflict of interest.
7. Representation: if representing a person or organization, include the organization's name, purpose, and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).
8. Travel: if an organization or company has financially paid your travel accommodations (e.g. airfare, hotel, meals, private vehicle mileage, etc).

Washington State Health Care Authority

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:

___Depuy Orthopedics Consultant_____

___Smith and Nephew Consultant_____

_____

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

7. If yes, Provide Name and Funding Sources: _____

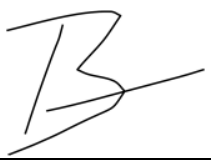
_____

_____

_____

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.

X 

Signature	Date	Print Name
	9/1/11	Phil Downer

Washington State Health Care Authority

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,
PO Box 42712, Olympia, WA 98504-2712

Washington State
Health Care Authority

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Washington State Health Care Authority

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5.	Research funding		
6.	Any other relationship, including travel arrangements	Y	

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

SMITH & NEPHEW, INC

TORNIER, INC

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		

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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.

X _____ 8/19/11 CARLOS GUANCHE

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742,

Washington State Health Care Authority

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

Employee of Smith & Nephew, Inc., Advanced Surgical Devices

	Potential Conflict Type	Yes	No
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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.

X Paul M. Just 09/01/2011 Paul M. Just, PharmD, BCPS

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

Comments On the Spectrum Research's Final Report of a Health Technology Appraisal of Femoroacetabular Impingement (FAI) Surgery

Washington State Health Care Authority
Health Technology Clinical Committee
Seattle, WA

September 16, 2011

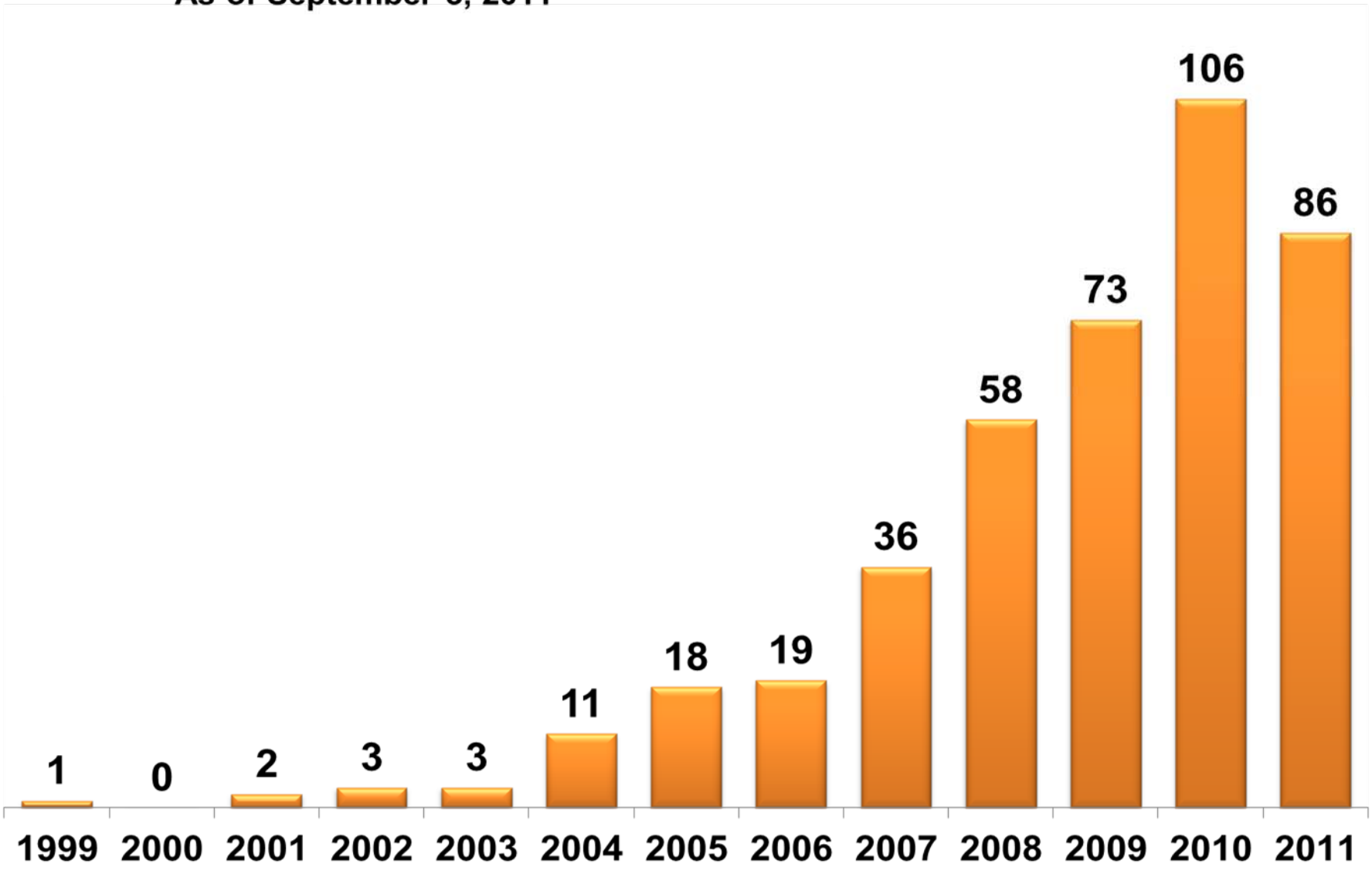
Paul M. Just, PharmD, BCPS
Director, Healthcare Economics
Advanced Surgical Devices Division
Smith & Nephew, Inc.
Andover, MA

OVERVIEW

- The diagnosis and treatment options for FAI is a rapidly evolving science so period differences exist in the published literature relative to state-of-the-art management approaches.
- Spectrum's HTA report findings are inconsistent with the preponderance of recent objective well-recognized review entities including:
  - NICE
  - Most US Commercial insurers' appraisals
  - Recent systematic reviews excluded from the final report
- The change of the key questions to require comparison to non-surgical options is unfounded. Application today of concurrent comparison non-surgical cohorts is of questionable ethics.
- The majority of 24 errors and 17 issues identified in our comments on the draft report remain unchanged in the final report (see supporting documentation Appendix A)
- Failure to cover, reimburse and pay adequately for surgical repair of symptomatic FAI would be a disservice to Washington state residents.

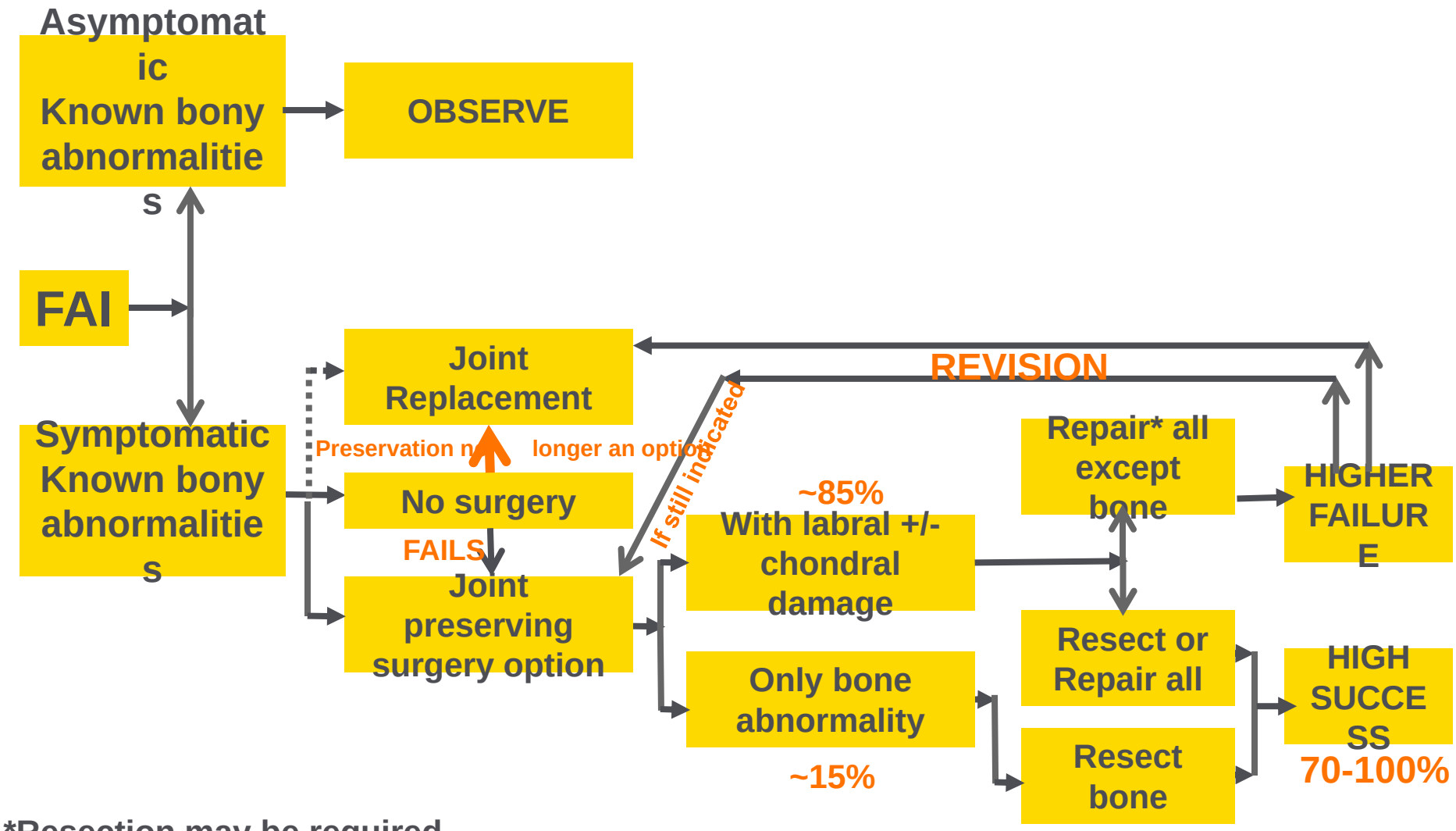
Publications Mentioning FAI (by Entrez Date)

As of September 3, 2011



From PubMed

Treatment Options for Symptomatic FAI



*Resection may be required

ERRORS

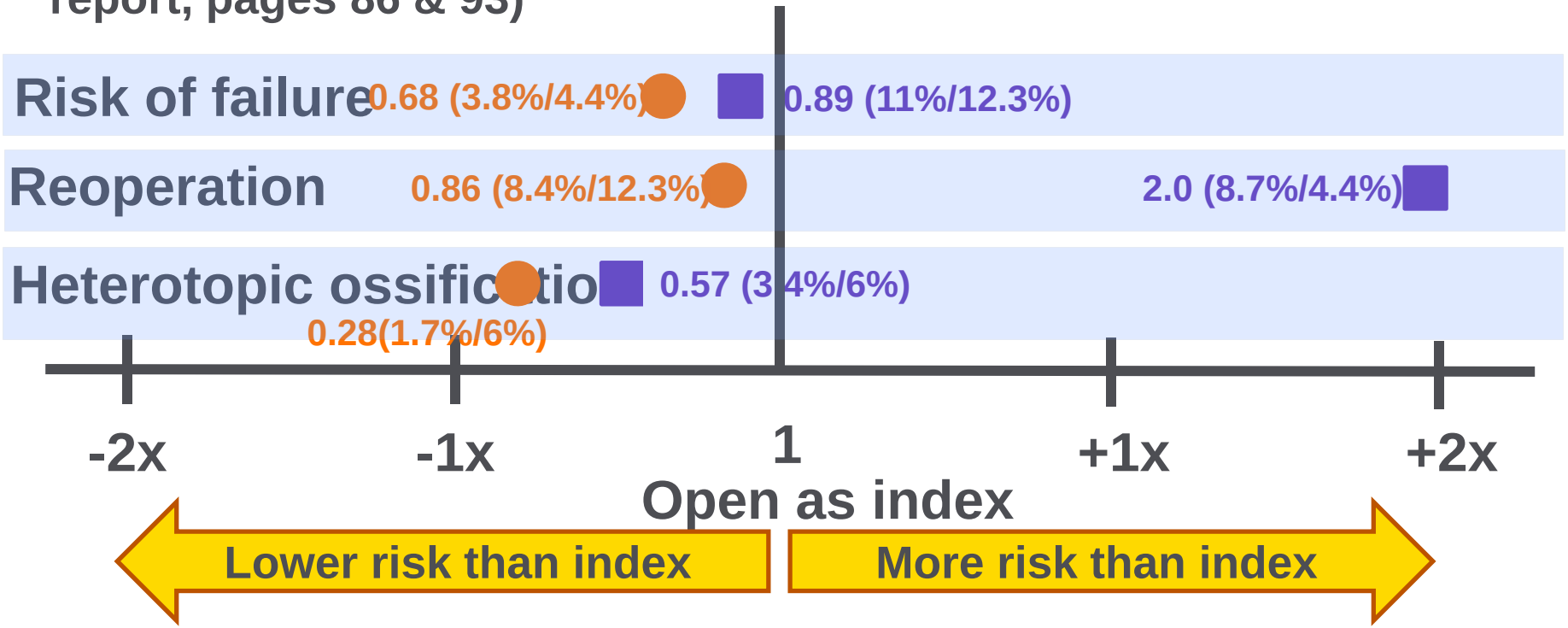
- We commented on 24 errors in the draft report with evidence for each.
- Of these, 22 remain unchanged in the final report. All are detailed in the attached Appendix A of the supporting documentation for these slides.
- Additional errors were noted
- Examples
  - P23: Stating there is no procedure code for FAI.
    As of 2011 there are three: 29914, 29915 and 29916
  - P33: Misquotes a NICE provisional guidance on arthroscopic surgery for FAI as a final guidance
  - Report concludes based on Martin, etal that there is no evidence the diagnosis of FAI can be obtained from the clinical exam." That paper states, "This study was a small case series that was not meant to provide conclusive answers regarding the accuracy of a clinical examination…." *No individual diagnostic test for FAI is intended to be applied independently.*
  - Combining complication rate data between surgical procedures across several study reports.

ISSUES and OMISSIONS

- We commented on 17 issues of concern in the draft report with evidence for each.
- Of these, 16 remain unchanged in the final report. All are detailed in the attached Appendix A of the supporting documentation for these slides.
- Examples:
  - Patients were their own controls in many case series reports. Appendix B lists 17 studies with over 1030 surgically repaired patients identifying that all had failed non-surgical treatment prior to surgery and that 75% to 100% had successful outcomes measured by return to activity or hip function scores.
  - Inappropriate and inconsistent to casually dismiss clinical outcome data from 32 case series but use them to extract complication data. *When effectiveness is controversial, the literature usually contains divergent reports for outcomes. This is NOT the case for this literature.*
  - Inclusion criteria for reviewed data are sometimes compromised. Limit to English language not supported with use of German language paper on HOS. (Page 69)
  - Three recent peer-reviewed systematic reviews were excluded from the final report.

INTERPRETIVE CHALLENGES - example

Failure to adequately address differences between surgical approaches. Relative comparison using open hip surgery as the reference index. (Data from the final report, pages 86 & 93)



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We are smith&nephew

Leah Hole-Curry, JD
Program Director, Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

VIA E-MAIL

September 2, 2011

Dear Ms. Hole-Curry:

Smith & Nephew, Inc. is a global medical technology business specializing in Orthopaedics (Trauma and Total Joint Reconstruction), Endoscopy and Advanced Wound Management. Smith & Nephew is a global leader in the development and manufacture of devices used in arthroscopic surgery.

We appreciate that the Washington State Health Care Authority Health Technology Assessment Program (HTA) has invited comments to be made at the September 16, 2011, meeting of the Health Technology Clinical Committee on the final Health Technology Assessment of Hip Surgery Procedures for Treatment of Femoroacetabular Impingement Syndrome.

I plan to attend and make comments. My Conflict of Interest Disclosure form has been submitted and here attached is a powerpoint presentation to reinforce my comments. In addition, in the form of two Appendices, referenced documentation supporting the facts included in the powerpoints is attached.

Please contact us should additional clarification be required.

Sincerely,

Paul M. Just, PharmD, BCPS
Director, Healthcare Economics

Mobile: +1-978-761-9071

APPENDIX A.

Page	Concern	Detail
6-7	Issue	Key questions 3, 4, 5, and 6 as specified in the draft report are different from the published Final Key Questions. It is not appropriate to evaluate surgical repair for symptomatic FAI against a standard of no surgery. Regardless, the draft report fails to recognize that patients in most trials served as their own controls. One criteria for surgery frequently identified, was six months or longer of conservative management that had failed to resolve the symptoms resulting in the patients not being able to perform activities at the level that existed prior to symptom onset. Because of this, patients actually served as their own controls in one-way crossover trials.
9,12, 49,103	Issue	1. The appraisal states "inclusion and exclusion criteria of a clinical trial define the population of interest, in this case, those thought to have FAI." The report appears to fail to recognize that the case definition applied in a majority of peer-reviewed publications, generally retrospective analysis of prospectively collected data, originated from visual documentation at surgery that the patients had bony impingement. Rather, it focused on the ability of what it calls the "case definition" to accurately reflect within individual reports the predictive reliability of well accepted non-invasive diagnostic criteria for FAI to reliably identify patients confirmed during surgery to have actual hip impingement. As a result, the draft report appears to be challenging the validity of the majority of publications evaluating patient outcomes following intra-operatively confirmed bony impingement in hip joints. The result is a report that inappropriately understates the favorable outcomes revealed in the peer-reviewed literature. It fails to differentiate outcomes according to the surgical technique applied in the repair and the report itself demonstrates inconsistency in study evaluation. 2. The definition of FAI is well established across the spectrum of primary, secondary and tertiary literature. FAI has been described and is defined by intra-operative pathoanatomic visual findings. Non-invasive clinical and radiographic evidence of the anatomic pathology have been subsequently associated based on numerous peer-reviewed publications of various classifications since the pathoanatomy was first conceptualized as a unique entity and defined in 1999.[1] 3. In 2011, The National Library of Medicine introduced the Medical Subject Heading, "Femoracetabular Impingement" defining it as "A pathologic mechanical process that can lead to hip failure. It is caused by abnormalities of the ACETABULUM and/or femur combined with rigorous hip motion, leading to repetitive collisions that damage the soft tissue structures."[2] 4. Stoller's Atlas of Orthopaedics and Sports Medicine identifies that FAI is "caused by an abnormal abutment between the proximal femur and the acetabular rim" and that it presents in cam, pincer and mixed cam-pincer morphologies of which the latter is most frequently reported. Further details are provided including 21 figures (Stoller's figures 3.101 to 3.121) displaying in fine detail the pathologic abnormalities.[2, 3]

Page	Concern	Detail
10,13, 92,104	Error	1. The statement that "there is no evidence that one specific treatment resulted in better outcomes than another" is not based in fact. Numerous studies referenced in the draft report but questionably discredited reasonably provide consistent evidence that patients receive benefit from surgical repair of FAI. The statement in the draft report that "27 case series were found that reported on clinical outcomes following treatment for FAI in non- or recreational athletes. All report improvement in pain, patient reported and clinical reported hip outcome scores, patient satisfaction and return to normal activities following FAI surgery," should stand without the inappropriate qualification following it. 2. A 2010 systematic review of six common indications routinely applied for hip arthroscopy concluded that the level of evidence among all was highest for FAI at grade B. All other indications received a lower grading for the level of supporting evidence.[4] This source is included in the draft report references.
10	Error	The draft report incorrectly identifies two studies comparing labral debridement to labral refixation as "…studies which investigated the effectiveness of various surgical treatments for FAI."
10, many	Issue	An Egyptian study[7] published in a Hong Kong journal of 37 patients with "Mild FAI" but excluded from participation in the study if they had evidence of "major bony pathology" should not have received the credibility and focus provided to it throughout the report. Emara, et.al. report in an Egyptian population that 33 of 37 patients with "mild" FAI responded favorably to conservative management when measured at 25 – 28 months so long as they modified their lifestyle to avoid impingement activities.[7] It is not unreasonable to question whether the reported patients had FAI as defined in the majority of Western literature. The report did not define how degrees of FAI severity were assessed. It did state that patients were excluded if their alpha angle exceeded 60 degrees or radiographic assessment revealed "any evidence of hip arthritis or a non-spherical femoral head," or "major bony pathology." No definition of what was meant by "bony pathology" was provided nor was the scale identifying what was considered "major" pathology from lesser pathology. Finally, the report states that patients were instructed to perform physiotherapy that included "stretching exercises." It is typically believed, as stated by Parvizi, et.al. (draft report reference 97) that, "Physical therapy with an emphasis on improving passive range of motion or stretching is largely counterproductive and exacerbates the symptoms."[8]
13	Error	The Tonnis Classification of hip dysplasia is not an outcome criterion for response to FAI surgery.
14	Error	The draft report inappropriately presents a simple average of reoperation rates reported for arthroscopic and open surgery for symptomatic FAI. This fails to distinguish the relative nearly 16 percent lower rate of reoperation noted elsewhere

Page	Concern	Detail
		in the draft report of 3.8 percent for arthroscopy and 4.4 percent for open procedures.
15	Error	The draft report fails to elucidate evidence that "the causes of hip pain, the natural history of FAI, and its relationship to osteoarthritis are unclear…" Rather, labral pathology as a source of the pain and various levels of evaluation deliver evidence on these relationships.[9-13] On page 21, the draft report identifies that its reference 40 identified that a pistol grip deformity was associated with hip osteoarthritis. Ganz, et.al. elucidate the data supporting the association between unrepaired FAI and the progression or development of osteoarthritis and identify that "the strategy of treatment [for FAI] should be to reconstruct a hip morphology allowing motion not interrupted by FAI before major rim and cartilage damage is established." [11] Parvizi and colleagues[8] and Leunig and associates[14] concur that not treating FAI in symptomatic patients risks progression of the pathology to osteoarthritis. The former state, "continued FAI leads to progression of the destructive process and advancement of labral and chondral lesions"[8] while the latter state that "delay in the surgical correction of symptomatic patients with thee bony abnormalities may lead to disease progression to the point where joint preservation is no longer indicated."[14] Parvizi and colleagues go on to say that in younger patients conservative management may be "temporarily successful" but that "…such treatment usually fails to control the symptoms. Vaughn and Safran, despite recognizing that at the present time no evidence proves that surgery for FAI prevents the development of osteoarthritis, conclude that in asymptomatic patients with FAI morphology, "once the patient becomes symptomatic, then early surgical intervention is recommended before the damage to the joint becomes too advanced."[15]
15	Error	The draft report generalizes hip surgery as an "invasive procedure." On page 29 it states, "Hip arthroscopy is a minimally invasive procedure…." Considering that the report was tasked with identifying differences between surgical procedures used to repair FAI, this seeming difference is not identified.
15	Issue	Characterizing joint pathology as "relatively minor abnormalities" is an inappropriate opinion not based on evidence presented in the draft report.
31	Error	Reference 119 of the draft report is incorrectly identified as a meta-analysis. It is a systematic review and was excluded from the discussion evaluating the merits of evidence supporting surgical treatment, and in this case specifically arthroscopic treatment, of FAI.[4]
33	Error	The final report now reflects the fact that the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom updated its guidance in July 2011 on open FAI surgery directionally changing the recommendation. A separate guidance on the arthroscopic repair is expected to follow shortly. The final report incorrectly identifies a provisional guidance published in the spring as a final guidance
34	Issue	1. In discussing the systematic review by Bedi, et al[16] the draft report mentions one of three conclusions of the paper that supports a conclusion the draft report

Page	Concern	Detail
		had made. 2. The draft report fails to identify the three purposes defined for the analyses performed in the Bedi, et al paper, literature quality, differences in patient satisfaction between open and arthroscopic repair and differences in outcome between open and arthroscopic repair. The authors' conclusion regarding the other two questions addressed was, "our hypothesis that arthroscopic techniques are as effective as open surgical techniques I achieving satisfactory clinical outcomes in the treatment of FAI and labral pathology was supported."[16]
34	Issue	1. The draft review discusses detail and some findings of a systematic review of treatment for FAI performed by Clohisy and colleagues.[17] The review highlights statements made by the authors supporting a conclusion of the draft report. 2. The draft review fails to present in balance the authors' concluding statement, "In conclusion, our review of the literature suggests hip impingement surgery is associated with early relief of pain and improved function."[17] This conclusion is in contradiction to the conclusion presented in the draft report.
35	Issue	1. The draft review fails to identify and discuss three additional peer-reviewed systematic reviews of FAI surgery.[18-20] a. Botser, et al review open, combined and arthroscopic surgery for FAI and conclude, "Surgical treatment of FAI has shown consistent positive outcomes with all 3 approaches reviewed in this article" and, "However, the arthroscopic method showed the greatest short-term improvement in mHHS and the lowest rate of complications."[18] b. Matsuda and colleagues review open dislocation, mini-open, and arthroscopic surgeries for femoroacetabular impingement, concluding, "The open dislocation, mini-open, and arthroscopic methods for treating symptomatic FAI are effective in improving pain and function in short-term to midterm studies and are relatively safe procedures."[19] c. Ng et al evaluate surgical treatment of FAI regardless of procedure and conclude, "Surgical treatment for FAI reliably improves patient symptoms in the majority of patients without advanced osteoarthritis or chondral damage."[20]

Page	Concern	Detail
49-50	Error	1. Comments apply to draft are slightly modified in final but issues are not completely addressed. 2. The draft report states (4.1.3) that eight reports were identified that "appeared to be prospective." However, it goes on to say that five of these do not "describe inclusion criteria for the study." Contrary to this determination, on close inspection, three of these five indicate that pre-operative clinical and radiographic assessments were consistent with accepted criteria associated with FAI and impingement was found at surgery in all patients.[21-23] One[21] of these specifically comments on the occasional mis-alignment of pre-operative radiographic assessment and intra-operative finding. However, on page 75 of the draft report, another[22] of these three "prospective" reports is discussed in detail and called a "retrospective cohort" study. This failure to consistently apply the draft report's own criteria throughout the report confounds the report's reliability. 3. Among the two studies lacking clear criteria for patient inclusion, one is an Egyptian study of 37 patients that excluded those with "major bony pathology" and was designed to evaluate conservative management attained by permanent lifestyle modification.[7] It is not unreasonable to question the relative comparability of this population to the majority of surgical intervention studies in the Western literature. 4. For none of the three identified prospective reports does there appear to be a statement identifying the fact that all patients receiving surgery had impingement confirmed. This despite one stated purpose of this section of the report (draft report pages 9 and 46) to be to contrast the intra-operative visual inspection results as a "reference standard" to the non-invasive pre-operative clinical and radiographic assessments as a means of evaluating the diagnostic validity of those pre-operative determinations. 5. Furthermore, by focusing on the pre-operative diagnosis rather than the purpose of the published report evaluated, it was not recognized that one of the three prospective studies was a technical evaluation of an adjunctive device rather than a clinical evaluation of surgery outcome.[24] It is inappropriate to include this report in an evaluation of the clinical outcomes of FAI surgery. 6. Finally, five additional prospective[25-29] studies were not included in this analysis, although one of these[27], despite stating within its description of methods that it included a consecutive series of patients "prospectively studied" has been labeled as retrospective elsewhere.[19]
49	Error	The draft report claims Gedouin does not describe included patients. Actually the article states, "Surgery was indicated for disabling symptomatology of more than six months' duration. Included patients presented with clinical and radiological signs of impingement (1)." This adequately describes by scientific standards the patient

Page	Concern	Detail
		inclusion. The second sentence refers to a tertiary reference source for a description of the events qualifying the diagnosis. This is acceptable practice. Furthermore, the description does not seem materially different from that accepted in draft report reference 101.
50	Error	Table 5 fails to correctly characterize patient inclusion criteria used for Philippon, et.al. (draft report reference 101). The paper identifies that patients had "a minimum 6 weeks" of non-operative treatment prior to surgery, "the average time from onset of symptoms to date of surgery was 19 months," and that patients had a positive anterior impingement sign and/or a positive FABER test. A positive FABER test indicates a limited range of motion in the affected hip.
50	Error	The draft report claims Jager does not describe included patients. Actually the article states, "Typical radiographic findings of osseous bump deformities on the anterolateral head-neck junction were found in 22 hips of 17 patients (13 men, 4 women). All of the patients showed typical symptoms of femoroacetabular impingement." This is a reasonable statement qualifying the investigated patients. However, some patients included in this trial would not have been or would not be included in most controlled published prospective or retrospective series of FAI patients due to etiology or secondary findings. Two of these patients were diagnosed as having "severe osteoarthritis" which is an exclusion criterion for most FAI investigations performed today. This is reflective of the fact that this is an evolving science with current practice being modified by evidence previously reported.
50	Issue	The draft report places the reference Emara, et.al. 2010 (draft report reference 29) as one that appeared to be prospective. The report does not identify whether the data was collected prospectively or retrospectively. More significantly, it is not unreasonable to question whether the reported patients had FAI as defined in the majority of Western literature. The report specifies that patients had "mild" FAI without defining how degrees of severity were assessed. It also states that included patients could not have "major bony pathology" without defining what was meant by "bony pathology" or differentiating a severity of "major" pathology from something else. Finally, the report states that patients were instructed to perform physiotherapy that included "stretching exercises." It is typically believed, as stated by Parvizi, et.al. (draft report reference 97) that, "Physical therapy with an emphasis on improving passive range of motion or stretching is largely counterproductive and exacerbates the symptoms." Finally, the report is unclear that the diagnosis was accurate.
50	Issue	The draft report places the reference Philippon, et.al. 2010 (draft report reference 101) as one that appeared to be prospective. The report states that although data was prospectively collected it was retrospectively analyzed. The authors self-classify the report as presenting Grade IV evidence.
50-51	Issue	The draft report fails to evaluate a dissenting opinion of the principal work they describe purporting to document poor performance of the α-angle in evaluating the presence of FAI.[30]

Page	Concern	Detail
57	Error	The statement relative to no consistent case definition for FAI in prospective studies is addressed in the detail for page 47 of this document.
62	Error	The Tonnis Classification system is used to grade the severity of hip osteoarthritis evaluated on radiographs.
79	Error	The draft report incorrectly reports isolated labral surgery as surgery to repair FAI.
79	Error	The draft report incorrectly assesses two studies whose purpose was to evaluate corrective labral surgery alone versus combined with concurrent osteoplasty for impingement as assessing the outcome of FAI surgery.[5, 6]
79	Issue	Section 4.3.2 and Table 9 are flawed in evaluation of the literature demonstrating a lack of understanding by the draft report team. The citations described here relate to labral surgery which in isolation is a different surgery than FAI surgery. However, that said, because labral disease is interdependent with the presence of FAI, the conditions are not unrelated.[6, 31-37]
82-83	Issue	In evaluating the Bardakos et al 2008 study the draft report states, "The no osteoplasty group had slightly worse function pre-operatively compared with the osteoplasty group…" as based on the modified Harris Hip Score. This is a biased statement lacking objectivity because the work states that there was no significant difference in this parameter between groups (P=0.59).[5]
82-83	Error	An important error in the discussion of the Bardakos et al 2008 study was reporting that there was no significant difference (P=0.06) in the excellent/good scores for the osteoplasty group compared to the no osteoplasty group. In fact, the paper reported a significant difference favoring the osteoplasty group (P=0.043).[5]
83	Error	The annotated review of Bardakos et.al. 2008 (draft report reference 2) states that clinical follow-up was by "follow-up visit" or telephone interview. The latter is correct but the former was follow-up by mail. [5]
91	Issue	The draft report fails to expand on the volume of peer-reviewed reports and the number of patients and hips according to type of surgery.
92	Error	Errors in interpretation of the presented summary information for short-term effectiveness of FAI surgery have already been described earlier in this table.
93	Issue	The quantity and severity of complications related to the different surgical approaches to FAI repair are not well discussed in the draft report. The tables alone are insufficient to represent a considered interpretation of the published facts and quantity of literature differentiating the issues.
94	Error	We question the appropriateness of including a single report of a severe complication of arthroscopy in a patient with a hip pathology unrelated to the remit. This complication occurred in a patient treated for a acetabular fracture and not FAI.
94	Issue	What is "symptomatic hardware?"
97	Error	The draft report summary mis-represents the data by inappropriately combining the

Page	Concern	Detail
		simple average of reoperation rates for patients following arthroscopic or open repair of FAI. The risk of reoperation for open repair is relatively about 16 percent higher than that for arthroscopic repair.
99	Error	The summary represents multiple interpretive errors in that the draft report fails to recognize that numerous retrospective analyses of prospectively collected data identify that patients often served as their own controls because surgery was performed only in those patients who failed to respond to an appropriate duration of conservative management.[7, 21, 22, 24, 26, 29, 38-46] These reports are included in the draft report reference but were inappropriately dismissed as poor evidence during the review process. FAI is a relatively new entity and the approach to treatment is an evolving science. However, early in its evaluation, Jager and colleagues well documented the failure of conservative treatment to successfully resolve the expressed symptoms when the underlying pathology was not surgically repaired.[22] With such documentation, it becomes difficult for institutional review boards or practicing surgeons to ethically approve of comparative clinical evaluations in which one treatment group would receive no treatment because evidence existed that no treatment is ineffective. From a practical perspective, it is difficult to imagine a patient agreeing to such a randomization during an informed consent process. **The expectation of the Washington State HCA that such evidence should exist is unreasonable.** The ethics of changing the final Key Questions to require such a comparison would make for an interesting discussion.
103-105	Issue	In the summary for Key Question 3 on page 101, the effectiveness section specifically comments on one study purporting to present evidence on the clinical outcomes of patients with FAI who were managed conservatively. This is another example of the mis-weighting and biased credit given to the Emara et al study[7] because the detail of this study was not critically appraised or discussed in the body of the draft report. A fair appraisal of comparable rigor as applied to reports of favorable clinical outcomes of surgical repair of FAI should have discovered issues of concern with the case definition applied in this report. Other comments on the findings reported in the final summary have been defined throughout this table.

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APPENDIX B

Reports confirming patients failed non-surgical treatment as a prerequisite to surgical repair of FAI.[2-18]

Reference	Supporting statement	Patients N (hips)	Favorable outcome
Jager, etal[1]	"Nine patients (10 hips; average age 34.5 years) with moderate clinical symptoms (up to 5 points on the visual analogue pain scale, which ranges from 0 “no pain” to 10 “severe pain”) but morphological signs of degenerative destruction of hip joints underwent nonoperative treatment with physiotherapy and antiinflammatory cyclooxygenase-2 (COX-2) inhibitor drugs. In cases of progression of symptoms over more than 6 months, total hip replacement was indicated (group A). In six patients (eight hips; average age 27.3 years) with labral defects but only minor cartilage destruction on MRI, the bump was removed surgically: in five hips via trochanter flip osteotomy and surgical dislocation and in two hips via an anterior surgical approach without hip dislocation (group B). Two patients (four hips, average age 49.5 years) with severe signs of osteoarthritis on standard radiographs underwent bilateral total hip replacement (group C)." "In contrast to patients who underwent the above treatments, all nonoperatively treated patients were still complaining of pain and hip dysfunction."	17	9/17
Bizzini, etal[2]	"The athletes were suffering from unspecific hip/groin pain for an average time of 13 months (range, 9-18 mo) from onset to surgery (Table 1). They all had failed conservative treatment; massage and gentle traction of the hip joint were helpful in a momentary reduction of the symptoms, while forceful stretching and ROM exercises exacerbated the symptoms."	5	100%
Byrd&Jones[3]	"The indication for hip arthroscopy was recalcitrant hip pain with imaging evidence of intraarticular pathology or clinical findings of persistent hip symptoms, as previously described, that were unresponsive to non-operative measures including activity modification and time [7]."	200 (207)	83%
Byrd&Jones[4]	"Also, there was imaging evidence of intra-articular pathologic changes or clinical findings of persistent hip symptoms unresponsive to nonoperative measures including activity modification and time."	200	90%

Reference	Supporting statement	Patients N (hips)	Favorable outcome
Espinosa, etal[5]	"All patients had not responded to conservative treatment of the femoro-acetabular impingement, which included activity modification, restriction of athletic pursuits, and avoidance of symptomatic motion for a minimum of six months."	52 (60) O,D	76% E/G (25 resected) 94% E/G (35 repair)
Flecher, etal[6]	"Inclusion criteria were mechanical pain in the inguinal fold, buttocks or trochanter region that was reproduced during passive mobilization of the hip in flexion and internal rotation, on-going for at least 6 months, failure of conservative treatment (treatment of symptoms, rehabilitation),…" Note: A study designed to test a distraction device rather than outcomes following surgery for FAI. However, this was included in the final report as a prospective outcome study in error.	23 AS	100%
Gedouin, etal[7]	"Surgery was indicated for disabling symptomatology of more than 6 months' duration."	110 (111) AS	94% (105/111)
Graves&Mast[8]	"We retrospectively reviewed the clinical records and radiographs of 51 selected patients with a diagnosis of femoroacetabular impingement who had failed nonoperative management and were… "	51 (48) (46 patients completed)	96% (of hips, 46/48)
Haviv&O'Donnell[9]	"The indication for surgery was pain in the hip accompanied by mechanical symptoms not responsive to nonoperative treatment for at least 12 weeks."	82 (164)	90% (74/82 no reoperation)
Heyworth,etal[10]	"The mean interval between the primary hip arthroscopy and recurrence of symptoms was 6.1 months… …all 23 patients reported groin pain, had pain that became worse with activity, and had no significant improvement with conservative measures, which included anti-inflammatory medications and physical therapy. In 13 of 24 procedures (54%) there was no improvement in symptoms at any time point after the primary surgery. The mean interval between the prior and revision surgery was 25.6 months (range, 7 to 43 months)." NOTE: Purpose was to evaluate revision procedures in patients hypothesized not to have had their bony impingement lesion addressed in initial operation.	23 (24) AS revision	19/24 had unaddressed impingement

Reference	Supporting statement	Patients N (hips)	Favorable outcome
Javed&O'Donnell[11]	"The indications for arthroscopy were the failure of conservative treatment for pain over a minimum of six months, limitation of internal rotation of the affected hip and a positive impingement test on flexion, adduction and internal rotation."	40 AS	75%
Meermans,etal[12]	"We reviewed the data of hip arthroscopies performed from 2000 till 2007 in 52 patients with a painful cam impingement not resolving with non-operative treatment." NOTE: "The goal of this study was to determine the prevalence of associated acetabular cartilage lesions and labral tears in patients with cam-type femoro-acetabular impingement."	52 AS	N/A
Nho, etal[13]	"We identified, from January 2007 to November 2008, high-level athletes…who…because of failed nonsurgical treatment consisting of physical therapy, oral anti-inflammatories, and inability to maintain competition."	47 AS	79% return to play at 9.4 ±4.7 months
Philippon,etal[14]	"Inclusion criteria for this study included professional athletes with at least one positive physical exam finding, at least one positive radiographic finding, and failure of at least 6 weeks of conservative therapy."	45 AS	93% (42/45, return to pro sport)
Philippon,etal[15]	"The mean time from date of onset of symptoms to surgery was 10.6 months (range, 6 weeksY30 months; Table 1 included patient demographics). No patient had either clinical or radiographic evidence of prior hip pathology. Indications for surgery included persistent pain despite conservative management, mechanical symptoms, and…"	16 AS	100% (16/16 return to play)
Philippon,etal[16]	"Inclusion criteria consisted of professional hockey players who were unable to perform at the professional level due to unremitting and debilitating hip pain." "Prior to arthroscopic intervention no athletes improved with nonoperative treatment. The nonoperative treatment protocol included a minimum of 6 weeks of nonsteroidal anti-inflammatory drugs, hip-joint injections, physical therapy, and/or activity modification."	28	100% (return to pro play)
Singh&O'Donnell[17]	"All players had symptoms for at least 6 weeks to 3 months and had received conservative treatment from the club doctors and physiotherapists. None had responded well to conservative therapy."	24 (27) AS	96% (23/24 pts)

Reference	Supporting statement	Patients N (hips)	Favorable outcome
Yun,etal[18]	"The indications for a surgical dislocation were as follows: a ≥ 1 year duration of symptoms, no response to 2-3 months of conservative treatments (Fig. 1), and …"	15 O,D	100%

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Agency Medical Director Comments

Agency Experience:

Hip Surgery for Femoroacetabular Impingement (FAI)

Sept 16, 2011

Hip Surgery for FAI: Background

- Femoroacetabular Impingement (FAI) syndrome has been described in the last 10-20 years
- The diagnosis relies largely on physical exam findings and what are often subtle radiographic imaging findings, but there is no standard case definition
- FAI is believed to be a cause of pain and limitation of function in relatively young people, including athletes
- Surgical intervention is believed by proponents to be superior to non-surgical management
  - Modifies anatomic features thought to cause the syndrome
  - Purported to improve pain and function
  - Purported to decrease risk for development of osteoarthritis (OA) of the hip

Agency Concerns

Safety Concerns (Medium)

- Young age of patients; long-term benefits and harms unknown
- Risk of surgical procedure
  - Re-operation
  - Heterotopic ossification
  - Nerve injury

Efficacy Concerns (High)

- Evidence for short-term efficacy – improved pain and function?
- Evidence for long-term efficacy – reduced risk for hip OA?
- Uncertain case definition

Cost Concerns (Medium)

- Weak evidence for efficacy, so potentially not cost-effective
- Potential for over-utilization due to case definition uncertainty and difficulty identifying cases from billing data
- Some evidence for increasing utilization

Coverage Overview: All Agencies

- DSHS: No formal coverage/non-coverage, no restrictions
- 2007-2010 PEB: No formal coverage/non-coverage, no restrictions
  - Payment denied as experimental, paid on appeal
- 2011 PEB/Regence policy:
  - Post or pre-op review
  - Xray or MRI showing cam or pincer angle within specified range
  - Failed conservative management
  - No concurrent diagnosis of osteoarthritis
- L&I: No formal coverage/non-coverage, no restrictions
  - All surgeries require prior authorization

Estimated Utilization Cost- All Agencies

Estimated FAI Hip Surgeries , Day of Surgery Costs, 2007-2010					
Calendar Year	2007	2008	2009	2010	4 Year Total
PEB	$61,626	$96,653	$225,815	$119,138	$503,232
DSHS	$27,914	$43,670	$94,995	$131,354	$297,932
L&I	$166,204	$345,206	$388,364	$553,039	$1,452,813
Total	$255,744	$485,529	$709,174	$803,531	$2,253,977

Case Cost Examples

PEB Figure 1 – Day of Surgery Costs per FAI Claim

Year	Member Number	Paid Per Surgery Date
2008	**1**	$4,103
	2	$4,103
	3	$14,533
	4	$4,103
	5	$3,899
	6	$6,900
2009	**7**	$11,222
	8	$11,696
2010	**9**	$5,307
	10	$8,982
	11a	$9,448
	11b	$11,174
Grand Total		$95,470

Case Examples, Diagnosis Coding, Gender and Age Distribution

PEB Figure 2 – Payments and Member counts by Diagnosis

Diagnosis code Description	Member Count	Total Paid
ARTICULAR CARTILAGE DISORDER, PELVIC REGION AND THIGH	9	$32,522
CHONDROMALACIA	1	$8,982
ENTHESOPATHY OF HIP REGION	1	$10,039
OTHER JOINT DERANGEMENT, NOT ELSEWHERE CLASSIFIED, PELVIC REGION AND THIGH	8	$28,080
OTHER SYNOVITIS AND TENOSYNOVITIS	1	$4,601
SPRAIN AND STRAIN OF OTHER SPECIFIED SITES OF HIP AND THIGH	1	$11,246
Grand Total		$95,470

PEB Figure 3 – FAI Claims, Mbrs by Gender & Age

Gender/Age Group	Member Count
F	
19-35	3
36-50	5
51-65	1
Total	**9**
M	
19-35	1
51-65	1
Total	**2**
Total	**11**

Case Example

- Right hip pain following fall injury. Conservative care, injections tried for 1.5 yrs.
- Negative MR arthrogram of right hip and pelvis. No evidence of any significant labral pathology. No significant degenerative changes are seen (radiologist)
- Clinical and radiographic FAI + labral tear (surgeon)
- Arthroscopic surgery: labral repair, osteoplasty and chrondroplasty of femoral head and neck.
- 7 months post surgery for FAI and labral tear symptoms not improved.
- Symptoms ongoing at 14 months post surgery

Summary

- There is no sufficiently reliable method of diagnosing FAI
- There is inadequate evidence that FAI causes pain, decreased function, or accelerated osteoarthritis
- There is no evidence that surgical intervention for FAI is more efficacious than non-surgical intervention
- There is no evidence that surgical intervention for FAI reduces risk for long-term OA of the hip
- Claims of short-term benefits of surgical intervention for FAI are based on uncontrolled studies (case series)
- Safety of surgical intervention for FAI is in question; heterotopic bone formation and nerve injury have been reported in significant numbers of patients

AMDG Considerations

1. Case definition of FAI syndrome is imprecise
2. Evidence of efficacy of surgical intervention for short-term benefit is very weak and for long-term benefit does not exist
3. There are significant safety concerns related to surgical intervention for FAI syndrome
4. There is no evidence to demonstrate cost-effectiveness of surgical intervention for FAI syndrome

AMDG Recommendations

Based on the available evidence and agency experience the AMDG recommends:

Non-coverage of surgical intervention for FAI syndrome

Agency Utilization, Hip Reconstruction

Count of Procedures by Year, 2005-2008

UMP, L&I, & Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008	Total
00.85 (total hip resurfacing)	0	3	20	22	**45**
00.86 (resurfacing, femoral head)	0	1	2	2	**5**
00.87 (resurfacing, acetabulum)	0	0	0	0	**0**
81.51 (total hip replacement)	432	471	487	614	**2004**
81.52 (partial hip replacement)	108	100	82	102	**392**
Total	**540**	**575**	**591**	**740**	**2446**

Agency Utilization, Hip Reconstruction

Amount Paid* by Procedure by Year, 2005-2008

UMP, L&I, & Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008	Total
00.85 (total hip resurfacing)	$0	$69,406	$404,120	$454,032	**$927,558**
00.86 (resurfacing, femoral head)	$0	$19,991	$36,344	$60,457	**$116,792**
00.87 (resurfacing, acetabulum)	$0	$0	$0	$0	**$0**
81.51 (total hip replacement)	$5,639,160	$6,378,458	$6,389,632	$9,036,877	**$27,444,126**
81.52 (partial hip replacement)	$1,264,504	$940,592	$957,011	$1,246,261	**$4,408,368**
Total	**$6,903,663**	**$7,408,447**	**$7,787,107**	**$10,797,626**	**$32,896,844**

FEMOROACETABULAR IMPINGEMENT (FAI) SYNDROME TECHNOLOGY ASSESSMENT

Spectrum Research, Inc.

Joseph R. Dettori, PhD, MPH
Robin Hashimoto, PhD
Erika D. Brodt, BS

Health Technology Clinical Committee Meeting
Washington State Technology Assessment Program
Seattle, Washington

SPECTRUM RESEARCH

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BACKGROUND FAI

- **Recent diagnosis in primarily younger, active individuals and athletes**
- **Often presenting with groin/hip pain, limited hip motion and limitation to activities**

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2

CONCEPT:

- **Abnormal contact between the proximal femur and acetabulum, particularly during flexion and internal rotation**
- **Due to minor morphological hip abnormalities**
- **Thought to result in labrum tears, chondral lesions, and progressive osteoarthritis (OA)**

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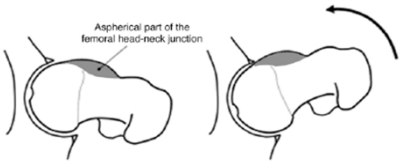
3

CLASSIFICATION

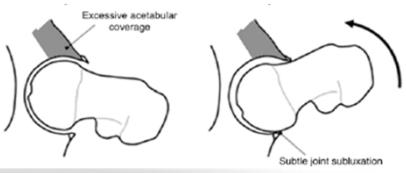
Cam-type impingement

- Non-spherical femoral head or abnormality at the head-neck junction
- Results in increased femoral head radius leading to abnormal contact with the acetabular rim in full flexion



Pincer-type impingement

- Functionally deep or retroverted acetabulum
- Results in overcoverage of the femoral head (relative anterior, focal anterior, or global overcoverage)



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TREATMENTS

Non-operative

- **Activity modification**
- **NSAIDS**
- **Pelvic postural training**
- **Physical Therapy (?)**

Surgery

- Arthroscopy
- Open dislocation of the hip
- Arthroscopy combined with a mini-open approach

Purposes of Surgery:

1) to remove abnormal outgrowths of bone and damaged cartilage
2) to reshape femoral neck (CAM) for sufficient clearance with acetabulum
3) reduce pain & slow progression of OA

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HOWEVER…

Ambiguity about:

- **The causes of hip pain**
- **Natural history of FAI**
- **Relationship of FAI to OA**
- **Uncertain case-definition of FAI**
- **Uncertain patient selection criterion for surgical procedures**
- **Questions regarding efficacy/effectiveness, safety and cost effectiveness of surgery for FAI**

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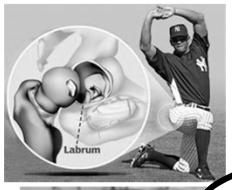
Natural history of FAI: Does it lead to OA?



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FAI → Hip Osteoarthritis?

Inference based on cross-sectional associations between abnormal hip morphology and OA

e.g.

Gosvig et al 2010 - deep acetabular socket and pistol grip deformity associated with an increase risk hip OA (RR = 2.2 and 2.4)

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However, one recent longitudinal study suggests otherwise

Hartofilakidis et al 2011:

Followed 96 asymptomatic hips with 1 or more morphological features associated with FAI

F/U = 18 years, mean age: 49 years (16-65)

OA prevalence: 18%

Authors' conclusion: "a substantial proportion of hips with femoroacetabular impingement may not develop osteoarthritis in the long-term"

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Furthermore:

Radiographic findings suggestive of FAI are common in healthy asymptomatic young adults, especially males.

N=2060	Cam-type deformity	Pincer-type deformity
Males	35%	34%
Females	10	17%

Laborie et al. 2011

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Reichenbach et al 2010 selected a random sample of 244 asymptomatic males undergoing conscription for the Swiss Army

73% had MRI evidence of a cam-type deformity (grade 1, 2 or 3)

24% had evidence of grade 2 or 3

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Hack et al 2010 had 200 asymptomatic volunteers from among Canadian hospital workers and medical students

	Cam-type deformity
Males	25%
Females	5%
IR ≤20º	25%
IR ≥20º	5%

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Kang et al 2010 :

39% of asymptomatic hips had 1 or more:

- Acetabular retroversion
- Crossover sign
- Coxa profunda
- Abnormal alpha angle
- Abnormal head-neck offset

74% had aspherical femoral head in at least one plane

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KEY QUESTIONS

1. Is there a consistent or agreed upon case definition for FAI? Is it reliable and valid?
2. What are the expected treatment outcomes of hip surgery for FAI? Are there validated outcome instruments? Has clinically meaningful improvement in outcomes been defined for FAI?
3. What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with no surgery
4. What is the evidence of the safety of hip surgery for FAI compared with no surgery?
5. What is the evidence that hip surgery for FAI compared with no surgery has differential efficacy or safety issues in sub-populations?
6. What evidence of cost implications and cost-effectiveness of hip surgery compared with no surgery exists for FAI?

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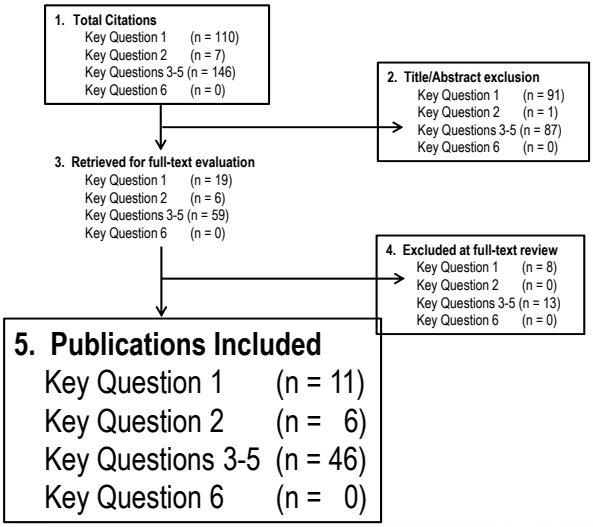
LITERATURE SEARCH



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KEY QUESTION 1: CASE DEFINITION

Significant numbers of publications describing various clinical and imaging criteria:

- **Groin pain associated with sitting, walking, or athletic activities**
- **Reduced ROM**
- **Positive impingement/FAIR/FABER test**
- **One or more imaging findings suggestive of morphological abnormalities**

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KQ1: STRATEGY TO ANSWER QUESTION

1. Inclusion/exclusion criteria from clinical trials
2. Validity studies assessing the "diagnosis" of FAI using symptoms, physical exam and imaging results

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STRATEGY 1. INCLUSION/EXCLUSION CRITERIA

Step 1. RCTs (N = 0)

↓

Step 2. Prospective non-randomized comparative studies (N = 0)

↓

Step 3. Prospective case-series (N = 7)

↓

Step 4. Prospective case-series with inclusion/exclusion criteria (N = 4)

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	Horisberger et al 2010	Philippon et al 2010	Fletcher et al 2011	Stahelin et al 2008
INCLUSION CRITERIA				
Pain	"symptomatic"	yes, preventing hockey play	yes, groin, buttock or trochanter	no
Length of pain	no	no	≥6 months	no
Failed non-op treatment	no	no	yes	no
+ impingement	yes	yes	yes	yes
Type of FAI	cam or mixed	cam, pincer or mixed	not stated	cam only
+ imaging sign	yes, osseous bump, α-angle >50º	cam: abnormal head-neck junction AND α-angle >55º pincer: coxa profunda or protrusion OR acetabular retroversion	yes, unspecified	yes, α-angle >50º
Limited ROM	yes	no	no	no
EXCLUSION CRITERIA				
Osteoarthritis	Tönnis grade III	no	Tönnis grade II or III	Tönnis grade III
Previous surgery	yes	no	no	yes
Precedent trauma	yes	no	no	no

STRATEGY 2: VALIDITY OF DIAGNOSIS USING CLINICAL EXAM, TESTS OR IMAGING

	Sensitivity	Specificity	Additional measurements
Clinical exam (Martin et al)			% agreement: 65% (6 surgeons)
Impingement test (Lohan et al)	76.9%	87.2%	PPV: 85.7% NPV: 79.1%
α-angle MR arthrography (Lohan et al)	39.3% (3 observers)	70.1% (3 observers)	PPV: 54.7% (3 observers) NPV: 53.5% (3 observers)

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KEY QUESTION 1: RELIABILITY

	Intraobserver reliability (ICC or k)	Interobserver reliability (ICC or k)
Clinical exam		
Impingement test		0.58
Imaging diagnosis		
"FAI", "dysplasia", or "normal"	0.61	0.80
Imaging		
α-angle	0.60 - 0.88	0.52 - 0.95
head-neck offset	0.43 – 0.73	0.19 - 0.24
pistol grip deformity	0.65	0.65
focal prominence	0.65	0.84
head sphericity	0.55-60	0.41 - 0.46
flattening of the femoral head	0.66	0.76
crossover sign	0.46 – 0.70	0.39
posterior wall sign	0.55 – 0.95	0.63
ischial spine sign	0.58 – 0.90	0.54
excessive acetabular coverage	0.49 – 0.71	0.75
acetabular depth	0.61	0.39
acetabular inclination	0.73	0.64
pelvic rotation	0.57	0.21

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SUMMARY KQ 1 – CASE DEFINITION

- **The most consistent case definition of FAI (cam or mixed) as defined by inclusion/exclusion criteria:**
  - **hip/groin pain**
  - **positive clinical impingement test**
  - **α-angle >50-55º**

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SUMMARY KQ 1 – CASE DEFINITION

- No evidence that the diagnosis of FAI can be obtained from clinical exam alone
- Impingement sign – (one study, prevalence = 50%)
  PPV: 86% NPV: 79%
  Reliability: only moderate

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SUMMARY KQ 1 – CASE DEFINITION

- Even though the α-angle showed moderate to high interobserver reliability, it had poor diagnostic value
- Other imaging tests had variable degrees of reliability, but no others were tested for diagnostic validity

Level of Evidence: Very low
due to lack of study quality, quantity and consistency of results

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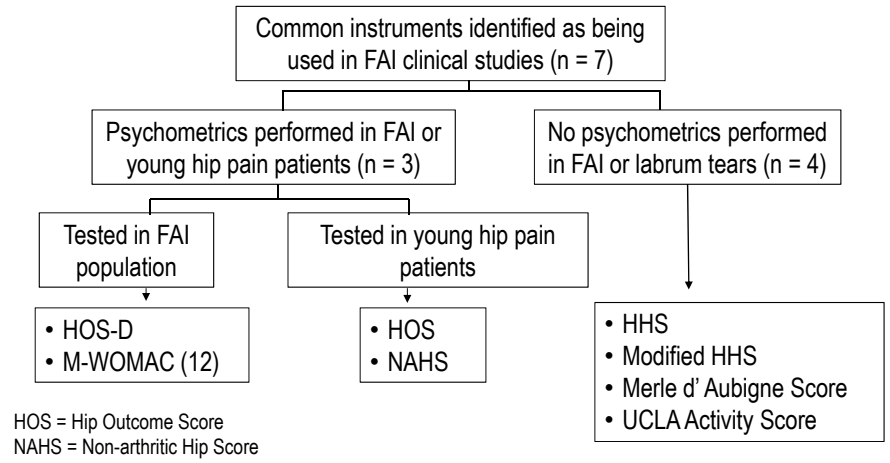
KEY QUESTION 2: TREATMENT OUTCOMES



HOS = Hip Outcome Score
NAHS = Non-arthritic Hip Score
M-WOMAC (12) = Modified Western Ontario and McMaster Universities Arthritis Index, 12 questions
HHS = Harris Hip Score

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KEY QUESTION 2: TREATMENT OUTCOMES

	Validity			Reliability		
Instrument	Content	Criterion	Construct	Internal consistency	Reproducibility	MCID
HOS/HOS-D	–	NR	+	+	+/-	+
12-item m-WOMAC	+/-	NR	+/-	+/-	NR	NR
NAHS	+	+	+	+/-	+/-	NR

HOS, MCID
9 points for ADL subscale
6 points for sports subscale

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SUMMARY KQ 2 – OUTCOMES

- Validity: only one (NAHS) of the three instruments was adequately tested for validity
- Reliability was inadequately tested for all three outcome measures
- The MCID was defined to be 9 points for the ADL subscale and 6 points for the sports subscale of the HOS-D in FAI patients

Level of Evidence: Very low
due to lack of study quality, quantity and consistency of results

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KEY QUESTION 3: EFFECTIVENESS OF FAI SURGERY

- No RCTs
- 5 retrospective comparative studies:
  - Conservative vs. FAI surgery vs. THA (1 study)
  - Labral debridement vs. labral refixation (2 studies using historical controls)
  - No Osteoplasty vs. osteoplasty (2 studies using historical controls)

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KQ 3: COMPARATIVE EFFECTIVENESS nonop vs. open FAI vs. THA

Author	Outcome (F/U 1.8 years)	Results No. of cases (%)		
Jager 2004		Nonoperative (n = 9)	Open FAI (n = 6)	THA (n = 2)
	Pain free	0 (0)	6 (100)	2 (100)
	Return to work/sports	6 (67)	6 (100)	2 (100)

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KQ 3: COMPARATIVE EFFECTIVENESS debridement vs. refixation, labrum tear

Author	Outcome	Results		F/U
		Debridement	Refixation	(years)
		N = 34	N = 37	
Larson 2009	Failure*	11.1%	7.7%	1.6
	Conversion to THA	0%	2.6%	
	MHHS (% improvement)	36.8%	49.7%	
	VAS (0-10) (% improvement)	81.3%	83.9%	
		n = 25	n = 35	
Espinosa 2006	Merle d'Aubigné Pain score (mean change score, % change)	186%	273%	2.0

*Failure definition: Modified Harris Hip Score < 70, subsequent debridement of a hip that had undergone labral refixation, or conversion to THA

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KQ 3: COMPARATIVE EFFECTIVENESS
no osteoplasty vs. osteoplasty

Author	Outcome	Results		F/U (years)
		No Osteoplasty	Osteoplasty	
Bardakos		n = 47	n = 24	> 1
2008	MHHS (% change)	40%	41%	
		n = 23	n = 25	2.0
Nepple	MHHS (% change)	39%	40%	
2009	Failure*	22%	0%	
	Conversion to THA	9%	0 (0)	

*Failure definition: Modified Harris Hip Score < 70 or need for additional surgery

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KEY QUESTION 3: CASE-SERIES

Outcome	Arthroscopy		Open Dislocation		Mini-open	
	No. studies (hips)	Risk, % (95% CI)	No. studies (hips)	Risk, % (95% CI)	No. studies . (hips)	Risk, % (95% CI)
THA conversion	9 (N=875)	4.7 (3.5, 6.3)	5 (N=204)	8.3 (5.3, 12.9)	5 (N=226)	6.2 (3.7, 10.1)
OA progression	3 (N=168)	2.4 (0.9, 5.9)	2 (N=115)	23.5 (16.7, 32.0)	3 (N=157)	8.9 (5.4, 14.4)
Pt. Satisfaction	3 (N=201)	82.1 (76.2, 86.8)	1 (N=34)	82.4 (66.5, 91.7)	1 (N=33)	90.9 (76.4, 96.9)

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KEY QUESTION 3: CASE-SERIES

Outcome	Arthroscopy		Open Dislocation		Mini-open	
	No. studies (hips)	% mean change	No. studies (hips)	% mean change	No. studies (hips)	% mean change
HOS (ADL)	1 (N=112)	25.4				
NAHS	6 (N=288)	44.2			1 (N=41)	20.1
WOMAC	3 (N=80)	29.9	1 (N=34)	33.0		
HHS	4 (N=482)	32.2	2 (N=108)	33.9	1 (N=14)	19.3

HOS: Hip Outcome Score
NAHS: Nonarthritic Hip Score
HHS: Harris Hip Score

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KEY QUESTION 3: SUMMARY EFFICACY

Level of Evidence:
No data available

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KEY QUESTION 3: SUMMARY (EFFECTIVENESS)

Short term (≤5 years)

- No good evidence that one treatment resulted in better outcomes than another
  - ✓ surgery versus no surgery
  - ✓ labral debridement versus refixation
  - ✓ osteoplasty versus no osteoplasty

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KEY QUESTION 3: SUMMARY (EFFECTIVENESS)

Short term (≤5 years)

- Several case series report improvement in pain, function, satisfaction and return to activities following FAI surgery
- Unknown if improvement is a result of surgery, postop rehab, change in activity, or placebo

Level of Evidence: Very low for short-term effectiveness
due to lack of study quality, quantity

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KEY QUESTION 3: SUMMARY (EFFECTIVENESS)

Long term (≥ 10 years)

Level of Evidence: No data available

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KEY QUESTION 4: SAFETY

	Arthroscopy			Open Dislocation			Mini-Open		
Complication	Studies	Hips	%	Studies	Hips	%	Studies	Hips	%
Reoperation	14	1263	3.8	7	180	4.4	6	334	8.7
Head-neck fx	11	688	0.2	5	227	0	3	175	0.6
AVN	8	366	0	6	173	0	2	217	0
Osteonecrosis	5	304	0	6	227	0	3	110	0
Trochanteric nonunion	4	121	0	5	202	2.0	2	134	0
Heterotopic ossification	11	1319	1.7	5	168	6.0	5	327	3.4
DVT/PE	8	607	0	4	131	0	1	41	2.4
Neurological	15	1431	1.2	5	227	0	5	243	22.2
Infection	12	1148	0.3	5	139	0	3	258	1.2
Other	3	236	1.7	2	85	12.9	1	117	29.1

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KEY QUESTION 4: SUMMARY

Safety of FAI surgery

- Reoperation (other than THA conversion) occurred in 4% (arthroscopy and open dislocation) and 9% of the patients (mini-open)
- There was only one reported head-neck fracture (0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion
- HO occurred in 2 to 3% of those receiving arthroscopy or mini-open, and 6% in those receiving open dislocation

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KEY QUESTION 4: SUMMARY

Safety of FAI surgery

- Neurological complications were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure.

Level of Evidence: Low
due to lack of study quality

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KQ5: DIFFERENTIAL EFFICACY

- No studies compared differential efficacy of treatment in subpopulations
- Five studies looked at outcomes following surgery in two subpopulations:
  - Osteoarthritis
  - Chondral damage

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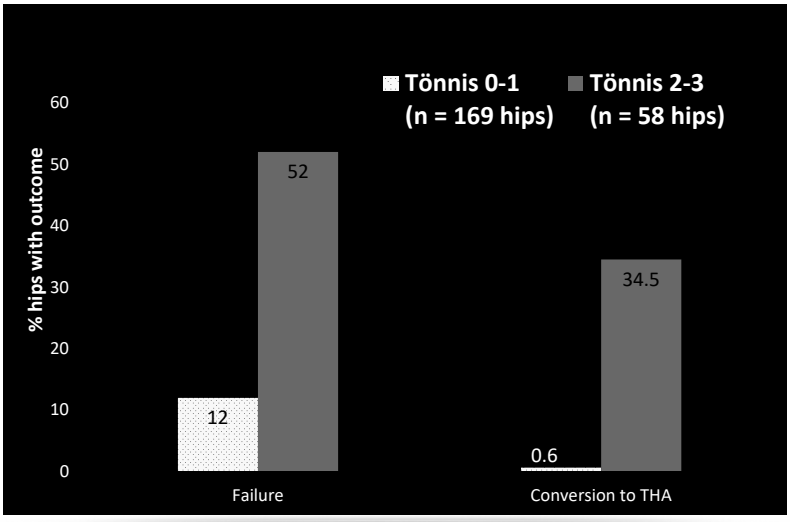
KQ5: PRE-OPERATIVE OSTEOARTHRITIS



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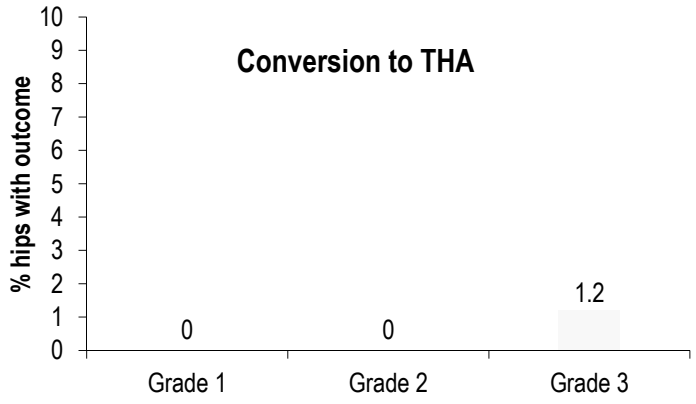
KQ5: DIFFERENTIAL EFFECTIVENESS (CHONDRAL DAMAGE)



Conversion to THA (Haviv 2010)

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KEY QUESTION 5: SUMMARY

- No study evaluated the differential efficacy or safety of treatment for FAI
- Outcomes following FAI surgery were consistently worse in patients with greater preoperative osteoarthritis compared with those with less osteoarthritis
- There was no reported difference in outcomes in patients with varying degrees of chondral damage assessed during surgery

Level of Evidence: Very low
due to lack of study quality, quantity and consistency of results

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KEY QUESTION 6: COST EFFECTIVENESS

- We were unable to find any cost-effectiveness, cost utility or costing studies on this topic.

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Conclusion:

1. No data for efficacy of surgery or long-term effectiveness
2. Very low evidence on effectiveness of surgery in the short term
3. Conversion rate to THA depends on preoperative osteoarthritis status
4. Short term reoperation rate ranges from 4% to 9%

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Conclusion:

5. The idea of a low morbidity procedure that could prevent progression of DJD in young people with abnormal hip morphology is attractive . . .

   however, data are limited to support this hypothesis

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Questions?

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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 these 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.
- 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.

[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

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

3. Factors for Consideration - Importance

At the end of discussion at 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.

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

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
CMS National Policy Decisions – WA HTA Centers for Medicare and Medicaid Services		No national or local coverage determinations or policies for the Centers for Medicare and Medicaid Services (CMS) regarding the surgical treatment of FAI syndrome.		N/A
Guidelines – WA HTA Page: 33 *National Institute for Health and Clinical Excellence (NICE)* *Arthroscopy*	2007	The National Institute for Health and Clinical Excellence (NICE), (which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales) concluded in 2007 that current evidence on the efficacy and safety of both arthroscopic surgery for the treatment of FAI syndrome "does not appear adequate for these procedures to be used without special arrangements for consent and for audit or research"; further publications of safety and efficacy outcomes will be needed. NICE stated that only surgeons with specialist expertise in arthroscopic hip surgery should perform this procedure for FAI and that the natural history of FAI syndrome and the selection of patients for this procedure are uncertain; further research on these issues will be useful.		
Guidelines – WA HTA Page: 33 *National Institute for Health and Clinical Excellence (NICE)* *Arthroscopy*	2011	In July 2011, NICE published an updated report on arthroscopy for FAI syndrome in the form a rapid review of the medical literature and specialist opinion. The review is based on approximately 1126 patients from three non-randomized controlled trials, five case-series, and one case-report. Several short-comings in the available literature were addressed such as overall poor study quality, limited prospective data collection in case-series, variability of outcome assessment scales used and lack of validation of these scales, heterogeneity in treatments making comparison between studies difficult, and descriptions of hip impingement pathology/lesions not well defined in all studies. The specialists' concluded that "there is no proof yet that this procedure is efficacious, but the technique may have a place in preventing the development of osteoarthritis of the hip in some patients". They also stated that use of		

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
		this procedure will become more widespread, but should remain with the confines of the specialist dealing with hip disorders in young adults.		
Guidelines – WA HTA Page: 33 *National Institute for Health and Clinical Excellence (NICE)* *Open Dislocation*	2011	NICE published an updated guidance report on open surgery for FAI in July 2011 stating that "current evidence on the efficacy of open femoro-acetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term. With regard to safety, there are well recognized complications. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit with local review of outcomes.		

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

	Hip Surgery Procedures for Treatment of Femoroacetabular Impingement Syndrome
Safety Outcomes	**Safety Evidence**
Mortality	
Morbidity	
Revision / Reoperation Rates	
Adverse Event Types and Functions: ▪ Peri-operative ▪ Fractures ▪ Nerve damage	
Medically Related Complications	
Other Adverse Events	
Efficacy – Effectiveness Outcomes	**Efficacy / Effectiveness Evidence**
Effectiveness of hip surgery ▪ Open ▪ Arthroscopic ▪ No surgery	
Short-term / long-term effectiveness	
Conversion to total hip arthroplasty (THA)	
Development or progression of osteoarthritis	
Impact on: ▪ Function ▪ Pain ▪ Range of Motion ▪ Return to Work ▪ Quality of Life ▪ Activities of daily living	
Patient Satisfaction	
Other Patient Outcomes	
Special Population / Considerations Outcomes	**Special Population Evidence**
Gender	
Age	

Psychological or psychosocial co-morbidities	
Baseline functional status ▪ Type of deformity ▪ Extent of osteoarthritis ▪ Cartilage damage	
Patient Characteristics	
Provider Type	
Patient Selection Criteria	
Payer or Beneficiary Type	
Cost	**Cost Evidence**
Cost Implications ▪ Direct ▪ Indirect	
Cost - Short term - Long term	
Cost Effectiveness	

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.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

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.

Clinical Committee Findings and Decisions

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.

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?