

# **Hip Surgery Procedures for Treatment of Femoroacetabular Impingement Syndrome – Re-review**

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Final evidence report

October 22, 2019

**Health Technology Assessment Program (HTA)**

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# **Hip Surgery Procedures for Treatment of Femoroacetabular Impingement Syndrome – Re-review**

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***October 22, 2019***

This technology assessment report is based on research conducted by a contracted technology assessment center, with updates as contracted by the Washington State Health Care Authority. This report is an independent assessment of the technology question(s) described based on accepted methodological principles. The findings and conclusions contained herein are those of the investigators and authors who are responsible for the content. These findings and conclusions may not necessarily represent the views of the HCA/Agency and thus, no statement in this report shall be construed as an official position or policy of the HCA/Agency.

The information in this assessment is intended to assist health care decision makers, clinicians, patients and policy makers in making sound evidence-based decisions that may improve the quality and cost-effectiveness of health care services. Information in this report is not a substitute for sound clinical judgment. Those making decisions regarding the provision of health care services should consider this report in a manner similar to any other medical reference, integrating the information with all other pertinent information to make decisions within the context of individual patient circumstances and resource availability.

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## Executive Summary

### Introduction

Femoroacetabular impingement (FAI) results from abnormal morphology of the acetabulum and femoral head/neck resulting in abnormal contact between the proximal femur and acetabulum during the end range of hip motion, particularly flexion and internal rotation. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in overcoverage of the femoral head). Clinically, patients frequently present with a combination of both types. Morphologic characteristics of FAI and labral tears on radiographs in asymptomatic patients appear to be common.<sup>25</sup> Abnormal contact between the femur and acetabulum may result in impingement and pain and/or reduced function; this may depend on activity level. Repetitive motion, particularly vigorous motion may result in joint and labral damage. A recent consensus document has suggested that the term femoroacetabular impingement syndrome (FAIS) be used for symptomatic presentation of FAI.<sup>27</sup> There is mixed evidence linking FAI to later development of osteoarthritis (OA)<sup>60</sup>; some studies suggest that cam lesions may be linked to OA development, but the impact of pincer lesions is less clear.<sup>46,62</sup> One recent study reported no difference in the risk of OA progression between patients with FAI and those with normal hip morphology.<sup>89</sup>

Initial management of FAI/FAIS usually is non-operative and can include a variety of treatments including non-steroidal anti-inflammatory drugs (NSAIDs), core strengthening, physical therapy (PT), steroid injections, activity modification and pelvic postural retraining.<sup>3,23,39,44,50,56,87</sup> While there appears to be no clear consensus on optimal non-operative treatment and limited high quality evidence on various types of non-operative care,<sup>27,56,87</sup> some recent prospective pilot randomized controlled trials suggest that an FAIS-specific PT program has the potential for a positive effect on hip pain, function, and hip adductor strength.<sup>42</sup> Proponents of operative treatment believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration. Surgical options to correct FAI include arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur. The 2016 Warwick Agreement, an expert consensus document, acknowledged that there is no high-level evidence to support the definitive treatment of FAIS and that conservative care, rehabilitation and surgery may play a role in different patients. Furthermore, there appears to be a lack of consensus and substantial inconsistency regarding specific indications or criteria for surgical treatment of FAIS across the literature.<sup>4,72</sup>

While the understanding of the etiology, history and clinical presentation of FAI/FAIS has evolved, the causes of hip pain, the natural history of FAI and its relationship to osteoarthritis remain unclear. The case definition and selection criterion of patients for surgery has historically been unclear. Furthermore, questions remain about the efficacy and effectiveness, safety and cost effectiveness of hip surgery for FAIS.

## Policy context/Reason for selection

This topic was originally reviewed in 2011. It is being re-reviewed in 2019 due to newly available published evidence.

## Objectives:

The aim of this report is to update the 2011 HTA on Hip Surgery Procedures for the Treatment of Femoroacetabular Impingement Syndrome (FAIS) by systematically reviewing, critically appraising and analyzing new research evidence comparing the safety and efficacy of operative procedures for the treatment of FAI/FAIS compared to non-operative treatments. Information on case definition/diagnostic criteria for FAI/FAIS and validated outcomes measures from the original report were updated as contextual questions.

### Contextual questions (Key Questions 1 and 2 from previous report)

1. Is there updated information published subsequent to the 2011 report regarding a consistent or agreed upon case definition for FAI/FAIS? What is the evidence of reliability and validity of these case definitions?
2. Are there additional/new validated outcomes measurement instruments used for evaluation of function or pain in FAIS patients in the updated evidence base? Is there information on clinically meaningful improvement for new validated measures used in the evidence base?

### Key questions (Key Questions 3-6 from on the previous report):

1. What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with non-operative for FAI/FAIS? Including consideration of short-term ( $\leq 5$  years) intermediate-term ( $> 5$  years to  $< 10$  years) and long-term ( $\geq 10$  years) outcomes.
2. What is the evidence of the safety of hip surgery for FAI/FAIS compared with non-operative treatment?
3. What is the evidence that hip surgery for FAI/FAIS compared with non-operative treatment has differential efficacy or safety in subpopulations (e.g. age, sex, psychological or psychosocial comorbidities, baseline characteristics, deformity type, degree of osteoarthritis or cartilage damage, provider type, payer type)?
4. What is the cost-effectiveness of surgery for FAI/FAIS compared with non-operative treatments in the short and long term?

Inclusion and exclusion criteria are summarized as follows and are detailed in the full report. Briefly, included studies met the following requirements with respect to participants, intervention, comparators, outcomes, and study design:

### Scope:

**Population:** Adults and children undergoing primary/initial treatment for FAI (symptomatic or asymptomatic).

**Intervention:** Operative treatment for FAI/FAIS (open, arthroscopic or combination).

**Comparators:** The focus was on non-operative treatment (may include, but not limited to, exercise, rehabilitation and manual therapies, activity modification, NSAIDs, injections, etc.); comparisons of surgical interventions (e.g. open vs. arthroscopic, labral repair vs. labral debridement) were included for completeness and to provide information regarding safety primarily.

**Outcomes:**

Primary Clinical outcomes:

- Functional outcome (validated patient- and clinician-reported hip scores, validated activities of daily living)
- Pain (validated measures)
- Conversion to THA

Secondary or indirect (intermediate) outcomes

- Range of motion (intermediate)
- Return to work or activity
- Quality of life
- Progression to arthritis

Safety outcomes:

- Complications/adverse events (peri-operative or longer-term)
- Revision surgery
- Additional/subsequent surgery (other than THA)
- Heterotopic ossification
- Trochanteric nonunion
- Failure of labral re-fixation
- Nerve damage
- Mortality

Economic outcomes:

- Long term and short term comparative cost-effectiveness measures

**Studies:** The focus was on high quality (low risk of bias) comparative studies (e.g., randomized controlled trials, comparative cohort studies with concurrent controls) for Key Questions 1-3. Case series with ≥40 patients that were designed specifically to evaluate safety or comprehensive systematic reviews specifically on safety were considered for inclusion. Case series focused on safety with fewer patients were considered for rare outcomes. No restrictions were placed on case series in pediatric or adolescent populations. For Key Question 3, RCTs that stratified on baseline patient characteristics and evaluated effect modification were included. Full, comparative, formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies) were sought for Key Question 4; studies using modeling may be used to determine cost-effectiveness.

## Methods

The draft key questions and scope are based on the 2011 report. They were available for public comment. All comments were considered in the finalization of the key questions. Responses to the public comments are posted on the Health Technology Assessment Program's website.

A formal, structured systematic search of the peer-reviewed literature was performed across multiple databases was conducted to identify publications (including clinical guidelines) published subsequent to the original 2011 report, i.e., from April 1, 2011 to May 14, 2019. The search process is detailed in the main report and Appendix B. Reference lists of relevant studies and the bibliographies of systematic

reviews were searched. All records were screened by two independent reviewers. Conference abstracts, non-English-language articles, duplicate publications that did not report different data or follow-up times, white papers, narrative reviews, preliminary reports, and incomplete economic evaluations were excluded. A list of excluded articles excluded at full text along with the reason for exclusion is available in Appendix C. Figure 2 in the full report outlines the results for the inclusion/exclusion process.

Consistent with the 2011 report, we focused on comparative studies evaluating operative versus non-operative treatments. Comparative studies that provide a direct comparison of treatments in the same underlying patient population were considered; indirect comparisons of case series were not considered. Studies which compared different surgical approaches or techniques for the treatment of FAIS were included for completeness only and to provide information regarding safety.. All comparative studies were assessed individually for risk of bias; however, strength of evidence was not assessed for outcomes related to efficacy or effectiveness for any of the studies evaluating only surgical interventions. All case series were considered high risk of bias.

Included studies reporting on primary outcomes of interest were critically appraised independently by two reviewers evaluating the methodological quality, study limitations and potential for bias based on study design as well as factors which may bias studies. Methods of assessing study quality are detailed in the full report. An overall Strength of Evidence (SOE) combined the appraisal of study limitations with consideration of the number of studies and the consistency across them, directness and precision of the findings to describe an overall confidence regarding the stability of estimates as further research is available. The SOE for all primary health outcomes was assessed by two researchers following the principles for adapting GRADE (Grades of Recommendation Assessment, Development and Evaluation) as outlined by the Agency for Healthcare Research and Quality (AHRQ).<sup>1,5,30,33</sup> The SOE was based on the highest quality evidence available from comparative studies for a given outcome. In determining the strength of body of evidence regarding a given outcome, the following domains were considered:

- **Risk of bias:** the extent to which the included studies have protection against bias
- **Consistency:** the degree to which the included studies report results that are similar in terms of effect sizes, range and variability.
- **Directness:** describes whether the evidence is directly related to patient health outcomes or comparisons of interventions are direct (head to head).
- **Precision:** describes the level of certainty surrounding the effect estimates.
- **Publication or reporting bias:** is considered when there is concern of selective publishing or selective reporting. This is difficult to assess particularly for nonrandomized studies.

Bodies of evidence consisting of RCTs are initially considered as High strength of evidence. In general, the GRADE and AHRQ methodologies initially consider nonrandomized studies as Low strength of evidence as such studies typically are at higher risk of bias due to lack of randomization and inability of investigators to control for critical confounding factors. Observational studies with few methodologic limitations which control for risk of bias via study conduct or analysis may be initially considered as moderate versus low, particularly for harms and outcomes when such studies may be at lower risk of bias due to confounding.<sup>7</sup> There are also situations where studies (particularly observational studies) could be upgraded if the study had large magnitude of effect or if a dose-response relationship is

identified and there are no downgrades for the primary domains listed above and confounding is not a concern.

Primary outcomes for this report were function (validated patient- and clinician-reported hip scores), pain (validated measures), conversion to total hip arthroplasty (THA) and adverse events. SOE was assessed for these primary outcomes only. For efficacy, only results for the comparison of operative versus non-operative treatment were assessed for SOE and details of other outcomes are provided in the full report with a focus on RCTs. SOE was not assessed for efficacy or effectiveness outcomes from studies comparing surgery to surgery. For safety, all study types were included in determination of SOE to provide an overall view of surgery-related complications. Evidence for effectiveness outcomes consisting of case series alone was considered insufficient evidence.

## Results

### Contextual Question 1

*Is there updated information published subsequent to the 2011 report regarding a consistent or agreed upon case definition for FAI/FAIS? What is the evidence of reliability and validity of these case definitions?*

#### Key points and comparison to 2011 report (Table A):

- The 2016 Warwick International Agreement provides expert consensus on the definition, diagnosis and general treatment options for FAIS. A 2019 consensus-based best practice guideline (Lynch, 2019) provides recommendations for patient evaluation and care before during and following hip arthroplasty for FAI as well as contraindications for arthroplasty to help decrease practice variability through all three stages and builds on the Warwick Agreement. Both documents acknowledge the paucity of high quality prospective and comparative studies on which to base FAIS diagnosis and treatment recommendations.
- The Warwick agreement recommends that diagnosis of femoroacetabular impingement syndrome (FAIS) be based on the triad of patient history, clinic tests for impingement and imaging findings. None of the criteria are pathognomonic for FAIS.
- Subsequent to the 2011, no high quality prospective accuracy studies specific to the diagnosis of FAI/FAIS as a distinct entity (versus FAI with labral tear) based on recommendations in the Warwick Agreement using surgery as a referent were identified. The agreement notes that there are not agreed upon thresholds for imaging diagnosis and that symptoms and clinical tests may not be specific to FAI. Thus, the findings from the 2011 report are generally still valid with regard case definition that includes hip/groin pain and positive impingement test and that evidence is very low (insufficient) for case definition, diagnostic accuracy of specific symptoms, clinical tests and imaging parameters and for the reliability for FAI criteria.

**Table A. Summary comparison of findings from 2011 and 2019 reports regarding case definition and diagnostic criteria, accuracy and reliability**

| <b>2011 Report</b><br>SOE: VERY LOW<br>(Insufficient)  | <b>2019 Report</b><br>(SOE: not formally assessed for contextual questions)  |
|--|--|
| <b>Case definition</b> <ul style="list-style-type: none"> <li>The most consistent case definition of FAI (cam or mixed) as defined by inclusion/exclusion criteria in prospective studies of treatment effectiveness includes hip/groin pain, positive clinical impingement test, and an <math>\alpha</math>-angle &gt;50-55°</li> </ul>   | <ul style="list-style-type: none"> <li><b>2016 Warwick Agreement</b> (expert consensus) defines FAI syndrome (FAIS) as a triad of symptoms, clinical signs and imaging findings. This emphasizes that symptoms, clinical signs and relevant imaging findings must all be present for diagnosis to distinguish it from “asymptomatic FAI” or “radiological FAI” that may be more descriptive of hip morphology versus a clinical disorder. The agreement does not specify thresholds for radiographic parameters.</li> <li><b>Inclusion/exclusion criteria</b> across 4 included RCTs most consistently define FAIS (regardless of morphologic type) based on inclusion/exclusion criteria across the RCTs includes hip or groin pain (assuming that “symptomatic” means pain was present) and positive imaging signs; one RCT noted the absence of agreed upon diagnostic thresholds</li> <li><b>Surgical criteria/indications:</b> Systematic reviews (SR) suggest a lack of consensus and substantial inconsistency regarding specific indications or criteria for surgical treatment of FAIS. A 2019 consensus-based best practice guideline alludes to general selection criteria for surgical candidates and list contraindications to surgery</li> </ul>   |
| <b>Diagnostic accuracy and reliability</b> <ul style="list-style-type: none"> <li>There is no evidence that the diagnosis of FAI can be obtained from clinical exam in one small study. One clinical test, the impingement sign, had a positive and negative predictive value of 86% and 79% in one study where the prevalence of FAI was 50%; however, in another study, the reliability of the impingement sign was only moderate.</li> <li>Even though the <math>\alpha</math>-angle showed moderate to high interobserver reliability in several studies, it had poor diagnostic value in identifying FAI. Other imaging tests assessing abnormalities of the</li> </ul> | <b>Diagnostic criteria</b> <ul style="list-style-type: none"> <li>High quality prospective studies on the accuracy of diagnostic criteria described in the agreement for FAIS compared with surgical findings were not identified. The evidence base cited in studies identified is of poor quality. None of the criteria described are pathognomonic for FAI or FAIS.</li> <li><b>2016 Warwick Agreement</b> specifies that the triad of symptoms, clinical signs and imaging findings must <b>all</b> be present to diagnose FAIS, but acknowledge that criteria are imprecise and their utility unclear. Consensus recommendations regarding criteria include:             <ul style="list-style-type: none"> <li><b>Symptoms:</b> Pain is the primary symptom, usually in hip or groin, but may be reported in lateral hip, anterior thigh, buttock, knee, and lower back, lateral and posterior thigh; typically motion-related or position-related.</li> <li><b>Clinical Tests:</b> FADIR impingement test and impingement testing to reproduce patient’s pain, ROM evaluation (including internal rotation in flexion), FABER distance; should also assess gait, single leg control, muscle tenderness. Image-guided anesthetic injection may help distinguish sources of hip pain.</li> <li><b>Imaging:</b> Morphologic assessment with plain radiographs and to rule out other painful conditions. Cross-sectional imaging (CT, MR, MRA) to further assess morphology and associated labral or chondral pathology (particularly if surgery is considered). The panel did not recommend precise diagnostic values for any common measures to define morphologies in routine clinical practice indicating FAIS is a complex interaction, during motion, between the acetabulum and femoral neck.</li> </ul> </li> <li><b>Accuracy (surgery referent) and reliability of symptoms and clinical tests:</b> <ul style="list-style-type: none"> <li>One systematic review and one retrospective study suggest that impingement tests may be sensitive but not specific for FAIS.</li> </ul> </li> </ul> |

| 2011 Report<br>SOE: VERY LOW<br>(Insufficient)   | 2019 Report<br>(SOE: not formally assessed for contextual questions)  |
|--|---|
| femur and acetabulum had variable degrees of reliability, but no others were tested for diagnostic validity. | <ul style="list-style-type: none"> <li>○ The retrospective study found that groin pain was the most sensitive (87%) and specific symptom (100%); most combinations of groin pain, impingement tests and FABER distance were sensitive (&gt;90%), but specificity was 0%</li> <li>○ Overall raw agreement for most clinical tests in one institution was substantial (58% to 99%).</li> <li>○ No prospective studies comparing the accuracy of diagnostic hip injection with surgical findings in patients with FAIS were identified</li> <li>• <b>Accuracy of imaging (surgery referent)</b> <ul style="list-style-type: none"> <li>○ Specific to FAI diagnosis, one SR reports sensitivities ranging from 71% to 91% for MRI/MRA and CT across 3 individual studies with specificities ranging from 60% to 89% using various criteria. Sensitivity (66%) and specificity (65%) of ultrasound were low. Pre-test FAIS prevalence was high; all tests impacted posttest probabilities to varying degrees; all but one study was retrospective. Another SR reported that most poor quality studies supported the use of various radiographic parameters for diagnosis of pincer-type FAI, higher quality studies were inconclusive.</li> <li>○ Two SRs suggest that MRI, MRA and CTA are useful for diagnosing labral and chondral pathology in FAIS patients. (See report)</li> </ul> </li> <li>• <b>Reliability of imaging</b> <ul style="list-style-type: none"> <li>○ Across four studies, interrater reliability varied by radiographic parameter, reader specialty and patient population, ranging from slight agreement (<math>\kappa = 0.06</math>) to substantial agreement (<math>\kappa</math> or ICC &gt; 0.61); agreement was most frequently fair to moderate across most parameters and diagnostic determination of FAI suggesting that interpretation is subjective.</li> </ul> </li> </ul> |

CT= computed tomography; CTA=computed tomography arthrography; FABER=flexion adduction external rotation test; FADDIR=flexion-adduction-internal rotation impingement test; FAI=Femoroacetabular Impingement; IR=internal rotation; LR=Likelihood ratio; MRA=magnetic resonance arthrogram; MRI=magnetic resonance imaging; NPV=negative predictive value; NR=not reported; SR= systematic review; US=ultrasound; vs.= versus

## Contextual Question 2

*Are there additional/new validated outcomes measurement instruments used for evaluation of function or pain in FAIS patients in the updated evidence base? Is there information on clinically meaningful improvement for new validated measures used in the evidence base?*

### Key points and comparison to 2011 report (Table B):

- New studies for the Tönnis system for grading OA showed only slight to fair interrater reliability and fair to moderate for intrarater reliability. By contrast another study reported substantial interobserver reliability for the Kellgren Lawrence grading system.
- Four new functional outcomes measures were used RCTs included in this update: iHOT-33 and iHOT-12, HAGOS, HOOS and OHS and in general appear to be valid and have good reliability.
- Updated MCIDS were identified for some outcomes measures compared with the prior report.

**Table B. Summary comparison of findings from 2011 and 2019 reports regarding validated outcome measurement instruments and clinically meaningful improvement**

| KQ 2, 2011 Report<br>SOE: VERY LOW (Insufficient)   | Contextual questions #2, 2019 Report<br>(SOE: not formally assessed for contextual questions)  |
|---|--|
| <p><u>Patient- and clinician reported outcomes</u></p> <ul style="list-style-type: none"> <li>• The Tönnis classification is often used to determine the extent of osteoarthritis in the hip. There were no studies found that assessed its validity. Reliability was tested in only one study and intra- and interobserver reliability in that study was moderate.</li> <li>• Seven hip outcomes measures were used commonly in FAI patients. Three have undergone psychometric analysis in FAI (HOS-D, M-WOMAC) or young hip-pain (HOS, NAHS) patient populations.</li> <li>• Only one, the Non-arthritis Hip Score (NAHS), of the three instruments was adequately tested for validity, and it was performed in a young hip-pain patient population.</li> <li>• Reliability was inadequately tested for all three instruments.</li> <li>• 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. The MCID has not been defined for any other outcome measures in FAI or young hip-pain patients.</li> </ul> | <p><u>Patient- and clinician reported outcomes</u></p> <ul style="list-style-type: none"> <li>• Two new studies found interrater reliability for the Tönnis classification to be slight to fair and intrarater reliability ranged from fair to moderate. Both conclude that reproducibility is not adequate. No validation studies in FAI patients were identified.</li> <li>• For the Kellgren Lawrence grading system from one general, population-based study reported substantial interobserver reliability. Construct validity and predictive validity for future THA were considered good.</li> <li>• Four additional hip measures were used in RCTs included in the update report: iHOT-33 and iHOT-12, HAGOS, HOOS and OHS.</li> <li>• In FAI patients, OHS demonstrated good construct validity without notable floor or ceiling effects as well as high internal consistency, internal and external responsiveness and ability to discriminate between patients. An MCID of 5.22 points was reported by different authors for adults undergoing THA.</li> <li>• A prospective longitudinal study in 50 young adults undergoing arthroscopy for FAI, labral lesion or chondroplasty (or combination) and 50 healthy age-matched adults evaluated the psychometric properties of the HAGOS, HOOS, HOS, i-HOT-33 and mHHS. Content validity for HOOS, HAGOS, and iHOT-33 and all measures were able to detect differences between the study groups. None demonstrated floor effects. Responsiveness was considered adequate for mHHS, HOOS and iHot-33.</li> <li>• Updated MCIDs in patients with hip pain and/or hip related procedures for measures are as follows: (see report for other measures) <ul style="list-style-type: none"> <li>• iHot-33 for patients undergoing arthroscopy for FAIS: pediatric, 10.7 pts, adults 12.1 pts</li> <li>• mHHS: pediatric patients undergoing arthroscopy for FAIS 9.7pts, adults, any arthroscopy 8 pts</li> <li>• Adult arthroscopy patients: HAGOS-pain: 6 points, HAGOS-symptoms: 10 points, HAGOS-ADL: 9 points, HAGOS-sport: 9 points, HAGOS-physical activity: 1point, HAGOS- QOL: 9 points</li> <li>• VAS pain (0-100 pts), adult arthroscopy patients: - 15 points</li> </ul> </li> </ul> |



## Key Questions 1-4

A total of 82 studies (across 84 publications) were identified that met inclusion criteria and addressed Key Questions 1 to 4: four randomized controlled trials (RCTs),<sup>28,45,52,66</sup> 16 observational comparative cohorts,<sup>2,9,10,13,21,37,41,48,57,69,74,75,78,81,88,91</sup> four systematic reviews (SRs) of case-series,<sup>8,18,59,77</sup> 55 case series (across 57 publications), and three formal cost-effectiveness analyses.<sup>28,54,84</sup> A total of 14 studies were in pediatric populations and included one observational cohort comparing operative versus non-operative treatment<sup>69</sup>, 11 case series of arthroscopy<sup>11,12,17,19,24,29,49,51,55,73,86</sup> and two case series of open hip dislocation surgery<sup>64,85</sup>.

Consistent with the 2011 HTA, the focus of this update report is on the efficacy and effectiveness of operative versus non-operative treatment for FAIS. The overall quality of the available evidence base for this comparison was considered fair; the primary evidence for this report is from RCTs considered to be predominately moderately low risk of bias. For safety, the overall quality of evidence was poor as the majority of data was from case series or comparative cohorts considered to be at high risk of bias.

### *Comparison with 2011 report*

No RCTs and only one poor quality cohort that compared operative treatment versus non-operative historical controls was identified for the 2011 report. For this update, we identified five new studies comparing operative versus non-operative treatment, three RCTs<sup>28,52,66</sup> and two observational comparative cohorts (one of which was in adolescents).<sup>41,69</sup> All studies reported short-term data (≤5 years) with the longest follow-up by a RCT being 24 months. Studies comparing different surgical approaches for the treatment of FAIS, as well as case series, are included for completeness only and to provide a more complete overview of surgical safety in FAIS. All but one comparative study was in adult populations; there is insufficient evidence from case series on the effectiveness of surgical intervention in adolescent populations.

While the addition of the three new RCTs addresses the primary evidence gap identified in the 2011 report, namely comparison of surgical intervention with non-operative treatment for FAIS, the SOE was low and effect sizes were small and of questionable clinical significance across most outcomes measures. Where improvement was noted, whether this improvement is a result of the surgery, or the postoperative rehabilitation, or the change in activity subsequent to the surgery or placebo is not known.

There was heterogeneity across trials in patient selection, operative procedures and control conditions, which may contribute to some of the inconsistencies in findings between trials. The extent to which non-operative treatments may reflect more recent concepts for such care in FAIS is unknown. Post-operative rehabilitation was poorly described and it is unclear how this may or may not impact outcomes. Surgical intervention included procedures for labral tear in >90% of patients resulting. It is unclear whether soft-tissue procedures (i.e. for labrum and cartilage) done without bone debridement may result in similar symptom relief. Similarly, it is unclear to what extent labral pathology seen in conjunction with FAI is due to the bone morphology and whether altering bone morphology prevents future pathology.

None of the RCTs or comparative studies for operative versus non-operative treatment reported on outcomes beyond 24 months. Based on this limited follow-up, it is unclear whether surgical intervention or non-operative management may impact progression to OA, long-term function and pain or

conversion to THA. Across included studies, including surgical cohorts and case series with long term ( $\geq 5$  years) follow-up, the ranges for conversion to THA and frequency of OA were wide.

Table C below provides a broad overview of the results and strength of evidence for the 2011 review compared with this 2019 review. (This overview does *not* connote any recommendations for policy). The focus of these reports was on the comparative efficacy/effectiveness and safety of operative versus non-operative treatments.

**Table C. Comparison of Key Findings between the 2011 Report and the 2019 Update Report.**

|   | 2011 Report  | 2019 Report Update   |
|---|--|--|
| <b>Efficacy, short-term (<math>\leq 5</math> years):</b>  | There is no evidence available to assess the short-term efficacy of FAI surgery compared with no surgery                 | <ul style="list-style-type: none"> <li>No studies comparing operative and non-operative care in asymptomatic patients were identified.</li> <li>3 RCTs comparing arthroscopy with physical therapy for FAIS in adults over the short-term (up to 24 months) were identified. Procedures to address labral tears were done in <math>&lt;90\%</math> of patients.</li> </ul> <p><b>Function</b></p> <ul style="list-style-type: none"> <li>Improvement favoring arthroscopy versus PT was seen for function at 6 to 8 months based on the International Hip Outcome Tool (iHOT-33) (3 RCTs) and the HOS-Sport subscale (2 RCTs); only the difference on the HOS-Sport subscale is likely clinically significant. (SOE: low)</li> <li>No clear difference between groups was seen for iHOT-33, HOS-ADL or HOS-Sport at 12 or 24 months. (SOE: low for the i-HOT-33 at 12 months [2 trials]; insufficient for the i-HOT-33 at 24 months and the HOS-ADL and -Sport subscales at both times [1 trial]).</li> </ul> <p><b>Pain</b></p> <ul style="list-style-type: none"> <li>In one RCT, greater improvement in pain (HAGOS) was reported following arthroscopy versus PT at 8 months; the difference may be clinically important, but the confidence interval is wide; fewer arthroscopy patients reported pain on hip flexion, adduction and the FABER test but there were no differences between groups on other assessments; clinical relevance of differences is unclear (SOE: low).</li> </ul> <p><b>Conversion to THA</b></p> <ul style="list-style-type: none"> <li>Across two RCTs, two arthroscopy patients (1.0%) compared with none who received PT required conversion to THA up to 24 months; sample size and short follow-up may impact the ability to adequately capture this event (SOE: insufficient).</li> </ul> |
| <b>Efficacy, intermediate- (&gt;5 years to &lt;10 years) or long-term (<math>\geq 10</math> years):</b> | There is no evidence available to assess the intermediate- or long-term efficacy of FAI surgery compared with no surgery | No evidence to assess the intermediate- or long-term efficacy of FAI operative versus non-operative was identified.  |

|   | 2011 Report  | 2019 Report Update  |
|---|--|---|
| <b>Effectiveness, short-term (<math>\leq 5</math> years):</b>   | <ul style="list-style-type: none"> <li>There is no evidence that one specific treatment resulted in better outcomes than another (surgery versus no surgery, labral debridement versus refixation, osteoplasty versus no osteoplasty).</li> <li>Several case series report improvement in pain, patient reported and clinician reported hip outcome scores, patient satisfaction and return to normal activities following FAI surgery. However, whether this improvement is a result of the surgery, or the postoperative rehabilitation, or the change in activity subsequent to the surgery or placebo is not known. (SOE: Insufficient)</li> <li>Approximately 8% of patients diagnosed with FAI who undergo surgery in published series go on to have a total hip arthroplasty within 3 years. (SOE: Insufficient)</li> </ul> | <ul style="list-style-type: none"> <li>Given the availability of higher-quality evidence from RCTs, SOE was not formally assessed for outcomes from observational studies.</li> <li>Evidence available from two poor quality (high risk of bias) observational cohorts was considered insufficient to assess the short-term effectiveness of arthroscopy versus non-operative treatment of FAIS in adults (1 study) or adolescents (1 study). The study in adolescents included an active comparator (formal PT plus activity modification, steroid injections). The adult study included only activity modification and NSAIDs.</li> <li>Consistent with the prior report, in general, across studies comparing operative approaches for FAIS, results were comparable between groups; when statistical differences were seen they tended to favor arthroscopy vs. open hip dislocation and labral repair vs. labral debridement. THA was performed in 3% vs. 13% (arthroscopy vs. open surgery, respectively) in one small cohort; the difference may be clinically important.</li> </ul> |
| <b>Effectiveness, intermediate (<math>&gt;5</math> years to <math>&lt;10</math> years) or long-term (<math>\geq 10</math> years):</b> | <ul style="list-style-type: none"> <li>There are no data available to assess intermediate- or long-term effectiveness of FAI surgery compared with no surgery.</li> <li>There are no data yet published to test the hypothesis that FAI surgery prevents or delays hip osteoarthritis or the need for total hip arthroplasty.</li> </ul>   | <ul style="list-style-type: none"> <li>There are no data available to assess intermediate- or long-term effectiveness of operative versus non-operative treatment for FAIS.</li> <li>Based on included operative vs. non-operative studies, there is still insufficient evidence that FAI surgery prevents or delays hip OA or the need for THA.</li> </ul>   |
| <b>Safety</b>   | <ul style="list-style-type: none"> <li>The risk of reoperation (other than conversion to THA) occurred in 4% (arthroscopy and open dislocation) and 9% of the patients (mini-open).</li> <li>There was only one reported head-neck fracture (0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion.</li> <li>Heterotopic ossification occurred in 2 to 3% of those</li> </ul>  | <ul style="list-style-type: none"> <li>Across 2 RCTs comparing arthroscopy vs. PT there were no deaths; serious and non-serious treatment-related AEs were more common following arthroscopy as might be expected given its invasive nature. (SOE: low)</li> <li>Across RCTs, SRs of case series, comparative surgery cohorts, and additional case series in adults and adolescents, it appears that the frequency of most serious surgical complications may be low (<math>&lt;3\%</math>). Surgical complications with higher risks from adult studies included transient nerve injury (0% to 25%; 0% to 9% excluding outliers) and revision surgery (0% to 8%). In case series of adolescents, no cases of physeal</li> </ul>  |

|   | 2011 Report  | 2019 Report Update   |
|---|--|--|
|   | <p>receiving arthroscopy or mini-open, and 6% in those receiving open dislocation.</p> <ul style="list-style-type: none"> <li>Neurological complications (nerve palsy, paresthesia, and neuropraxia) were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure. Most were transient in nature.</li> </ul> | <p>arrest/growth disturbance, femoral fracture, nonunion of the greater trochanter, avascular necrosis, acute iatrogenic slipped capital femoral epiphysis, or iatrogenic instability were seen. (SOE: low)</p>  |
| <b>Differential Efficacy and Safety</b> | No evidence  | <ul style="list-style-type: none"> <li>Evidence from two trials evaluating whether age, FAI type, sex, Kellgren Lawrence grade and study center modify the treatment effect following operative versus non-operative treatment was insufficient to draw conclusions.</li> </ul>  |
| <b>Cost-effectiveness</b>               | No evidence  | <ul style="list-style-type: none"> <li>Conclusions regarding the cost-effectiveness of hip arthroscopy compared with non-operative care were inconsistent across three cost-utility analyses.</li> <li>The only CUA (moderate quality) based on RCT data found that personalized PT was both more effective and less costly than arthroscopy at one year from the U.K. National Health Service perspective. The short-term horizon precluded evaluation of OA development or conversion to THA.</li> <li>Two poor quality CUAs from the U.S. found that arthroscopy was more cost-effective than non-operative care from a societal perspective over 10 year and more cost-effective than observation from a hospital cost perspective for a lifetime. Primary data sources were case series, expert opinion and retrospective survey of arthroscopy patients. Both used an unvalidated method for determining utility.</li> </ul> |

AVN = avascular necrosis; CUA= cost-utility analyses; FAbER = Flexion, Abduction and External Rotation; FAI/FAIS = femoroacetabular impingement/femoroacetabular impingement syndrome; HAGOS = Copenhagen hip and groin outcome score; HOS-ADL = Hip Outcome Score Activities of Daily Living subscale; HOS-Sport = Hip Outcome Score Sports subscale; HTA = health technology assessment; i-HOTT-33 = The international Hip Outcome Tool-33 items; NSAIDs = non-steroidal anti-inflammatory drugs; OA = osteoarthritis; PT = physical therapy; RCT = randomized controlled trial; SOE = strength of evidence; SR = systematic review; THA = total hip arthroplasty; U.K = United Kingdom.

## Summary of Results

### Key Question 1.

*What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with non-operative treatment for FAI/FAIS? Including consideration of short-term ( $\leq 5$  years) intermediate-term ( $> 5$  years to  $< 10$  years) and long-term ( $\geq 10$  years) outcomes.*

### Operative versus Non-operative Treatment

Three RCTs conducted in adult populations<sup>28,52,66</sup> and two observational comparative cohorts, one in adults<sup>41</sup> and one in adolescents,<sup>69</sup> that met inclusion criteria were identified. No studies reported on long-term ( $\geq 5$  years) outcomes comparing operative versus non-operative treatment.

- One RCT reported that more arthroscopy patients compared with physical therapy (PT) patients achieved clinically important improvements in function according to the Hip Outcome Score Activities of Daily Living (HOS-ADL) subscale: minimal clinically important difference (MCID)  $\geq 9$  points (51% vs. 32%; RR 1.6, 95% CI 1.1 to 2.3) and final score  $> 87$  points (48% vs. 19%; RR 2.5, 95% CI 1.5 to 4.0) (SOE: low) short term (8 months).
- Improvement favoring arthroscopy versus PT was seen for function based on the International Hip Outcome Tool (iHOT-33) (3 RCTs; pooled MD 1.94 on a 0-100 scale, 95% CI 0.13 to 3.03,  $I^2=0\%$ ) and the HOS-Sport subscale (2 RCTs; pooled MD 10.98 on a 0-100 scale, 95% CI 5.67 to 16.30,  $I^2=0\%$ ) at 6 to 8 months; however, only the difference on the HOS-Sport subscale is likely clinically significant. (SOE: low)
- No clear difference between groups was seen for functional outcomes at any other timepoint measured: i-HOT-33 at 12 months (2 trials) and 24 months (1 trial), and no difference the HOS-ADL and HOS-Sport subscales at 12 and 24 months in one RCT. (SOE: low for the i-HOT-33 at 12 months; insufficient for the i-HOT-33 at 24 months and the HOS-ADL and -Sport subscales at both timepoints).
- Greater improvement in pain based on the Copenhagen hip and groin outcome score (HAGOS) was reported by patients who received arthroscopy versus PT at 8 months (adjusted MD 12.7, 95% CI 8.1 to 17.2) in one RCT; the difference may be clinically important, but the confidence interval is wide. This same trial found that fewer arthroscopy patients reported pain on hip flexion, hip adduction and the FABER test but there were no differences between groups on other assessments; clinical relevance of differences is unclear. (SOE: low).
- Across two RCTs, two patients (1.0%) in the arthroscopy groups compared with no patient who received PT required conversion to total hip arthroplasty (THA) over 12 and 24 months; sample size and follow-up likely impacted the ability to adequately capture this event (SOE: insufficient).
- Two observational studies at moderately high risk of bias, one in adults and one in adolescents, reported similar functional results between patients who went on to have arthroscopy versus those who received conservative care only based on the modified Harris Hip Score (2 studies), Non-Arthritic Hip Score (NAHS, 2 studies) and the Western Ontario and McMasters

Osteoarthritis Index (1 study) at a mean of 27 months. In the study evaluating adolescent athletes, there was no difference between treatment groups (arthroscopy versus PT with or without steroid injection) in the proportion of patients who returned to sport.

- No comparative long-term evidence ( $\geq 5$  years) regarding comparative benefit of operative versus non-operative care was identified.
- The characteristics and frequency of non-operative care sessions varied across studies and in general, components of postoperative rehabilitation were not specified. The impact of these on results is unknown.

### Operative versus Operative Treatment

A total of 15 comparative studies were identified including one RCT<sup>45</sup> and 14 observational cohorts<sup>2,9,10,13,21,37,48,57,74,75,78,81,88,91</sup> comparing various surgical approaches to the treatment of FAIS, most commonly arthroscopy versus open hip dislocation and labral repair versus labral debridement. In addition, one case series in an adolescent population and 14 case series in adult populations with at least 5 years of follow-up were identified that reported progression to osteoarthritis (OA) or conversion to total hip arthroplasty (THA).

- In one small RCT, patients who received labral repair versus labral debridement, reported significantly better function according to HOS-ADL and HOS-Sport subscale scores at a mean follow-up of 32 months (short term). Baseline scores did not differ statistically between groups as reported by the authors; however, when comparing the change scores from baseline to follow-up on both functional measures the two treatment groups appear more similar. No other outcomes were reported by this trial.
- Across 12 observational cohorts comparing different surgical approaches to the treatment of FAIS, results varied across the function measures reported. In general, results were comparable between surgical treatment groups; when statistical differences were seen they tended to favor arthroscopy as opposed to open hip dislocation surgery and labral repair as opposed to labral debridement. Only two comparative cohort studies reported on pain (via various different measures) with inconsistent results. Only one, small cohort reported the proportion of patients who required THA with no significant difference seen between the arthroscopy and open surgery groups (3% vs. 13%, respectively); the difference may be clinically important.
- In Across 13 surgical case series with at least 5 years of follow-up, the frequency of conversion to THA in adults ranged from 2% to 34%; in the two large systematic reviews of case series, pooled THA rates were 6.3% and 6.5%. Only three of these case series reported progression to OA which ranged from 8% to 12%.
- Twelve surgical case series provided effectiveness data for pediatric populations receiving operative treatment for FAIS; statistically significant improvements from baseline were seen for function and pain (based on various measures) over a wide range of follow-up periods (mean 1.5 to 50 months). A high proportion of adolescent athletes (86% to 100%) returned to sport

following surgery as reported by five studies. No patient required a conversion to THA following arthroscopy in one small case series (N=28) of adolescent athletes followed for a mean of 40 months.

- Results for comparative studies of surgical intervention should be interpreted cautiously given their potential for high risk of bias. In the absence of studies comparing surgical intervention with active comparators (e.g. exercise, specific rehabilitation and manual therapies that may be designed to change the way the joint is being used), conclusions about the benefits of surgical intervention are limited.

## Key Question 2.

*What is the evidence of the safety of hip surgery for FAI/FAIS compared with non-operative treatment?*

In total, 58 studies (3 RCTs,<sup>28,52,66</sup> 12 cohort studies,<sup>9,10,13,21,37,48,57,74,75,78,88,91</sup> 4 SRs of cases series,<sup>8,18,59,77</sup> and 40 additional case series [across 42 publications])<sup>6,11,12,14-16,19,20,22,24,26,29,34-36,38,40,43,47,49,51,53,55,58,61,63,64,67,68,70,71,76,79,80,82,83,85,86,90</sup> provided data related to safety.

- Two RCTs comparing arthroscopy versus PT reported treatment-related adverse events (AEs) from both groups; there were no deaths and both serious and non-serious AEs were more common following arthroscopy. Given that arthroscopy is invasive while PT is not, one would not expect serious adverse events or death with PT. (SOE: low)
- Across RCTs, systematic reviews of case series, comparative surgery cohorts, and additional case series in adults it appears that the frequency of most serious surgical complications may be low (<3%). Surgical complications with higher risks included nerve injury (0% to 25%; 0% to 9% excluding outliers) and revision surgery (0% to 8%). In adolescent patients, limited information from case series also suggests that the complication rate is low (<3%); no cases of physal arrest/growth disturbance, femoral fracture, nonunion of the greater trochanter, avascular necrosis, acute iatrogenic slipped capital femoral epiphysis, or iatrogenic instability were seen in any study of adolescent patients. (SOE: low)

## Key Question 3.

*What is the evidence that hip surgery for FAI/FAIS compared with non-operative treatment has differential efficacy or safety in subpopulations (e.g. age, sex, psychological or psychosocial comorbidities, baseline characteristics, deformity type, degree of osteoarthritis or cartilage damage, provider type, payer type)?*

- Two RCTs,<sup>28,66</sup> both comparing arthroscopy with PT, formally evaluated effect modification. Age was found to modify the treatment effect in one of the two trials with results suggesting that difference in function may be greater and in favor of arthroscopy compared with physiotherapy for younger patients with the effect decreasing with increasing age; however the strength of evidence was insufficient.

**Key Question 4.**

*What is the cost-effectiveness of surgery for FAI/FAIS compared with non-operative treatments in short and long-term?*

- Conclusions regarding the cost-effectiveness of hip arthroscopy compared with non-operative care (including conservative care) were inconsistent across three cost-utility studies)<sup>28,54,84</sup> that met the inclusion criteria. Differences in methods, modeling, data sources and perspectives contribute to the inconsistent findings. Only one study was based on a head to head trial of operative versus non-operative care.
  - One moderate quality cost-utility analysis from the U.K. National Health Service perspective, based on the recent RCT comparing arthroscopy with personalized physical therapy (PT) by Griffin, et al, found that personalized PT was both more effective and less costly than arthroscopy at one year. The short-term follow-up didn't allow for evaluation of long-term outcomes, however, and the applicability to the U.S. healthcare system is unclear. The study was funded by the Health Technology Assessment Program of National Institute of Health Research.
  - Two poor quality cost-utility analyses from the U.S. found that arthroscopy was more cost-effective than non-operative care (based on expert opinion) from a societal perspective and more cost-effective than observation from a hospital cost perspective. Clinical data, health status information and assumptions for condition progression were from case series, expert opinion and for one study a retrospective survey of arthroscopy patients. Both used an unvalidated method for determining utility. One study was industry funded; the funding source for the other was not clear.



**Strength of Evidence Summary for Key Question 1: Efficacy Results for Operative (Arthroscopy) versus Non-operative (Physiotherapy) Treatment**

| Outcome*   | Time        | Studies, Year, N  | Reason for Downgrading   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE)        |
|--|-------------|---|--|--|----------------------|
| Proportion achieving clinically important improvement in HOS-ADL (0-100) | 8 mos.      | 1 RCT (N=188)<br>Palmer 2019                                  | Consistency Unknown  | <ul style="list-style-type: none"> <li>MCID (<math>\geq 9</math> points): 51% (51/100) vs. 32% (28/88); RR 1.6 (1.1 to 2.3)</li> <li>PASS (score <math>&gt; 87</math> points): 48% (48/100) vs. 19% (17/88); RR 2.5 (1.5 to 4.0)</li> </ul> <u>Conclusion:</u> More arthroscopy patients compared with PT patients achieved clinically important improvements in function. | ⊕⊕○○<br>LOW          |
| iHOT-33 (0-100, higher score = better function)                          | 6-8 mos.    | 3 RCTs (N=569)<br>Griffin 2018<br>Mansell 2018<br>Palmer 2019 | Inconsistency Yes <sup>2</sup> (-1)<br>Imprecision Yes <sup>4</sup> (-1)                       | Pooled MD 1.94 (0.13, 3.03), $I^2 = 0\%$<br><u>Conclusion:</u> Small improvement with arthroscopy vs. PT which is likely not clinically important.   | ⊕⊕○○<br>LOW          |
|  | 12 mos.     | 2 RCTs (N=395)<br>Griffin 2018<br>Mansell 2018                | Imprecision Yes <sup>4</sup> (-1)  | Pooled MD 6.55 (-0.19, 12.6), $I^2 = 0\%$<br><u>Conclusion:</u> No clear difference between groups across trials; one trial reached statistical significance favoring arthroscopy but the clinical relevance of the difference is unclear.   | ⊕⊕○○<br>LOW          |
|  | 24 mos.     | 1 RCT (N=74)<br>Mansell 2018                                  | Risk of Bias Yes <sup>1</sup> (-1)<br>Consistency Unknown<br>Imprecision Yes <sup>4</sup> (-1) | MD 6.30 (-6.11, 18.71)<br><u>Conclusion:</u> No difference between groups; crossover from PT to arthroscopy was high (70%) and sample size was small.  | ⊕○○○<br>INSUFFICIENT |
| HOS-ADL (0-100, higher score = better function)                          | 6-8 mos.    | 2 RCTs (N=296)<br>Mansell 2018<br>Palmer 2019                 | Inconsistency Yes <sup>2</sup> (-1)<br>Imprecision Yes <sup>4</sup> (-1)                       | Pooled MD 6.26 (-6.52, 16.96), $I^2 = 77\%$<br><u>Conclusion:</u> No difference between groups. The larger, better quality trial found a statistically significant improvement following arthroscopy vs. PT; difference may be clinically important.   | ⊕⊕○○<br>LOW          |
|  | 12, 24 mos. | 1 RCT (N=74)<br>Mansell 2018                                  | Risk of Bias Yes <sup>1</sup> (-1)<br>Consistency Unknown<br>Imprecision Yes <sup>4</sup> (-1) | 12 mos.: MD 4.90 (-3.65, 13.45)<br>24 mos.: MD 3.80 (-6.00, 13.60)<br><u>Conclusion:</u> No difference between groups at either timepoint; crossover from PT to arthroscopy was high (70%) and sample size was small.  | ⊕○○○<br>INSUFFICIENT |
| HOS-Sport (0-100, higher score = better function)                        | 6-8 mos.    | 2 RCTs (N=296)<br>Mansell 2018<br>Palmer 2019                 | Risk of Bias Yes <sup>1</sup> (-1)<br>Imprecision Yes <sup>4</sup> (-1)                        | Pooled MD 10.98 (5.67, 16.30), $I^2 = 0\%$<br><u>Conclusion:</u> Improvement with arthroscopy vs. PT; difference may be clinically important.  | ⊕⊕○○<br>LOW          |

| Outcome*                            | Time        | Studies, Year, N  | Reason for Downgrading  | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE)        |
|-------------------------------------|-------------|---|---|--|----------------------|
|                                     | 12, 24 mos. | 1 RCT (N=74)<br><br>Mansell 2018                        | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Consistency<br>Unknown<br>Imprecision<br>Yes <sup>4</sup> (-1) | 12 mos.: MD 0.60 (-12.04, 13.24)<br>24 mos.: MD 1.80 (-11.16, 14.76)<br><u>Conclusion</u> : No difference between groups at either timepoint; crossover from PT to arthroscopy was high (70%) and sample size was small.   | ⊕○○○<br>INSUFFICIENT |
| HAGOS pain subscale (0-100)         | 8 mos.      | 1 RCT (N=180)<br><br>Palmer 2019                        | Consistency<br>Unknown<br>Imprecision<br>Yes <sup>4</sup> (-1)  | adj. MD 12.7 (8.1 to 17.2)<br><u>Conclusion</u> : Improvement in pain favoring arthroscopy; difference may be clinically important.  | ⊕⊕○○<br>LOW          |
| Pain on hip assessment (%)          | 8 mos.      | 1 RCT (N=varies, see Results column)<br><br>Palmer 2019 | Consistency<br>Unknown<br>Imprecision<br>Yes <sup>4</sup> (-1)  | <ul style="list-style-type: none"> <li>Flexion: 47% (46/97) vs. 66% (56/85); RR 0.72 (0.56 to 0.93)</li> <li>Adduction: 31% (30/97) vs. 46% (39/84); RR 0.67 (0.46 to 0.97)</li> <li>FABER test: 44% (42/96) vs. 62% (52/84); RR 0.71 (0.53 to 0.94) [N=180]</li> </ul> <u>Conclusion</u> : Fewer patients who received arthroscopy versus PT reported pain on hip flexion, hip adduction and the FABER test; no differences between groups on other assessments: hip extension, abduction, internal and external rotation, and the FAdIR test. Clinical relevance of difference is unclear. | ⊕⊕○○<br>LOW          |
| Prescription opiate pain medication | 24 mos.     | 1 RCT (N=79)<br><br>Mansell 2018                        | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Consistency<br>Unknown<br>Imprecision<br>Yes <sup>4</sup> (-1) | <ul style="list-style-type: none"> <li>Number of days' supply: MD 6.5 (-98.4 to 111.4)</li> <li>Number of unique prescriptions: MD -0.8 (-7.0 to 5.4)</li> <li>Days to last prescription: MD -116.7 (-258.1 to 24.7)</li> </ul> <u>Conclusion</u> : Sample size was small and CIs were wide precluding firm conclusions.   | ⊕○○○<br>INSUFFICIENT |
| Conversion to THA (%)               | 12, 24 mos. | 2 RCTs (N=363)<br><br>Griffin 2018<br>Mansell 2018      | Imprecision<br>Yes <sup>4</sup> (-2)  | 1.0% (2/203) vs. 0% (0/160)<br><u>Conclusion</u> : No difference between groups; Sample size and follow-up likely impacted the ability to adequately capture this event  | ⊕○○○<br>INSUFFICIENT |

Adj. = adjusted; FABER = Pain on flexion, abduction, and external rotation; FAdIR = Pain on flexion, adduction, and internal rotation; HAGOS = Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; MD = mean difference; NAHS=non-arthritis hip score; OHS = Oxford hip score; PASS = patient acceptable symptom state; RR = risk ratio; THA = conversion to total hip arthroplasty; UCLA = University of California at Los Angeles activity score.

\*Higher values indicate better outcomes, with the exception of pain on hip assessment and number of days' supply of prescription opiate pain medication, for which lower values indicate better outcomes.

#### Reasons for downgrade:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details). Studies which did control for confounding via study design and/or

statistical analyses (e.g. Adequate randomization and concealment, matching, multivariate regression, propensity matching) may not be downgraded for risk of bias depending other potential sources of bias (e.g. substantial loss to follow-up).

2. Inconsistency: differing estimates of effects across trials; if point estimates/effect size across trials are in the same direction, do not vary substantially or heterogeneity can be explained, results may not be downgraded for inconsistency. The consistency of single studies is unknown; evidence from single studies was not downgraded. Consistency may also be unknown if there is substantial differences between study populations across studies.

3. Indirect, intermediate or surrogate outcomes may be downgraded.

4. Imprecise effect estimate for an outcome: small sample size and/or confidence interval includes both negligible effect and appreciable benefit or harm with the intervention may be downgraded; If sample size is likely too small to detect rare outcomes, evidence may be downgraded twice. If the estimate is statistically significant, it is imprecise if the CI ranges from “mild” to “substantial”. If the estimate is not statistically significant, it is imprecise if the CI crosses the threshold for “mild/small” effects. Wide (or unknown) confidence interval and/or small sample size may result in downgrade.

### Strength of Evidence Summary for Key Question 2: Safety Results with a Focus on Operative Treatment.

| Outcome*   | Studies, Year, N<br>Timing*  | Reason for<br>Downgrading   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality<br>(SoE) |
|--|--|---|--|------------------|
| <b>Operative (Arthroscopy) vs. Non-operative (Physiotherapy) treatment</b> |  |   |  |                  |
| Serious- and treatment-related adverse events                              | 2 RCTs (N=479)<br><br>Griffin 2018, 24 months<br>Palmer 2019, 8 months   | Consistency<br>Unknown<br>Imprecision<br>Yes <sup>4</sup> (-1)                | Treatment-related death:<br><ul style="list-style-type: none"> <li>No events in either treatment group [1 RCT, Griffin, N=284]</li> </ul> Serious, treatment-related AEs:<br><ul style="list-style-type: none"> <li>Griffin: 3.6% (5/138)<sup>†</sup> vs. 0% (0/146)</li> <li>Palmer: 0% (0/99) vs. 0% (0/96)</li> </ul> Other, potentially treatment-related AEs:<br><ul style="list-style-type: none"> <li>5.8% (8/138) (9 events) vs. 0.7% (1/146); RR 8.5 (95% CI 1.1, 66.8) [1 RCT, Griffin]</li> </ul> <u>Conclusion:</u> Given that arthroscopy is invasive while PT is not, one would not expect serious adverse events or death with PT, precluding definitive conclusions. | ⊕⊕○○<br>LOW      |
| <b>Adverse events associated with operative treatment</b>                  |  |   |  |                  |
| Heterotopic ossification (HO)  | <u>Adults</u><br>2 SRs of case series (N=9,222 hips)<br>Riff 2019, Minkara 2019<br><br>1 RCT (N=65)<br>Mansell 2018<br><br>4 cohorts (N=23 to 198)<br>Botser 2014, Larson 2012, Rego 2018, Roos 2017 | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <u>Adults</u><br><ul style="list-style-type: none"> <li>SRs: 0.5% (33/7241) and 0.8% (16/1981)</li> <li>RCT: 1.5% (1/65)</li> <li>Cohorts: range, 0% to 31%; excluding outlier [Roos 2017], 0% to 1%</li> <li>Case series: range, 0.6% to 4.7%</li> </ul> <u>Pediatrics</u><br><ul style="list-style-type: none"> <li>SR: 0.2% (1/435); arthroscopy 0% (0/354) vs. open hip dislocation 1.2% (1/81)</li> </ul>   | ⊕⊕○○<br>LOW      |

| Outcome*                 | Studies, Year, N<br>Timing*  | Reason for<br>Downgrading   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality<br>(SoE) |
|--------------------------|--|---|--|------------------|
|                          | <p>4 case series (N=360 to 1870, 1615 hips)<br/>Rhon 2019a, Larson 2016, Nossia 2014, Bedi 2012</p> <p><u>Pediatrics</u><br/>1 SR of case series (N=435)<br/>de Sa 2014</p> <p>2 case series (N=43, 44)<br/>Litrenta 2018, Sink 2013</p>   |   | <ul style="list-style-type: none"> <li>Case series: one case (2.3%) in each study (one arthroscopy and one open hip dislocation)</li> </ul> <p><u>Conclusion:</u> The frequency of HO ranged from 0% to 4.7% across all studies (excluding outlier in adults); in pediatric populations, the range was 0.2% to 2.3% across 1 SR and 2 small case series.</p>   |                  |
| Avascular necrosis (AVN) | <p><u>Adults</u><br/>1 SR of case series (N=7,241 hips)<br/>Riff 2019</p> <p>1 RCT (N=65)<br/>Mansell 2018</p> <p>4 cohorts (N=23 to 96)<br/>Botser 2014, Hingsammer 2015, Larson 2012, Roos 2017</p> <p>1 case series (N=1870)<br/>Rhon 2019a</p> <p><u>Pediatrics</u><br/>1 SR of case series (N=435)<br/>de Sa 2014</p> <p>4 case series (N=197)<br/>Byrd 2016b, Cvetanovich 2018, Larson 2019, Tran 2013</p> | <p>Risk of Bias<br/>Yes<sup>1</sup> (-1)<br/>Imprecision<br/>Yes<sup>4</sup> (-1)</p> | <p><u>Adults</u><br/> <ul style="list-style-type: none"> <li>SR: 0% (0/7241)</li> <li>RCT: 0% (0/65)</li> <li>Cohorts: 0% (0/198)</li> <li>Case series: 0.4% (8/1870)</li> </ul> </p> <p><u>Pediatrics</u><br/> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>Case series: 0% (0/197)</li> </ul> </p> <p><u>Conclusion:</u> AVN was very rare as reported by these studies with only 8 events (0.4%) reported by one large case series in adults.</p> | ⊕⊕○○<br>LOW      |
| Femoral fracture         | <p><u>Adults</u><br/>2 SRs of case series (N=9,222 hips)<br/>Riff 2019, Minkara 2019</p> <p>2 RCTs (N=203)<br/>Griffin 2018, Mansell 2018</p> <p>3 cohorts (N=23 to 96)<br/>Hingsammer 2015, Larson 2012, Roos 2017</p>  | <p>Risk of Bias<br/>Yes<sup>1</sup> (-1)<br/>Imprecision<br/>Yes<sup>4</sup> (-1)</p> | <p><u>Adults</u><br/> <ul style="list-style-type: none"> <li>SRs: 0.01% (1/7241) and 0.05% (1/1981)</li> <li>RCTs: 0.5% (1/203)</li> <li>Cohorts: 0% (0/175)</li> <li>Case series: range, 0% to 1%</li> </ul> </p> <p><u>Pediatrics</u><br/> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>Case series: 0% (0/44)</li> </ul> </p> <p><u>Conclusion:</u> Femoral fracture was rare ranging from 0% to 1% across all studies;</p>                       | ⊕⊕○○<br>LOW      |

| Outcome*                           | Studies, Year, N<br>Timing*  | Reason for<br>Downgrading   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality<br>(SoE) |
|------------------------------------|--|---|--|------------------|
|                                    | 6 case series (N=317 to 1870; 1615 to 14,495 hips)<br>Cvetanovich 2018, Dietrich 2014, Larson 2016, Merz 2015, Rhon 2019a, Zingg 2014<br><br><u>Pediatrics</u><br>1 SR of case series (N=435)<br>de Sa 2014<br><br>1 case series (N=44)<br>Sink 2013   |   | there were no instances reported in pediatric patients.  |                  |
| Nonunion of the greater trochanter | <u>Adults</u><br>2 cohorts (N=198, 201)<br>Buchler 2013, Rego 2018<br><br><u>Pediatrics</u><br>1 case series (N=44)<br>Sink 2013   | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <ul style="list-style-type: none"> <li>Adults: 0% and 2%; 0% across arthroscopy arms (N=66, 102) vs. 1% and 2% (N=96, 135) in open hip dislocation arms</li> <li>Pediatrics: 0% (open hip dislocation)</li> </ul> <u>Conclusion:</u> Across 3 studies, frequency of nonunion ranged from 0% to 2% with all cases occurring following open hip dislocation in adults.   | ⊕⊕○○<br>LOW      |
| Nerve injury‡                      | <u>Adults</u><br>2 SRs of case series (N=9,222 hips)<br>Riff 2019, Minkara 2019<br><br>2 RCTs (N=237)<br>Griffin 2018, Palmer 2019<br><br>5 cohorts (N=23 to 198)<br>Botser 2014, Cetinkaya 2016, Rego 2018, Roos 2017, Zingg 2013<br><br>4 case series (N=317 to 414; 1615 hips)<br>Cvetanovich 2018, Dietrich 2014, Larson 2016, Nossa 2014<br><br><u>Pediatrics</u><br>1 SR of case series (N=435)<br>de Sa 2014<br><br>5 case series (N=24 to 108) | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <u>Adults</u> <ul style="list-style-type: none"> <li>SRs: range, 0.01% to 0.4%</li> <li>RCTs: 2.1% (5/237)</li> <li>Cohorts: range, 0% to 25%; excluding outlier, 0% to 9%</li> <li>Case series: range, 0.1% to 18.8%; excluding outlier, 0.1% to 4.4%</li> </ul> <u>Pediatrics</u> <ul style="list-style-type: none"> <li>SR: 0.5% (2/435); arthroscopy 0.6% (2/354) vs. open hip dislocation 0% (0/81)</li> <li>Case series: range, 1.9% to 8.3%</li> </ul> <u>Conclusion:</u> Across all studies, nerve injury was reported in 0% to 25% of the populations. In adults, the highest rates were seen in the open hip dislocation arm of one small cohort (25%; 4/16) and in one case series (19%; 68/360) that included surgeons who were still learning; in pediatrics, the highest rate (8%; 2/24) was in one small case series evaluating adolescent athletes undergoing simultaneous bilateral hip | ⊕⊕○○<br>LOW      |

| Outcome*                      | Studies, Year, N<br>Timing*   | Reason for<br>Downgrading   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality<br>(SoE) |
|-------------------------------|---|---|--|------------------|
|                               | Byrd 2016a, Byrd 2016b,<br>Cvetanovich 2018, Degen<br>2017, McConkey 2019   |   | arthroscopy for FAIS. Excluding these<br>outliers, the range was 0% to 9%.   |                  |
| Superficial<br>infection      | <u>Adults</u><br>2 SRs of case series<br>(N=9,222 hips)<br>Riff 2019, Minkara 2019<br><br>2 RCTs (N=237)<br>Griffin 2018, Palmer 2019<br><br>3 cohorts (N=23 to 198)<br>Botser 2014, Rego 2018,<br>Roos 2017<br><br>2 case series (N=414; 1615<br>hips)<br>Cvetanovich 2018, Larson<br>2016<br><br><u>Pediatrics</u><br>3 case series (N=34 to 44)<br>Cvetanovich 2018, Sink<br>2013, Tran 2013 | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <u>Adults</u><br>• SRs: 0.3% (19/7241) and 0.2%<br>(4/1981)<br>• RCTs: 4.2% (10/237); requiring<br>antibiotics, 2.1% (5/237)<br>• Cohorts: 0% to 6%<br>• Case series: 1% in both<br><br><u>Pediatrics</u><br>• Case series: range, 0% to 2.7%<br><br><u>Conclusion:</u> Across all studies, the<br>frequency of superficial wound infection<br>ranged from 0% to 6%. | ⊕⊕○○<br>LOW      |
| Deep<br>infection             | <u>Adults</u><br>1 SR of case series (N=7241<br>hips)<br>Riff 2019<br><br>2 cohorts (N=79)<br>Botser 2014, Roos 2017<br><br>1 case series (N=1615 hips)<br>Larson 2016  | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <u>Adults</u><br>• SR: 0.01% (1/7241)<br>• Cohorts: 0% (0/79)<br>• Case series: 0.1% (1/1615 hips)<br><br><u>Conclusion:</u> Deep wound infection was<br>rare as reported by 4 studies ranging<br>from 0% to 0.1%. No study in pediatric<br>patients reported this complication.   | ⊕⊕○○<br>LOW      |
| Thrombo-<br>embolic<br>events | <u>Adults</u><br>2 SRs (N=11,818 hips)<br>Riff 2019, Bolia 2018<br><br>2 RCTs (N=203)<br>Griffin 2018, Mansell 2018<br><br>3 cohorts (N=23 to 198)<br>Botser 2014, Roos 2017,<br>Rego 2018<br><br>2 case series (N=414; 1615<br>hips)   | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <u>Adults</u><br><i>Pulmonary embolism (PE)</i><br>• 1 SR [Bolia]: 0.59% (95%CI 0.38% to<br>0.92%)<br>• 1 case series: 0.1% (1/1615 hips)<br><br><i>Deep vein thrombosis (DVT)</i><br>• 1 SR [Bolia]: 1.18% (95%CI 0.8% to<br>1.74%)<br>• RCTs: 0% (0/203)<br>• Cohorts: range, 0% to 3%<br>• Case series: range, 0.1% to 0.2%<br><br><i>PE or DVT</i>               | ⊕⊕○○<br>LOW      |

| Outcome*                                 | Studies, Year, N<br>Timing*  | Reason for<br>Downgrading  | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality<br>(SoE)       |
|--|--|--|---|------------------------|
|  | Cvetanovich 2018, Larson 2016  |  | <ul style="list-style-type: none"> <li>1 SR [Riff]: 0.1% (8/7241)</li> </ul> <p><u>Conclusion</u>: Thromboembolic events were rare as reported by 9 studies ranging from 0% to 1.2%. No study in pediatric patients reported these complications.</p>   |                        |
| Revision surgery                         | <p><u>Adults</u></p> <p>2 SRs of case series (N=9,222 hips)</p> <p>Riff 2019, Minkara 2019</p> <p>1 RCT (N=65)</p> <p>Mansell 2018</p> <p>10 cohorts (N=23 to 201)</p> <p>Botser 2014, Buchler 2013, Cetinkaya 2016, Domb 2013, Larson 2012, Menge 2017, Redmond 2015, Rego 2018, Webb 2019, Zingg 2013</p> <p>3 case series (N=314 to 1870)</p> <p><u>Pediatrics</u></p> <p>1 SR of case series (N=435)</p> <p>de Sa 2014</p> <p>9 case series (N=18 to 108)</p> <p>Byrd 2016a, Byrd 2016b, Cvetanovich 2018, Degen 2017, Larson 2019, Litrenta 2018, McConkey 2019, Sink 2013, Tran 2013</p> | <p>Risk of Bias</p> <p>Yes<sup>1</sup> (-1)</p> <p>Imprecision</p> <p>Yes<sup>4</sup> (-1)</p> | <p><u>Adults</u></p> <ul style="list-style-type: none"> <li>SRs: 1.9% (38/1981) and 3.2% (233/7241)</li> <li>RCT: 7.7% (5/65)</li> <li>Cohorts: range, 0% to 12%</li> <li>Case series: range, 1.2% to 6.5%</li> </ul> <p><u>Pediatrics</u></p> <ul style="list-style-type: none"> <li>SR: 3.0% (13/435); all occurred following arthroscopy (4.0%; 13/354)</li> <li>Case series: Arthroscopy range, 0% to 5.9% (8 case series); Open hip dislocation, 13.6% (6/44) (1 case series)</li> </ul> <p><u>Conclusion</u>: Across all studies, the frequency of revision surgery ranged from 0% to 13.6%. The highest rates occurred following open hip dislocation surgery (12% in open arm of one cohort in adults; 13.6% in one small case series in children).</p> | <p>⊕⊕○○</p> <p>LOW</p> |
| Additional surgery (other than revision) | <p><u>Adults</u></p> <p>4 cohorts (N=23 to 198)</p> <p>Botser 2014, Domb 2013, Rego 2018, Zingg 2013</p> <p><u>Pediatrics</u></p> <p>4 case series (N=24 to 44; 18 hips)</p> <p>Guindani 2017, Litrenta 2018, Novais 2016, Sink 2013</p>   | <p>Risk of Bias</p> <p>Yes<sup>1</sup> (-1)</p> <p>Imprecision</p> <p>Yes<sup>4</sup> (-1)</p> | <p><u>Hardware/screw removal</u></p> <p><u>Adults</u></p> <ul style="list-style-type: none"> <li>3 cohorts [Botser, Domb, Zingg]: 0% in arthroscopy arms (n=18 to 23) vs. 20%–80% across open hip dislocation arms (n=5 to 15).</li> </ul> <p><u>Pediatrics</u></p> <ul style="list-style-type: none"> <li>2 case series [Novais, Sink]: 12.5% (3/24), 20.5% (9/44); all open hip dislocation surgery</li> </ul> <p><u>Additional surgery</u></p>   | <p>⊕⊕○○</p> <p>LOW</p> |

| Outcome*                                      | Studies, Year, N<br>Timing*  | Reason for<br>Downgrading   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality<br>(SoE) |
|---|--|---|--|------------------|
|   |  |   | <u>Adults</u> <ul style="list-style-type: none"> <li>2 cohorts [Domb, Rego]§: 1% (1/102) and 5% (1/20) in arthroscopy arms vs. 0% across open hip dislocation arms (n=96, 10).</li> </ul> <u>Pediatrics</u> <ul style="list-style-type: none"> <li>2 case series [Litrenta, Guindani]: 2.3% (1/43), 11% (2/18 hips); all arthroscopy</li> </ul> <u>Conclusion</u> : Hardware removal occurred exclusively following open hip dislocation surgery across 5 studies, range 12.5% (pediatrics) to 80% (open arms of cohort studies). Additional surgeries ranged from 1% to 11%.  |                  |
| Other adverse events in pediatric populations | 1 SR of case series (N=435) de Sa 2014<br><br>4 case series (N=18 to 108) Byrd 2016b, Cvetanovich 2018, Larson 2019, Tran 2013 | Risk of Bias<br>Yes <sup>1</sup> (-1)<br>Imprecision<br>Yes <sup>4</sup> (-1) | <u>Physal arrest or growth disturbance</u> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>4 case series: 0% (0/197)</li> </ul> <u>Acute iatrogenic slipped capital femoral epiphysis (SCFE)</u> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>1 case series: 0% (0/34)</li> </ul> <u>Iatrogenic instability</u> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>1 case series: 0% (0/108)</li> </ul> <u>Various**</u> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> </ul> <u>Conclusion</u> : No cases of physal arrest/growth disturbance, SCFE, iatrogenic instability or various other complications were reported by 5 studies in pediatric populations; sample sizes may not have been sufficient to detect rare events. | ⊕⊕○○<br>LOW      |

Adj. = adjusted; FABER = Pain on flexion, abduction, and external rotation; FAdIR = Pain on flexion, adduction, and internal rotation; HAGOS = Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; MD = mean difference; NAHS=non-arthritis hip score; OHS = Oxford hip score; PASS = patient acceptable symptom state; RR = risk ratio; THA = conversion to total hip arthroplasty; UCLA = University of California at Los Angeles activity score.

\*Follow-up varied widely across the studies comparing different surgical treatments for FAI and across case series of surgical intervention (1.5 months to 120 months).

†The serious treatment-related adverse events included an overnight admission post-arthroscopy, scrotal haematoma requiring readmission, superficial wound infections that required oral antibiotics [2 patients], hip joint infection that required further surgery and ultimately a THA.



‡To include: lateral femoral cutaneous neurapraxia; femoral neurapraxia; pudendal neurapraxia; perineal neurapraxia; sciatic neurapraxia; and unspecified/other Neurapraxia.

§Included one case each of iliopsoas release due to new onset symptomatic internal snapping and compartment syndrome grade III.

\*\*Broken instrumentation, abdominal compartment syndrome, urinary/sexual dysfunction, chondral scuffing, labral penetration, or inadequate correction.

#### Reasons for downgrade:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details). Studies which did control for confounding via study design and/or statistical analyses (e.g. Adequate randomization and concealment, matching, multivariate regression, propensity matching) may not be downgraded for risk of bias depending other potential sources of bias (e.g. substantial loss to follow-up).
2. Inconsistency: differing estimates of effects across trials; if point estimates/effect size across trials are in the same direction, do not vary substantially or heterogeneity can be explained, results may not be downgraded for inconsistency. The consistency of single studies is unknown; evidence from single studies was not downgraded. Consistency may also be unknown if there is substantial differences between study populations across studies.
3. Indirect, intermediate or surrogate outcomes may be downgraded.
4. Imprecise effect estimate for an outcome: small sample size and/or confidence interval includes both negligible effect and appreciable benefit or harm with the intervention may be downgraded; If sample size is likely too small to detect rare outcomes, evidence may be downgraded twice. If the estimate is statistically significant, it is imprecise if the CI ranges from “mild” to “substantial”. If the estimate is not statistically significant, it is imprecise if the CI crosses the threshold for “mild/small” effects. Wide (or unknown) confidence interval and/or small sample size may result in downgrade.

#### Strength of Evidence Summary for Key Question 3: Differential Efficacy\*and Safety Results for Operative (Arthroscopy) versus Non-operative (Physiotherapy) Treatment for FAIS

| Outcome   | Time           | Studies, Year, N  | Reason for Downgrading  | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality (SoE)        |
|---|----------------|---|---|---|----------------------|
| Age (years);<br>FAI type (cam, pincer, mixed);<br>Sex; KL grade (0 or 1);<br>Study center (1-6) | 8 to 12 months | 2 RCTs<br><br>Griffin 2018 (N=358; iHOT-33)<br>Palmer 2019 (N=222; HOS-ADL) | Consistency<br>Unknown†<br>Imprecision<br>Yes <sup>4</sup> (-2) | Greater improvement on the HOS-ADL at 8 months with younger age in one RCT (Palmer 2019): adj. interaction effect -0.31 (-0.44, -0.18); the second RCT (Griffin) found no significant interaction for the effect of age (<40 vs. ≥40) on the iHOT-33 at 12 months.<br><br>There was no modifying effect seen for the following:<br><ul style="list-style-type: none"> <li>• FAI type (2 RCTs)</li> <li>• Sex, KL grade, baseline HOS-ADL, and study center (1 RCT, Palmer)</li> </ul> <u>Conclusion:</u> It is unclear whether age may modify treatment effect since outcomes, methods, and results across trials differ. | ⊕○○○<br>INSUFFICIENT |

Adj. = adjusted; FABER = Pain on flexion, abduction, and external rotation; FAdIR = Pain on flexion, adduction, and internal rotation; HAGOS = Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; MD = mean difference; NAHS=non-arthritis hip score; OHS = Oxford hip score; PASS = patient acceptable symptom state; RR = risk ratio; THA = conversion to total hip arthroplasty; UCLA = University of California at Los Angeles activity score.

\*Additional domains considered in studies performing a formal test of interaction for subgroup modification (i.e., HTE) based on recommendations from Ofman and Guya<sup>31,32,65†</sup>:

- Is the subgroup variable a characteristic specified at baseline or after randomization? (subgroup hypotheses should be developed a priori)
- Did the hypothesis precede rather than follow the analysis and include a hypothesized direction that was subsequently confirmed?

- Was the subgroup hypothesis one of a smaller number tested?

†Different methods were employed to evaluate the effect of age on treatment modification; one trial dichotomized age (<40 vs. ≥40) while the other evaluated age as a continuous variable which may have given it more power to detect a difference.

#### Reasons for downgrade:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details). Studies which did control for confounding via study design and/or statistical analyses (e.g. Adequate randomization and concealment, matching, multivariate regression, propensity matching) may not be downgraded for risk of bias depending other potential sources of bias (e.g. substantial loss to follow-up).
2. Inconsistency: differing estimates of effects across trials; if point estimates/effect size across trials are in the same direction, do not vary substantially or heterogeneity can be explained, results may not be downgraded for inconsistency. The consistency of single studies is unknown; evidence from single studies was not downgraded. Consistency may also be unknown if there is substantial differences between study populations across studies.
3. Indirect, intermediate or surrogate outcomes may be downgraded.
4. Imprecise effect estimate for an outcome: small sample size and/or confidence interval includes both negligible effect and appreciable benefit or harm with the intervention may be downgraded; If sample size is likely too small to detect rare outcomes, evidence may be downgraded twice. If the estimate is statistically significant, it is imprecise if the CI ranges from “mild” to “substantial”. If the estimate is not statistically significant, it is imprecise if the CI crosses the threshold for “mild/small” effects. Wide (or unknown) confidence interval and/or small sample size may result in downgrade.

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# 1 Appraisal

## 1.1 Background and Rationale

Femoroacetabular impingement (FAI) results from abnormal morphology of the acetabulum and femoral head/neck resulting in abnormal contact between the proximal femur and acetabulum during the end range of hip motion, particularly flexion and internal rotation. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in overcoverage of the femoral head). Clinically, patients frequently present with a combination of both types. Morphologic characteristics of FAI and labral tears on radiographs in asymptomatic patients appear to be common.<sup>55</sup> Abnormal contact between the femur and acetabulum may result in impingement and pain and/or reduced function; this may depend on activity level. Repetitive motion, particularly vigorous motion may result in joint and labral damage. A recent consensus document has suggested that the term femoroacetabular impingement syndrome (FAIS) be used for symptomatic presentation of FAI.<sup>65</sup> There is mixed evidence linking FAI to later development of osteoarthritis (OA)<sup>141</sup>; some studies suggest that cam lesions may be linked to OA development, but the impact of pincer lesions is less clear.<sup>107,144</sup> One recent study reported no difference in the risk of OA progression between patients with FAI and those with normal hip morphology.<sup>212</sup>

Initial management of FAI/FAIS usually is non-operative. Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration. Surgical options to correct FAI include arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

While the understanding of the etiology, history and clinical presentation of FAI/FAIS has evolved, the causes of hip pain, the natural history of FAI and its relationship to osteoarthritis remain unclear. The case definition and selection criterion of patients for surgery has historically been unclear. Furthermore, questions remain about the efficacy and effectiveness, safety and cost effectiveness of hip surgery for FAIS.

## 1.2 Contextual Questions

Key Questions 1 and 2 in the previous report will now serve as Contextual Questions for the purposes of this Update Report.

### Contextual Question 1 (Formerly KQ1)

Is there a consistent or agreed upon case definition for FAI? What is the evidence of reliability and validity of these case definitions?

### Contextual Question 2 (Formerly KQ2)

What are the expected treatment outcomes of hip surgery for FAI? Are there validated instruments related to hip surgery outcomes? Has clinically meaningful improvement in outcomes been defined for FAI?

### 1.3 Research Key Questions

#### Key Question 1 (Formerly KQ3):

What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with non-operative treatment for FAI/FAIS? Including consideration of short-term ( $\leq 5$  years) intermediate-term ( $>5$  years to  $<10$  years) and long-term ( $\geq 10$  years) outcomes?

#### Key Question 2 (Formerly KQ4):

What is the evidence of the safety of hip surgery for FAI/FAIS compared with non-operative treatment?

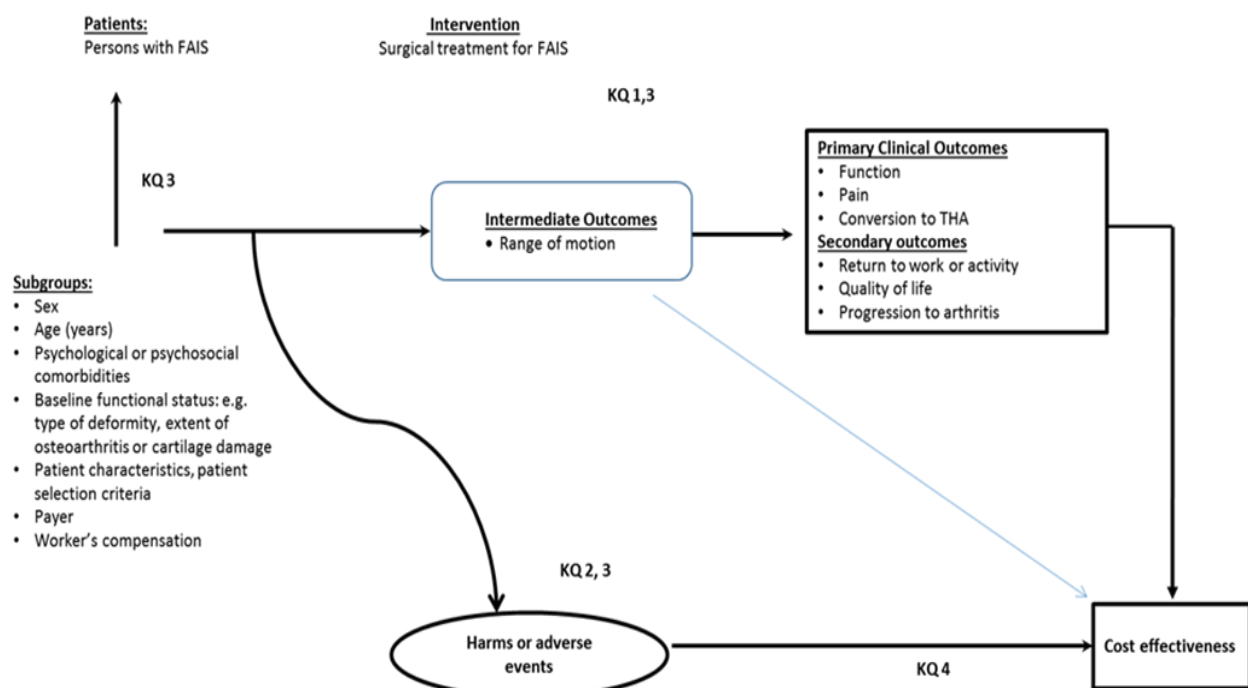
#### Key Question 3 (Formerly KQ5):

What is the evidence that hip surgery for FAI/FAIS compared with non-operative treatment has differential efficacy or safety issues in subpopulations (e.g. age, sex, psychological or psychosocial comorbidities, baseline characteristics, deformity type, degree of osteoarthritis or cartilage damage, provider type, and payer type)?

#### Key Question 4 (Formerly KQ6):

What is the cost-effectiveness of hip surgery for FAI/FAIS compared with non-operative treatments in the short and long term?

Figure 1. Analytic Framework



## 1.4 Key considerations highlighted by clinical experts

### 1.4.1 What is the prevalence of FAI? How frequent is it?

Subsequent to the 2011, additional studies evaluating the prevalence of FAI and FAIS have been published. (Table 1). For purposes of this section, populations reported as being symptomatic were considered to have FAIS, but studies generally did not report criteria for specific diagnosis of FAIS versus identification of FAI morphology on imaging (radiographs and/or modalities such as MRI or CT). Consistent with the previous report, there is a wide range of reported prevalence for FAI/FAIS.

The true prevalence of FAI morphologies and FAIS is difficult to assess for a number of reasons. First, a variety of primarily radiographic criteria have been used to evaluate and define the different morphologies. Second, persons with FAI morphology may or may not have symptoms such as pain or reduced range of motion. Across studies identified in the previous report and for this update, estimates varied across populations and are dependent on methods used to ascertain FAI morphologic features. Only a fraction of those with FAI morphology will be symptomatic and additional research on factors that may determine the onset of symptoms in some persons with FAI morphology but not others is needed.<sup>141</sup> Symptoms may be more common in young, active persons, particularly in athletes.<sup>141</sup>

**Table 1. Prevalence of FAI/FAIS in various populations**

| Impingement Type     | Study   | Athletes*  | Asymptomatic – General Population  | Symptomatic – General Population   |
|----------------------|---|--|--|--|
| <b>Cam</b>           | Mascarenhas 2016 <sup>130</sup><br>(n=60 studies) | 66.4% (SD, 23.5%)<br>(across 15 studies)                                     | 22.4% (SD, 6.2%)<br>(across 10 studies)  | 49% (SD, 21.2%)<br>(across 35 studies)   |
|                      | Frank 2015 <sup>55</sup><br>(n=26 studies)        | Mean, 54.80%<br>(across 7 studies)   | Mean, 23.10%<br>(across 19 studies)  | ---  |
|                      | Dickenson 2016 <sup>44</sup><br>(n=30 studies)    | Range, 48% to 75%<br>(across 30 studies)                                     | ---  | ---  |
|                      | Single Studies†                                   | Range, 9.8% to 69.4%<br>(n=5 studies; 705 hips) <sup>56,96,119,126,145</sup> | Range, 14% to 47%<br>(n=4 studies; 2039 patients) <sup>5,45,137,164</sup>                      | 22.2% of hips<br>(n=1 study; 998 hips) <sup>116</sup>  |
| <b>Pincer</b>        | Mascarenhas 2016 <sup>130</sup><br>(n=60 studies) | 51.2% (SD, 20.3%)<br>(across 15 studies)                                     | 57%<br>(1 study)   | 28.5% (SD, 19.2%)<br>(across 35 studies)   |
|                      | Frank 2015 <sup>55</sup><br>(n=26 studies)        | 50%<br>(across 7 studies)  | 74%<br>(across 19 studies)   | ---  |
|                      | Single Studies†                                   | Range, 1% to 37.9%<br>(n=4 studies; 445 hips) <sup>56,96,126,145</sup>       | Range, 10.6% to 25.8%<br>(n=3 studies; 1340 patients) <sup>5,137,164</sup>                     | 18.6% of hips<br>(n=1 study; 998 hips) <sup>116</sup>  |
| <b>Mixed</b>         | Mascarenhas 2016<br>(n=60 studies) <sup>130</sup> | 57.1% (6.1%)<br>(across 2 studies)   | 8.8% (5.1%)<br>(across 10 studies)   | 40.2% (18%)<br>(across 35 studies)   |
|                      | Single Studies†                                   | Range, 0% to 61.8%<br>(n=4 studies; 445 hips) <sup>56,96,126,145</sup>       | Range: 3.1% to 10.2%<br>(n=2 studies; 1140 patients) <sup>137,164</sup>                        | 48.9% of hips<br>(n=1 study; 998 hips) <sup>116</sup>  |
| <b>Labral Injury</b> | Frank 2015 <sup>55</sup><br>(n=26 studies)        | 65.40%<br>(across 7 studies)   | 73%<br>(Number of studies NR)  | ---  |
|                      | Single Studies†                                   | 33.8% to 51%<br>(n=2 studies; 280 hips) <sup>126,132</sup>                   | 41% (reviewer 1)<br>43% (reviewer 2)<br>(n= 1 study; 100 patients;<br>200 hips‡) <sup>47</sup> | 97% (reviewer 1)<br>96% (reviewer 2)<br>(n= 1 study; 100 patients;<br>200 hips‡) <sup>47</sup> |

\* Authors do not report whether or not athletes were experiencing hip pain, although the majority appear to be asymptomatic.

† Single studies represent those studies identified by our search that were published subsequent to the search dates of the SRs we have included.

‡ Hips are from same patients (i.e. one hip was symptomatic and the contralateral hip was not)

The previous report identified five studies assessing the prevalence of FAI based on the presence of morphological characteristics as found on imaging. One study<sup>108</sup>, in a population of healthy young adults (asymptomatic), found the prevalence of one or more findings for cam-type deformities was 35% for males and 10% for females; for pincer-type deformities, 34% for males and 17% for female. Another study<sup>171</sup>, in a random sample of 244 healthy (asymptomatic) young males, reported that 73% showed some MRI evidence of cam-type deformity. In a study of asymptomatic hip patients<sup>94</sup> (n=50 patients, 100 hips) that received a CT scan for abdominal trauma or nonspecific abdominal pain, the prevalence of

any bony characteristics associated with FAI was 39% (males: 48%; females 31%). A prospective population-based study<sup>62</sup> (n=4,151; mean age 65 years; 63% female) evaluating the prevalence of osseous malformations associated with FAI in a Danish population, found the prevalence of acetabular dysplasia was 4.3% in men and 3.6% in women; a deep acetabular socket, 15.2% of men and 19.4% of women; a pistol-grip malformation, 19.6% of men and 5.2% of women, the combination of pistol-grip deformity and deep acetabular socket, 2.9% of men 0.9% of women. The final study<sup>210</sup> (n=34 patients; 68 hips) examined the prevalence of radiographic signs of FAI in athletes with long-standing adductor-related groin pain, finding that the prevalence of having one or more FAI signs was 94% with only 4 hips (6%) without any signs of FAI.

A limited search for this update report found three systematic reviews (SRs)<sup>44,55,130</sup> and fifteen additional studies<sup>5,45,47,54,56,75,96,116,119,126,132,137,145,164,168</sup> published subsequent to the search dates of the SRs providing information regarding the prevalence of FAI. Some cross over of included studies across the SRs was present. Consistent with the previous report, there appears to be a wide range of prevalence of FAI morphology types. All studies evaluated the radiographic evidence of FAI, and thus are not likely to take into account the clinical aspects (i.e. positive impingement test, etc.) that indicate FAIS. Additionally, most studies were retrospective. Across the studies, various criteria were used to determine whether a morphologic feature associated with FAI was present, likely accounting for some of the variability of the estimates.

Among studies reporting prevalence of FAI in asymptomatic patients representing the general population, two SRs<sup>55,130</sup> and four additional studies<sup>5,45,137,164</sup> were identified. The two SRs reported the mean prevalence of cam type FAI to be 22.4% (across 10 studies)<sup>130</sup> and 23.1% (across 19 studies)<sup>55</sup>; prevalence across four additional studies (n=2039 patients)<sup>5,45,137,164</sup> ranged from 14% to 47%. The two SRs reported the mean prevalence of pincer type FAI to be 57% (across 1 study)<sup>130</sup> and 74% (across 19 studies)<sup>55</sup>; prevalence across three additional studies (n=1340 patients)<sup>5,137,164</sup> ranged from 10.6% to 25.8%. One SR<sup>130</sup> reported the mean prevalence of mixed type FAI to be 8.8% (across 10 studies), and two additional studies (n=1140 patients)<sup>137,164</sup> reported prevalence of mixed type FAI to be 3.1% and 10.2%. (Table 1)

One SR<sup>130</sup> and one additional study<sup>116</sup> were identified reporting prevalence of FAI in symptomatic hip patients. The pooled mean proportion of patients with radiographic presence of cam, pincer, and mixed type FAI reported by the SR were 49%, 28.5%, and 40.2%, respectively. The single additional study reported on a group of 499 patients (998 hips) that presented to two orthopedic surgeons with the diagnosis of hip pain. The radiographic prevalence of cam, pincer, and mixed type FAI in this study population was reported to be 22.2%, 18.6%, and 48.9%. (Table 1)

Among studies reporting prevalence of FAI in athletes, three SR<sup>44,55,130</sup>s and five additional studies<sup>56,96,119,126,145</sup> were identified. Authors did not comprehensively report whether or not athletes were experiencing hip pain, although the majority appeared to be asymptomatic. Two SRs reported the mean prevalence of cam type FAI to be 66.4% (across 15 studies)<sup>130</sup> and 54.8% (across 7 studies)<sup>55</sup>; the third SR<sup>44</sup> reported that prevalence of cam type FAI ranged from 48% to 75% (across 30 studies). Prevalence across 5 additional studies (n=705 hips)<sup>56,96,119,126,145</sup> ranged from 9.8% to 69.4% of all hips. The two SRs reported the mean prevalence of pincer type FAI to be 51.2% (across 15 studies)<sup>130</sup> and 50% (across 7 studies)<sup>55</sup>; prevalence across four additional studies (445 hips)<sup>56,96,126,145</sup> ranged from 1% to 37.9% of all hips. %. One SR<sup>130</sup> reported the mean prevalence of mixed type FAI to be 57.1% (across 2 studies), and four additional studies (n=445 hips)<sup>56,96,126,145</sup> reported prevalence of mixed type FAI to

range from 0% to 61.8%. (Table 1) One additional study (47 professional ballerinas; 94 hips)<sup>75</sup>, reported that 31.9% of hips had radiographic presence of cam type FAI and 74% of hips had presence of at least two radiographic indications of pincer FAI. Since the authors did not explicitly state that patients exclusively had one type or the other, it was unclear as to what proportion of patients may have had mixed type FAI. A final study<sup>54</sup> of 60 adult male professional soccer players (120 hips) reported that 92.5% of all hips included in their study showed radiographic evidence of cam or pincer morphology.

One SR and three single studies were identified reporting on proportion of patients presenting with a labral tear/injury. Across seven studies included in the SR, labral injury was found on MRI without intra-articular injection in 65.4% of hips in asymptomatic athletes and 73% of hips in an asymptomatic general population. Two additional studies (n=280 hips) reported that 33.8%<sup>126</sup> and 51%<sup>132</sup> of athletes had presence of a labral tear. In a study of 100 patients with one symptomatic hip and one contralateral asymptomatic hip, labral tears were found in 41% (reviewer 1)/43% (reviewer 2) of the asymptomatic hips and 97% (reviewer 1)/96% (reviewer 2) of the symptomatic hips. Three studies reported on the prevalence of bilateral impingement. Presence of bilateral impingement was reported to be 83% in one study (n=499 patients, 998 hips)<sup>116</sup> of symptomatic hip patients and 60.8% (70/130) in a study<sup>119</sup> of elite ice hockey players. In a final study (n=2596 patients)<sup>168</sup>, 9.3% of males and 2.5% of females were found to have presence of bilateral FAI.

#### 1.4.2 What is the etiology and natural history of FAI?

While there has been additional research into the etiology and natural history of FAI/FAIS since the 2011 report, a number of questions remain regarding the etiology, causes of FAI, sources of pain, and progression of OA in FAI/FAIS.

The etiology of FAI and FAIS are not well understood. Most FAI is considered idiopathic.<sup>107</sup> Associations between conditions or procedures that may alter hip joint anatomy and development of secondary FAI have been reported: It has been associated with prior trauma (e.g. femoral neck fracture malunion), post-surgical consequences of specific acetabular procedures as well as certain pediatric hip disorders such as slipped capital femoral epiphysis (SCFE) and Legg–Calve–Perthes disease (LCPD) and developmental hip dysplasia. A familial association and possible genetic factors have also been suggested in addition to environmental factors.<sup>64,107</sup> FAI and FAIS are frequently seen in young athletic populations and studies have suggested that high-intensity physical activity during skeletal development may change bone morphology and development of cam lesions.<sup>64,107</sup>

As noted in the previous section, there is a high prevalence of bony morphology across asymptomatic and symptomatic individuals. The frequency, progression, severity and mechanisms of symptom development in FAI are poorly understood and it is unclear what may cause the onset of symptoms in some persons with FAI morphology but not others. Patients with FAI often present with labral and/or chondral injury secondary to bony impingement, which some believe give rise to symptoms.<sup>107,141</sup> This doesn't however explain the large proportion of asymptomatic patients that have labral tears or chondral injury. Some recent studies suggest that patient factors, including measures of mental health status, may have stronger associations with presence and severity of patient symptoms than intra-articular findings.<sup>92,211</sup> Another study suggests that femoral damage based on MRI mapping may be a greater contributor to clinical symptoms versus acetabular or labral damage.<sup>63</sup>

The conceptual model of FAI suggests that there are morphological abnormalities of the proximal femur and/or acetabulum resulting in abnormal contact at the end range of motion, particularly in flexion, internal rotation and adduction. Initially the hip may be asymptomatic but continued contact through excessive motion results in pain, chondral lesions, labral tears and progressive hip osteoarthritis.<sup>59,97,156,195,39,70,106,127</sup> However, the data to support this hypothesis is unclear and inconsistent. The 2011 report briefly summarized two studies as follows:

- Hartofilakidis et al.: in persons with asymptomatic hips with  $\geq 1$  radiographic FAI morphologic feature followed for 18.5 years, prevalence of OA 17.7% based on radiographs at final follow-up, however the prevalence of AO in persons without FAI morphology was not reported. Osteoarthritis among those who did not have a morphological feature associated with FAI was not reported. From this study it appears that a substantial proportion of hips with morphological features associated with FAI may not develop radiographic evidence of osteoarthritis in the long-term.
- Bardakos investigated the effect of radiological parameters on the progression of osteoarthritis in patients under 55 years of age with a history of symptomatic idiopathic hip arthritis, Tönnis grade 1 or 2. At >10 years, the prevalence of progression was similar between hips with initial Tönnis grade 1 and 2 and authors concluded that that mild to moderate osteoarthritis in hips with a pistol-grip deformity will not progress rapidly in all patients. Twenty eight (65%) showed evidence of osteoarthritis progression. Only one radiographic parameter typically associated with cam impingement was associated with progression. In one-third, progression will take more than ten years to manifest, if ever. While individual geometry of the proximal femur and acetabulum partly influences this phenomenon, a hip with cam impingement is not always destined for end-stage arthritic degeneration.

There continues to be inconsistent evidence linking FAI to progression or later development of osteoarthritis (OA).<sup>141</sup> Some studies suggest that cam lesions may be linked to OA development, but the impact of pincer lesions is less clear.<sup>107,144,213</sup> As described in a recent review, for cam-type FAI, some longitudinal studies have reported associations between various radiographic features (e.g. alpha angle) and development of end-stage OA,<sup>3</sup> the need for THA<sup>33,202</sup> and radiographic OA<sup>61,202</sup> while others have not reported a statistical association between FAI morphology and OA.<sup>212</sup> One recent study reported no difference in the risk of OA progression between patients with FAI and those with normal hip morphology.<sup>212</sup> In contrast, many of these same studies reported no association between radiographic measures for pincer-type FAI morphology and OA development and others suggest a protective effect.<sup>212</sup> Evaluation of other imaging parameters and/or biomarkers for diagnosing FAI/FAIS and evaluating its potential as a risk factor for cartilage damage, inflammation and progression to OA also appear to have yielded mixed results and further research is required.<sup>70</sup>

Several factors may contribute to the discrepancies across studies and difficulty drawing definitive conclusions regarding the potential progression of FAI to arthritis. First a variety of radiographic parameters related cam and pincer morphologies have been evaluated for associations with OA. Some studies reported associations between specific imaging measures of FAI morphology (e.g. alpha angle) and radiographic diagnosis of OA. Unfortunately the diagnostic accuracy and reliability for many frequently used radiographic parameters may not be high (See Contextual Question 1). Second, radiographic signs of OA taken alone may not be correlated with symptoms of OA and conversely, patients with hip pain may not have radiographic evidence of OA.<sup>104</sup> Additionally The quality and timing of studies also needs to be considered. A number of studies have been retrospective or cross sectional. For retrospective evaluations of radiographs, it should be remembered that once OA begins to develop

from a separate cause, osteophytes on the femoral head may give the false impression of an underlying deformity.<sup>181</sup> Lastly, although statistical associations may be present, causality should not be presumed, particularly from cross sectional, case series and retrospective studies.

## 1.5 Outcomes Assessed

The primary efficacy/effectiveness outcomes of interest for this report are listed below.

- Function (validated patient- and clinician-reported hip measures)
- Pain (validated measures)
- Conversion to total hip arthroplasty

Other clinical outcomes reported included quality of life (based on validated instruments), range of motion (intermediate), return to work or activity and progression to arthritis

Outcomes are detailed in the evidence tables in the appendices and/or the body of the report. Summary tables for case series are also found in the appendices.

Strength of evidence was assessed for the primary clinical outcomes only.

## 1.6 Washington State Utilization Data

The Femoroacetabular Impingement (FAI) analysis includes utilization data from the following Washington agencies: the Department of Labor and Industries (LNI) Workers' Compensation Plan, the Public Employees Benefit Board Uniform Medical Plan (PEBB/UMP), and Medicaid Managed Care (MCO) and Medicaid Fee-for-Service (FFS).

FAI claims were identified by Current Procedure Terminology codes (CPT) 29914, 29915, with or without 29916 also present. The analysis involved extracting qualifying paid claims (denied claims received a separate analysis and were not included in utilization counts). The analysis period includes four (4) calendar years (CY) from 2015 through 2018.

Initial criteria identified and extracted all claims with FAI CPTs or combinations of these codes. Any additional claims associated with the date-of-services of the FAI coded claims were then identified and extracted. Claims were sorted by paid versus unpaid and paid claims were analyzed by subject with all date-of service claims or charges associated with the FIA procedure(s). Data evaluation included utilization by member; analysis of individual and aggregate CPT codes by age and calendar year; and by total claim costs incurred by a member on the date of their service.

## Coding

| TYPE | CODE  | Procedure Code Description  |
|------|-------|---|
| CPT  | 29914 | Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion)       |
|      | 29915 | Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion) |
|      | 29916 | Arthroscopy, hip, surgical; with labral repair                                      |



### 1.6.1 Findings

The Department of Labor and Industries (LNI) Workers' Compensation Plan, the Public Employees Benefit Board Uniform Medical Plan (PEBB/UMP), and Medicaid FFS reported less than the minimum number of individuals necessary to release findings and protect patient confidentiality.

#### Medicaid MCO Utilization and Expenditure Data, CY 2015 – 2018

| Medicaid MCO     | 2015      | 2016      | 2017      | 2018      |
|------------------|-----------|-----------|-----------|-----------|
| Unique Members   | 66        | 62        | 77        | 72        |
| Encounters       | 68        | 63        | 82        | 75        |
| Total Paid DOS*  | \$230,247 | \$219,329 | \$252,869 | \$213,036 |
| Average Paid DOS | \$3,386   | \$3,481   | \$3,083   | \$2,840   |

#### Medicaid MCO Top 20 Diagnoses for Claims with FAI procedures, CY 2015 - 2018

| Description    | ICD-9/ICD-10                                     | Count |
|----------------|--|-------|
| <b>M25851</b>  | OTHER SPECIFIED JOINT DISORDERS RIGHT HIP        | 68    |
| <b>M25852</b>  | OTHER SPECIFIED JOINT DISORDERS LEFT HIP         | 70    |
| <b>S73192A</b> | OTHER SPRAIN OF LEFT HIP INITIAL ENCOUNTER       | 50    |
| <b>S73191A</b> | OTHER SPRAIN OF RIGHT HIP INITIAL ENCOUNTER      | 52    |
| <b>M24151</b>  | OTHER ARTICULAR CARTILAGE DISORDERS RIGHT HIP    | 41    |
| <b>M24152</b>  | OTHER ARTICULAR CARTILAGE DISORDERS LEFT HIP     | 30    |
| <b>71805</b>   | Artic cartil dis-pelvis                          | 16    |
| <b>8438</b>    | Sprain hip & thigh NEC                           | 16    |
| <b>7265</b>    | Enthesopathy of hip                              | 14    |
| <b>71895</b>   | Jt derangement NOS-pelvis                        | 13    |
| <b>M24851</b>  | OTHER SPECIFIC JOINT DERANGEMENTS RIGHT HIP NEC  | 10    |
| <b>71885</b>   | Jt derangement NEC-pelvis                        | 9     |
| <b>M24852</b>  | OTHER SPECIFIC JOINT DERANGEMENTS LEFT HIP NEC   | 9     |
| <b>71985</b>   | Joint dis NEC-pelvis                             | 8     |
| <b>M76891</b>  | OTH SPEC ENTHESOPATHIES RT LOW LIMB EXCLUDE FOOT | 4     |
| <b>71945</b>   | Joint pain-pelvis                                | 5     |
| <b>M25859</b>  | OTHER SPECIFIED JOINT DISORDERS UNSPECIFIED HIP  | 5     |
| <b>M76892</b>  | OTH SPEC ENTHESOPATHIES LT LOW LIMB EXCLUDE FOOT | 4     |
| <b>M7612</b>   | PSOAS TENDINITIS LEFT HIP                        | 4     |
| <b>M25551</b>  | PAIN IN RIGHT HIP                                | 4     |

## 2 Background

### 2.1 History of Femoroacetabular Impingement as a Diagnosis: Epidemiology and Burden of Disease

In the early 1960s, hip damage as a result of femoroacetabular contact was reported as a consequence of childhood disease, particularly slipped capital femoral epiphysis.<sup>25,82</sup> In 1974, Stulberg et al noted that subtle anatomic abnormalities of the hip, particularly a decreased head-neck offset of the proximal femur, was associated with early development of osteoarthritis (OA).<sup>200</sup> Ganz et al in the early 1990s described six cases of femoral neck-acetabular impingement following fracture and malunion of the femoral neck.<sup>57</sup> Ganz subsequently in 2001 described a technique for surgical dislocation of the hip that allowed direct observation of the joint.<sup>58</sup> Following this description, Ganz and colleagues proposed FAI as a mechanism for the development of early osteoarthritis for nondysplastic hips based on in situ inspection of the damage pattern of over 600 surgical hip dislocations.<sup>59</sup> From that point forward, a significant number of other articles on the treatment, prognosis and diagnosis of FAI have been published, as well as numerous reviews.

In parallel with the increase in publications, the number of surgical procedures performed that specifically address FAI/FAIS has also expanded. According to a study of the American Board of Orthopaedic Surgery database, the number of arthroscopic hip surgeries for FAI increased over 600% between 2006 and 2010<sup>18</sup>, and one systematic review cited arthroscopy for FAI as the “preferred technique,” representing 50% surgical approaches compared to 34% for open surgical dislocation and 16% with the mini-open approach.<sup>31</sup> This quick escalation in surgical procedures to treat a previously unrecognized condition has raised concerns amongst physicians and healthcare funders due to the uncertainties regarding the true natural history of the disease and the ambiguities around clinical diagnosis.

It has been suggested that FAI is a precursor to hip OA<sup>200</sup>, particularly cam morphology<sup>4,51</sup>, pointing to the fact that in cam impingement, the femoral head “migrates” anteriorly and superiorly to the acetabulum, which has been shown in the literature to contribute to OA.<sup>51</sup> However, others suggest that there is no association between hip impingement and development of OA. A study of 162 patients – 48 with hip dysplasia, 74 with FAI, and 40 with normal hip pathology – under the age of 55 years who were followed for a minimum of 10 years assessed the natural history and progression of osteoarthritis in non-arthritic hips based on morphological characteristics. It was found that degenerative change occurred earliest in patients with hip dysplasia, whereas the risk of progression to OA or need for total hip replacement of patients with FAI did not show a statistically significant difference compared to structurally normal hips.<sup>212</sup>

In most cases, patients presenting with FAIS will also present with a labral tear. Impingement problems are thought to cause increased stress on the labrum, leading to labral pathology<sup>67</sup> and therefore articular cartilage damage since the damaged labrum can no longer do its job of providing a protective cushion for the joint. However, the prevalence of both abnormal bony morphology and labral lesions are common among asymptomatic populations as well. Frank et al completed a systematic review of 26 studies comprising 2,114 asymptomatic hips to determine the prevalence of FAI and labral tears in asymptomatic persons. The overall prevalence of asymptomatic hips with pincer lesions was 67% and cam lesions was 37%, and labral injury was found on MRI in 68.1% of hips.<sup>55</sup> Thus, many individuals present with clinically insignificant bony morphology and “dormant” labral pathology, indicating that a “normal” hip joint is rare amongst the general population. Further, the age-standardized prevalence of

symptomatic hip OA was found to be only 4.2%<sup>103</sup>, indicating that the connection between abnormal hip morphology and labral lesions, and the presence of OA is nebulous. Prophylactic treatment for asymptomatic individuals is not currently recommended as there is no evidence that doing so will decrease their risk of developing FAI syndrome or osteoarthritis.<sup>65</sup>

The terminology for FAI has evolved since the last report such that FAI syndrome (FAIS) is preferred and emphasizes that symptoms, clinical signs and relevant imaging findings must all be present for diagnosis to distinguish it from “asymptomatic FAI” or “radiological FAI” that may be more descriptive of hip morphology versus a clinical disorder.<sup>65</sup> In this report we have attempted to use FAIS to distinguish symptomatic populations; however some places in the report may use FAI if symptomology was unclear.

## 2.2 Mechanism of Femoroacetabular Impingement

The proposed mechanism of FAI is one where abnormal contact occurs between the proximal femur and acetabulum during the end range of hip motion, particularly flexion and internal rotation. This abnormal contact is believed to be due to morphologic abnormalities of the acetabulum or proximal femur (or both) resulting in labrum tears, chondral lesions, and progressive osteoarthritis<sup>59,90,156</sup>

## 2.3 Classification of Femoroacetabular Impingement

Two distinct types of FAI have been proposed by Ganz and coworkers<sup>59</sup> depending on where the abnormal morphology occurs; abnormal morphology of the femur is termed “cam impingement” and of the acetabulum, “pincer impingement”.

Cam-type impingement is associated with a non-spherical femoral head or an abnormality at the head-neck junction.<sup>59,95,112,120</sup> The malshaped proximal femur has the effect of increasing the radius of the femoral head, leading to abnormal contact with the acetabulum at the end of hip motion. This type of impingement has also been associated with slipped capital femoral epiphysis, Leg-Calvé-Perthes disease, osteonecrosis and post-traumatic deformities of the femur.<sup>95,120,142,195</sup>

Pincer-type FAI is characterized by a functionally deep or retroverted acetabulum resulting in overcoverage of the femoral head.<sup>59,95,110,120,195</sup> This overcoverage may be a relative anterior overcoverage, as seen in retroverted acetabuli, focal anterior overcoverage or a global acetabular overcoverage, often the result of coxa profunda or protusio acetabuli.<sup>59,95,142</sup>

While FAI has been classified into these two types, a mixed-type impingement, with characteristics of both cam and pincer-type FAI, has also been described.<sup>19,20,79,88,161,163</sup> However, at least one study that purposed to evaluate the acetabulum in those with a diagnosis of cam or pincer FAI reported that cam hips were slightly shallower than normal whereas pincer hips were deeper.<sup>36</sup> They concluded that cam and pincer hips are distinct pathoanatomic entities.

## 2.4 Technologies & Interventions

### 2.4.1 Non-operative Treatment

A variety of non-operative approaches have been used to treat FAIS including non-steroidal anti-inflammatory medications, core strengthening, physical therapy (PT), steroid injections, activity modification and pelvic postural retraining.<sup>7,52,90,105,120,134,207</sup> An important distinction must be made between non-operative interventions of passive conservative care (i.e. activity modification and chemical anti-inflammatory interventions) and rehabilitative exercise-based therapies (i.e. PT and exercise), as the later may provide increased clinical benefits compared to the former.<sup>65,101</sup> While there appears to be limited high quality evidence on various types of non-operative care<sup>65,134,207</sup>, some recent prospective pilot randomized controlled trials suggest that an FAIS-specific PT program has the potential for a positive effect on hip pain, function, and hip adductor strength<sup>99</sup>, and that FAIS may be amenable to conservative treatment strategies as well. It is unknown to what extent these therapies may impact hip degeneration or development of osteoarthritis.<sup>95,120</sup>

Until recently, our knowledge regarding optimal exercise/PT interventions for patients with FAIS was limited. PT interventions across clinical trials varied substantially and were not typically designed to be FAIS-specific. A 2019 editorial article<sup>101</sup> suggested that the PT programs utilized by two of the RCTs<sup>66,125</sup> included in this review do not reflect current best practice of PT for FAIS since both protocols were developed prior to 2012. Additionally, some authors have suggested that physical therapy focused only on improving range of motion or stretching may in fact aggravate impingement symptoms in some cases.<sup>90,156</sup>

### 2.4.2 Operative Treatment

The fundamental goals of surgical intervention in the treatment of FAI/FAIS, regardless of the type of impingement or the surgical technique used, are to correct the underlying morphologic abnormalities of the femur and/or acetabulum and address possible pathologic changes present in the labrum and articular cartilage in order to improve hip range of motion and alleviate areas of abnormal contact.<sup>59,90,95,120,156</sup>

- *Cam Impingement*

In cam-type impingement, the goals of surgery are to remove any asphericity of the femoral head and improve the head-neck offset. Debridement of bony abnormalities of the head and femoral osteotomy at the level of the head and neck, base of neck and intertrochanteric level, have all been used to correct underlying morphologic abnormalities and restore the head-neck offset in femoral causes of FAI.<sup>59,95,120,142</sup>

- *Pincer Impingement*

In pincer-type impingement, surgery is aimed at reducing the prominence of the acetabular rim, debriding the degenerative labral tissue and reattaching normal labral tissue.<sup>59,95,120</sup> Periacetabular osteotomy has also been performed in cases of severe acetabular retroversion.<sup>120,142</sup>

In dealing with labral abnormalities, it has been suggested that resecting the labrum should be avoided if at all possible. However, if the acetabular rim needs to be resected the labrum can be taken down as part of the approach and surgically refixed.<sup>59,120</sup>

Three operative approaches are frequently used to accomplish the goals of surgical intervention; arthroscopy (most commonly), open hip dislocation surgery, or arthroscopy with a limited open approach (mini-open).

- *Arthroscopy*

Hip arthroscopy is a minimally invasive procedure that has gained favor in treating cam, pincer or mixed-type FAI.<sup>95,112,199</sup> Similar to treatment through an open approach, the goals of treating FAI with arthroscopy are correcting underlying structural deformities of the femur in cam-type impingement and reduction of overcoverage of the acetabulum in pincer-type FAI. This is accomplished through a minimally invasive approach, utilizing 2 to 3 ports and, unlike the open approach, does not involve surgical dislocation of the hip. Although this procedure is less invasive than an open procedure, there are limitations to what can be done arthroscopically. Posterior based lesions can be challenging to treat, difficulty assessing the true depth of bony resection may lead to over or under resection, resecting a retroverted acetabulum is technically difficult, and it is difficult to treat chondral lesions.<sup>95,112</sup> Protrusio has also been cited as being difficult to treat arthroscopically given the difficulty in performing dynamic assessment of hip motion intraoperatively.<sup>112</sup> All RCTs included in this report as well as the majority of all other studies included used an arthroscopic approach to operative treatment of FAI/FAIS.

- *Open Approach*

Ganz et. al. described an open procedure for the treatment of FAI in which a lateral hip incision is made, followed by trochanteric osteotomy and Z-shaped capsulotomy. The hip is dislocated anteriorly, allowing for a full 360° view of the femoral head and acetabulum.<sup>58</sup> Since this original description, other open approaches have been used based on the nature of the underlying abnormal morphology present. In one case series, the trochanteric slide exposure was utilized when there was extensive posterior-inferior acetabular impingement and the iliofemoral exposure was performed when isolated anterior FAI was present.<sup>142</sup> The open approaches allow for adequate debridement of aspherical portions of the femoral head and the acetabular rim as well as providing excellent exposure to inspect articular surfaces.<sup>59,142</sup> Femoral osteotomies at the level of the head and neck, base of neck and intertrochanteric osteotomies can also be performed when an open approach is utilized. It has been hypothesized that complex bony abnormalities are better treated with an open approach, compared to arthroscopic or arthroscopic assisted procedures.<sup>120</sup> However, the disadvantages of this procedure include a relatively long rehabilitation time due to trochanteric osteotomy and a potential impairment of hip proprioception due to capsulotomy and resection of the ligamentum teres.<sup>34,121</sup>

- *Arthroscopy with Limited Open Approach*

Combining arthroscopy with a mini-open approach allows for the treatment of focal cam impingement and addressing labral and chondral lesions with an improved exposure compared to arthroscopy alone.<sup>78,117,177</sup> Similar to arthroscopy, the inability to address posterior based lesions is a known limitation when utilizing this approach.<sup>95</sup> Of the studies included in this report, only a few case series used a mini-open approach.

## 2.5 Indications and Contraindications

The 2016 Warwick Agreement, an expert consensus document, acknowledges that there is no high-level evidence to support the definitive treatment of FAIS and that conservative care, rehabilitation and

surgery may play a role in different patients. The panel further suggests that decision making should employ a multidisciplinary group that has access to and knowledges about all of the options. No specific criteria or indications for surgery for FAIS are described. Authors do, however, indicate that it is rarely indicated to offer surgery to persons with an asymptomatic cam or pincer morphology.

There appears to be a lack of consensus and substantial inconsistency regarding specific indications or criteria for surgical treatment of FAIS across the literature. One older systematic review<sup>9</sup> of indications used by clinicians to address FAI with surgical dislocation (N= 15 studies, 12 were case series) reported that pain and the impingement sign were the most common clinical criteria for surgery and that the most common radiologic criteria were derived from MRI/MRA versus plain radiographs and included description of labral tears and cartilage damage. A more recent scoping review<sup>160</sup> of 108 studies reported that only 56% of studies identified followed the Warwick Agreement consensus of using a combination of symptoms, clinical signs and diagnostic imaging for FAIS diagnosis. Across the studies reporting on the triad, the most commonly reported criteria were  $\geq 6$  months of hip pain, decreased hip flexion and internal rotation, positive impingement sign,  $\alpha$ -angle  $> 50^\circ$  and a positive cross-over sign. Only 44% described previous failure of non-operative or physiotherapist led rehabilitation as part of surgical decision making. The most common criterion for FAIS surgery was related to imaging evidence (92%) and only 12% of studies reported use of diagnostic intra-articular injection as an FAIS diagnostic criterion.

The Lynch 2019<sup>123</sup> consensus-based best-practices guideline (BPG) recommends that a standard minimum 3 month duration of conservative care is recommended and alludes to general selection criteria for surgical candidates. Their recommendations list the following contraindications to arthroscopy: Joint space narrowing ( $< 2$ mm anywhere along the lateral and/or medial sourcil or OA, Tönnis grade  $\leq 2$ , and pain not localized to the hip or out of proportion due to psychological issue. Obesity and severe femoral retro or anteversion with gait abnormality are also listed as contraindications but hypermobility and skeletal immaturity are not.

Several authors have cited patient selection as an important factor in outcomes of surgery for FAI, particularly the difficulty of achieving a successful outcome in patients with advanced osteoarthritis prior to surgery.<sup>88,117,147,177</sup> One author found that patients with greater than 50% joint space narrowing, predominance of aching pain at rest and bipolar grade 4 lesions on MRI had universally poor outcomes following surgery for FAI.<sup>114</sup>

## 2.6 Potential Complications/Harms of FAI surgery

It has been suggested that complications/harms for FAI surgery can be grouped into major, moderate and minor categories.<sup>35</sup> Potential major complications include avascular necrosis, femoral head-neck fracture, loss of fixation requiring revision, deep infection, symptomatic or significant limitation of hip motion due to heterotopic ossification, neurovascular injury, and symptomatic venous thromboembolism. Potential moderate complications include symptomatic hardware, with or without removal. Potential minor complications include asymptomatic heterotopic ossification, superficial infection, and urinary tract infection.

## 2.7 Clinical Guidelines

ECRI Guideline Trust (formerly, National Guideline Clearinghouse), PubMed, Google and Google Scholar, and references of included studies were searched for guidelines related to treatment of FAIS.

Additionally, several professional societies were searched for clinical practice guidelines including, but not limited to, the American Association of Orthopaedic Surgeons, American Orthopaedic Association, and American Board of Orthopaedic Surgery. Updated versions of all guidelines included in the previous report were looked for.

No newly published clinical practice guidelines were found to be published since the prior report. The prior report identified the 2011 National Institute for Health and Clinical Excellence (NICE) Clinical Practice Guidelines for Arthroscopic and Open hip surgery. There have been no updates to the NICE guidelines since the publications of the previous report. Though no formal evidence based clinical guidelines were identified, we did locate two expert consensus documents<sup>65,123</sup>, which are summarized in Table 2 below.

**Table 2. Summary of Expert Consensus Documents**

| Guideline                    | Evidence Base   | Recommendation  | Strength of Recommendation |
|------------------------------|---|---|----------------------------|
| <b>The Warwick Agreement</b> | Expert opinion based on selected systematic reviews and seminal literature (explicit inclusion/exclusion criteria or critical appraisal process not described). | <ul style="list-style-type: none"> <li>• <b>FAIS definition:</b> FAIS is a motion-related clinical disorder of the hip with a triad of symptoms, clinical signs, and imaging findings. It represents a symptomatic premature contact between the proximal femur and the acetabulum.</li> <li>• <b>FAIS diagnosis:</b> Symptoms, clinical signs and imaging findings must be present in order to diagnose FAI syndrome.</li> <li>• <b>Treatment of FAIS:</b> FAI syndrome can be treated by conservative care, rehabilitation or surgery. Conservative care may involve education, watchful waiting, and lifestyle and activity modification. Physiotherapy led rehabilitation aims to improve hip stability, neuromuscular control, strength, range of motion and movement patterns. Surgery, either open or arthroscopic, aims to improve the hip morphology and repair damaged tissue. The good management of the variety of patients with FAI syndrome requires the availability of all of these approaches. No specific criteria or indications for surgery for FAIS are described.</li> <li>• <b>Management of asymptomatic FAIS patients:</b> It is not known which individuals with cam or pincer morphologies will develop symptoms, and therefore FAI syndrome. Preventive measures may have a role in higher risk populations, but it is rarely indicated to offer surgery to these individuals.</li> </ul> | NR                         |

| Guideline         | Evidence Base  | Recommendation   | Strength of Recommendation |
|-------------------|--|--|----------------------------|
| <b>Lynch 2019</b> | Based on a systematic review <sup>138</sup> conducted to assess risk factors and outcomes related to arthroscopic management of FAI and a survey of 24 questions administered to the development group of 15 hip arthroscopists. | <p><u>Preoperative</u></p> <ol style="list-style-type: none"> <li>1. Patients should receive education regarding FAI</li> <li>2. Conservative treatment should include a standard minimum duration of 3 months, including: <ol style="list-style-type: none"> <li>a. Trial of rest</li> <li>b. Trial of NSAIDs</li> <li>c. Activity modification or restriction</li> <li>d. Physical therapy</li> <li>e. No opioids</li> </ol> </li> <li>3. Permit less than the full duration of conservative treatment with the following clinical history: <ol style="list-style-type: none"> <li>a. Professional athletes or out-of-season athletes</li> <li>b. Patients who are undergoing PT with no or marginal improvement as deemed by the surgeon and physical therapist</li> <li>c. High baseline mental health (per the VR-12 questionnaire)</li> <li>d. Successful surgery on the contralateral side</li> </ol> </li> <li>4. Assess joint parameters for proceeding with surgery before completing the full duration of conservative tx: <ol style="list-style-type: none"> <li>a. High Alpha angle</li> <li>b. Low Tonnis grade</li> <li>c. Large cam-type deformity in the absence of osteoarthritic changes</li> <li>d. Large combined deformity in the absence of osteoarthritic changes</li> <li>e. Large ROM limitations with pain</li> </ol> </li> <li>5. Obtain an MRI in the setting of a previous hip scope with intra-articular pain</li> </ol> <p><u>Contraindications to hip arthroscopy:</u></p> <ul style="list-style-type: none"> <li>• Joint space narrowing (&lt;2 mm anywhere along the lateral and/or middle source) or OA</li> <li>• Tonnis grade ≥2</li> <li>• Severe femoral retro or anteversion with gait abnormality</li> </ul> | NR                         |



| Guideline | Evidence Base | Recommendation   | Strength of Recommendation |
|-----------|---------------|--|----------------------------|
|           |               | <ul style="list-style-type: none"> <li>• Pain not localizing to the hip, or out of proportion due to psychosocial issue</li> <li>• Obesity to where access cannot be obtained</li> <li>• Broken Shenton's line</li> </ul> <p><u>Not considered to be contraindications to surgery:</u></p> <ul style="list-style-type: none"> <li>• Hypermobility (Beighton hypermobility score <math>\geq 5</math>)</li> <li>• Skeletal immaturity are not contraindications<sup>†</sup></li> </ul> <p><u>Surgical Recommendations</u></p> <p><u>Guide bone resection by:</u></p> <ul style="list-style-type: none"> <li>• Plain preoperative radiographs</li> <li>• Visualization of the femoral head-neck contour &amp; re-establishing the slope/junction</li> <li>• Conducting a dynamic exam assessing areas of impingement</li> <li>• Intraoperative fluoroscopy</li> <li>• Including any hard, sclerotic bone</li> <li>• In patients with labral tears, perform a labral repair, rather than debridement only</li> <li>• Labral reconstruction (vs. repair) should be done in a revision surgery with a labral deficiency</li> <li>• Surgery for bilateral FAI should generally be completed via a staged approach</li> <li>• A nonprofessional athlete or young patient is not an indication for a concomitant procedure</li> <li>• Perform capsular plication in ligamentous laxity (Beighton Score <math>\geq 5</math>, Ehlers–Danlos)</li> <li>• Perform capsular plication during hip arthroscopy in the setting of a patient with borderline dysplasia</li> <li>• Address both femoral and acetabular pathology in combined lesions</li> </ul> |                            |

FAIS=Femoroacetabular Impingement Syndrome; NR=Not Reported

## 2.8 Previous Systematic Reviews & Health Technology Assessments

Systematic reviews and health technology assessments (HTAs) were found by searching PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and the National Guideline Clearinghouse from April 1, 2011 to May 14, 2019. Reviews published since the previous report were selected for summary with a focus on those of highest quality. Reference lists of relevant studies and the bibliographies of systematic reviews were hand searched. See Appendix B for search terms and full search strategy.

**Table 3. Summary of Selected Previous Systematic Reviews of Surgery for FAIS**

| Author, year<br>Search dates  | Purpose   | Treatment vs.<br>Comparators                 | Primary Outcomes   | Evidence-base<br>Used                                   | Primary Conclusions  |
|---|---|--|--|---|--|
| <b>Riff 2019</b><br><i>January 1, 2009<br/>to June<br/>10, 2017</i> | To evaluate the safety and efficacy of hip arthroscopy for Femoroacetabular impingement syndrome by assessing complications, comprehensive procedure survivorship, and the influence of labral and capsular management on procedure survivorship. | Noncomparative (looking at arthroscopy only) | Number of reoperations, specifically conversions to THA, revision hip arthroscopy, or periacetabular osteotomy, number of complications, changes in surgical technique over time, and preoperative and postoperative patient-reported outcomes (International Hip Outcome Tool, Hip Outcome Score, Activities of Daily Living [HOS-ADL], Hip Outcome Score, Sports Specific Scale [HOS-SSS], modified Harris Hip Score [mHHS], Non-Arthritic Hip Score, visual analog scale, and Short Form 12 physical and mental scores. | 68 studies (Level of evidence I=1, II=2, III=22, IV=43) | <b>Patient Reported Outcomes:</b> Significant postoperative improvements were observed for all patient-reported outcomes evaluated including the International Hip Outcome Tool, HOS-ADL, HOS-sport, mHHS, Non-Arthritic Hip Score, and VAS<br><b>Complications:</b> The most common complications were neurologic (53%), heterotopic ossification (24%), infection (15%), and thromboembolic (7%).<br><b>Reoperation/Conversion to THA:</b> Conversion to total hip arthroplasty (456 cases) was the most common reason for reoperation, followed by revision hip arthroscopy (226 cases) and periacetabular osteotomy (7 cases). The rate of arthroplasty conversion was lower than 10% in 43 of 59 studies reporting this outcome. The average interval to arthroplasty conversion was 58 months.<br><b>Author's Conclusions:</b> Arthroplasty conversion occurred in fewer than 10% of cases in the clear majority of series. Labral repair (compared with labral debridement) and capsular closure (compared with unrepaired capsulotomy) |

| Author, year<br>Search dates  | Purpose   | Treatment vs.<br>Comparators                 | Primary Outcomes   | Evidence-base<br>Used   | Primary Conclusions   |
|---|---|--|--|---|---|
|   |   |  |  |   | were associated with a lower risk of conversion to arthroplasty. Throughout the study interval, there were shifts in surgical technique favoring labral repair over debridement and capsular repair over unrepaired capsulotomy. The study is limited by selection bias because cases in which labral and capsular repair was performed may have had superior tissue that was more amenable to repair.  |
| <b>Minkara 2019</b><br><br><i>Past 12 years<br/>[article was<br/>published on<br/>January 26,<br/>2018 – search<br/>date not<br/>specified]</i> | To evaluate risk factors and outcomes after arthroscopic management of FAI, including return to play, revision rate, surgical and nonsurgical complications, change in a-angle, intraoperative bone resection, and patient-reported outcomes. | Noncomparative (looking at arthroscopy only) | Complications, return to sport, alpha-angle, modified Hip Harris Score, Non-arthritic Hip Score, HOS-ADL, HOS-sport, WOMAC, VAS, SF-12 mental and physical, iHOT, Sports Frequency Score | 31 studies (1 RCT, 1 prospective cohort, 3 retrospective cohorts, 26 case series) | <b>Patient Reported Outcomes:</b> All patient-reported outcomes improved postoperatively, with the highest increase observed in the Hip Outcome Score sports scale (41.7 points; 95% CI 34.1 to 49.4; $p<0.001$ ).<br><b>Reoperation/Conversion THA:</b> The pooled risk of reoperation after hip arthroscopy, including revision surgery or subsequent total hip arthroplasty, was 5.5% (95% CI 3.6% to 7.5%). The risk of clinical complications was 1.7% (95% CI 0.9% to 2.5%).<br><b>Return to activity:</b> In total, 87.7% of patients demonstrated return to sport after surgery (95% CI, 82.4%-92.9%, $P<0.001$ )<br><b>Author's Conclusion:</b> A high percentage of patients return to sport activities after hip arthroscopy for FAI, with a low rate of complications and reoperation. All patient-reported outcome measures, except for mental health, significantly improved after surgery. |
| <b>Kierkegaard 2017</b>   | To investigate pain, activities of daily living (ADL) function, sport function, quality of life and satisfaction at different time points   | Noncomparative (looking at arthroscopy only) | Preoperative and postoperative hip pain and/or hip   | 26 studies (primarily 22 case series, 3 cohort studies, 1 RCT –                   | <b>Function and Pain:</b> In patients with FAI, hip pain reduction and ADL function improvements may be achieved between 3 and 6 months after surgery, while sport  |

| Author, year<br>Search dates           | Purpose  | Treatment vs.<br>Comparators | Primary Outcomes   | Evidence-base<br>Used  | Primary Conclusions  |
|--|--|------------------------------|--|--|--|
| <i>Database inception to Sept 2015</i> | after hip arthroscopy in patients with femoroacetabular impingement (FAI). |                              | function during ADL and sport and/or quality of life and/or postoperative satisfaction absolute scores | comparative studies included comparisons of revision surgery versus surgery) | <p>function improvements occurs between 6 months and 1 year after hip arthroscopy. Hip pain, ADL and sport function improvements are evident at least up to 3 years after hip arthroscopy in patients with FAI. Average scores from patients indicate residual mild hip pain and/or hip function during ADL and sport lower than their healthy counterparts after hip arthroscopy. In patients with FAI, hip pain reduction and ADL function improvements may be achieved between 3 and 6 months after surgery, while sport function improvements occurs between 6 months and 1 year after hip arthroscopy. Hip pain, ADL and sport function improvements are evident at least up to 3 years after hip arthroscopy in patients with FAI. Average scores from patients indicate residual mild hip pain and/or hip function during ADL and sport lower than their healthy counterparts after hip arthroscopy.</p> <p><b>Author's Conclusions:</b> On average, patients reported earlier pain and ADL function improvements, and slower sport function improvements after hip arthroscopy for FAI.</p> <p>However, average scores from patients indicate residual mild hip pain and/or hip function lower than their healthy counterparts after surgery. Owing to the current low level of evidence, future RCTs and cohort studies should investigate the effectiveness of hip arthroscopy in patients with FAI.</p> |

| Author, year<br>Search dates  | Purpose   | Treatment vs.<br>Comparators                     | Primary Outcomes                                      | Evidence-base<br>Used  | Primary Conclusions   |
|---|---|--|---|--|---|
| <b>Gohal 2019</b><br><br><i>Database inception to June 10, 2018</i> | To systematically assess the HRQL outcomes after arthroscopic management of FAI.  | Noncomparative (looking at arthroscopy only)     | iHOTT-33, SF-12, EQ-5D, HAGOS, HOOS, Oxford Hip Score | 29 studies (24 case series, 3 case-control studies, 1 retrospective comparative cohort, 1 RCT) | Across the 29 included studies there were 6476 patients (6959 hips). Significant improvements were reported in all studies assessing generic HRQL outcomes, including the 12-Item Short Form Health Survey (range of mean postoperative scores, 82.2-89.8), and EuroQOL-5D scores (range of mean postoperative scores, 0.74-0.87) between 12 and 24 months postoperatively. Significant improvements were similarly identified in the hip-specific HRQL outcomes scores, with the majority of studies also reporting improvement between 12 and 24 months postoperatively. Mean improvement in International Hip Outcome Tool-33 scores from preoperative values to postoperative values ranged from 22.7 to 43.2 ( $I^2 = 44\%$ ), for studies with follow-up between 12 and 24 months |
| <b>Bolia 2018</b><br><br><i>January 2000 to March 2017</i>          | Report the proportion of venous thromboembolic events in patients undergoing hip arthroscopy for FAI  | Noncomparative (looking at arthroscopy only)     | Rate of deep vein thrombosis and pulmonary embolism   | 73 studies (38 in the meta-analysis; 11 comparative cohorts, 27 case series)                   | The meta-analyzed rate of deep vein thrombosis in patients undergoing primary hip arthroscopy for FAI syndrome was 1.18% (95% CI 0.8% to 1.74%). The meta-analyzed rate of pulmonary embolism in patients undergoing primary hip arthroscopy for FAI syndrome was 0.59% (95% CI 0.38% to 0.92%)   |
| <b>Gupta 2014</b><br><br><i>1999 and June 2013</i>                  | To evaluate the literature to determine complications of hip arthroscopy, with a secondary focus on how to minimize complications and risks | hip arthroscopy versus open surgical dislocation | Rate of complications and reoperations                | 81 studies (Level of evidence II=4, III=8, IV=53, V=17)  | A total of 285 complications were reported, for an overall rate of 4.5%. There were 26 major complications (0.41%) and a 4.1% minor complication rate. The overall reoperation rate was 4.03%. A total of 94 hips underwent revision arthroscopy. Regarding open procedures, 150 patients (93%) underwent either total hip  |

| Author, year<br>Search dates  | Purpose   | Treatment vs.<br>Comparators  | Primary Outcomes   | Evidence-base<br>Used                  | Primary Conclusions   |
|---|---|---|--|--|---|
|   |   |   |  |  | arthroplasty or a hip resurfacing procedure. The conversion rate to total hip arthroplasty or a resurfacing procedure was 2.4%.   |
| <b>Zhang et al. 2016</b><br><br><i>Database inception to Aug 2016</i> | This meta-analysis aims to evaluate the efficacy and safety of hip arthroscopy versus open surgical dislocation for treating femoroacetabular impingement (FAI) through published clinical trials                       | hip arthroscopy versus open surgical dislocation  | Alpha angle improvement, Nonarthritic Hip Scores (NAHS), modified Harrison Hip Score (mHHS), Hip Outcome Score-Activities of Daily Living (HOS-ADL), Hip Outcome Score-Sport Specific Subscale (HOS-SSS), reoperation rates, complications | 5 cohort studies                       | Hip arthroscopy resulted in higher NAHS and lower reoperation rates, but had less improvement in alpha angle in patients with cam osteoplasty, than open surgical dislocation.<br><b>Reoperation Rate:</b> Data reporting on reoperation rate are described in 4 studies that included a total of 292 hips. This meta-analysis demonstrated that more additional operations were required after open surgical dislocation than after hip arthroscopy (relative risk [RR]: 0.40, 95% CI: 0.17–0.95, P= 0.04, I2=0%; Fig. 4A).<br><b>Complications:</b> Data reporting on complications are described in 2 studies that included a total of 61 hips. This meta-analysis demonstrated no statistical difference in complications between hip arthroscopy and open surgical dislocation (RR: 0.76, 95% CI: 0.12–4.63, P= 0.76, I2=0%; Fig. 4B). |
| <b>Fairley et al. 2016</b><br><br><i>Jan 2000 to July 2015</i>        | The optimal therapy for femoroacetabular impingement (FAI) is unclear. The aim of this systematic review was to examine the evidence for surgical and non-surgical treatment of FAI on symptom and structural outcomes. | Surgical and non-surgical treatment, Open Surgery vs. arthroscopy, Different arthroscopic techniques with each other, | Symptoms assessed by validated tools, hip bone shape (radiographic measures, joint degeneration, or progression to joint replacement   | 18 studies (16 cohort studies, 2 RCTs) | Although evidence supports improvement in symptoms after surgery in FAI, no studies have compared surgical and non-surgical treatment. Therefore no conclusion regarding the relative efficacy of one approach over the other can be made. Surgery improves alpha angle but whether this alters the risk of development   |

| Author, year<br>Search dates   | Purpose  | Treatment vs.<br>Comparators   | Primary Outcomes | Evidence-base<br>Used  | Primary Conclusions  |
|--|--|--|------------------|--|--|
|  |  | Different open surgical techniques with each other                   |                  |  | or progression of hip OA is unknown. This review highlights the lack of evidence for use of surgery in FAI. Given that hip geometry may be modified by non-surgical factors, clarifying the role of non-surgical approaches vs surgery for the management of FAI is warranted.   |
| <b>Forster-Horvath et al. 2016</b><br><br><i>Database inception through April 2016</i> | To perform a systematic review comparing outcomes of labral debridement/segmental resection with labral reconstruction as part of a comprehensive treatment strategy for femoroacetabular impingement. | Acetabular Labral Debridement/Segmental Resection vs. Reconstruction |                  | 20 studies (12 case series or case-control studies, 1 RCT, 7 cohort studies) | <p>Twelve studies explored outcomes after labral debridement/resection in a total of 400 hips, whereas 7 studies reported on outcomes after labral reconstruction in a total of 275 hips. One additional matched-pair control study compared labral resection (22 hips) with reconstruction (11 hips). The surgical intervention was a revision in 0% to 100% for group 1 versus 5% to 55% for group 2. A direct anterior approach was not performed in group 2, and cam-type impingement appeared to make up a larger percentage of group 1. The Tönnis grade ranged from 0 to 1 for group 1 versus 0.3 to 1.1 for group 2. Joint replacements were performed in 0% to 30% and 0% to 25%, respectively. The modified Harris Hip Score was the most widely used patient-reported outcome measure and suggested that labral reconstruction was not inferior to labral debridement/segmental resection.</p> <p>Clinical outcomes after labral debridement/segmental resection versus labral reconstruction were found to be comparable. In the setting of unsalvageable labral pathology, labral reconstruction was used more frequently</p> |

| Author, year<br>Search dates | Purpose | Treatment vs.<br>Comparators | Primary Outcomes | Evidence-base<br>Used | Primary Conclusions  |
|------------------------------|---------|------------------------------|------------------|-----------------------|--|
|                              |         |                              |                  |                       | <p>as a revision option whereas debridement may be more commonly used in the index setting.</p> <p><b>Reoperation:</b> Of the patients, 0% to 25% underwent conversion to THA. Outcomes after revision labral treatment in the setting of FAI have consistently been shown to be inferior to those of primary surgical procedures in the literature. There were more patients in group 2 who underwent labral reconstruction as a revision procedure. Therefore, these patients may have exhibited more extensive chondral wear, capsular scarring, or injury, and compensatory myotendinous adaptations or neurogenic pain modulation may have developed through the chronicity of their hip disease. A sophisticated labral procedure may have been inadequate to resolve these layered challenges.</p> <p><b>Conversion:</b> Overall, for both groups, the range of conversion to hip arthroplasty was 0% to 30%. Because one study did not stratify the type of labral procedure (debridement/ segmental resection vs refixation), it is difficult to make precise conclusions on the THA conversion rate. Nonetheless, patients who underwent labral debridement/ segmental resection were not found to transition to THA more frequently than those who underwent labral reconstruction.</p> |



| Author, year<br>Search dates   | Purpose  | Treatment vs.<br>Comparators | Primary Outcomes  | Evidence-base<br>Used                          | Primary Conclusions  |
|--|--|------------------------------|---|--|--|
| <b>Griffin et al. 2017</b><br><br><i>Database inception to June 2016</i> | To review the outcomes of hip arthroscopy in older adults and identify factors associated with treatment failures. | Noncomparative               | Patient-reported Outcomes (validated), Quality of Life, Range of Motion, Reoperation, Complications | 8 studies (3 cohort studies and 5 case series) | <p><b>Complications:</b> Overall complication rate of 5.1% (8/157 patients) across five studies. 1 deep venous thrombosis, 1 case of heterotopic ossification (HO), 1 superficial wound infection resolved with oral antibiotics, 1 deep wound infection, 3 cases of psoas tendinitis, and 2 cases of transient sensory neurapraxia (perineum and foot).</p> <p><b>Reoperation:</b> Seven of 8 studies reported reoperation rates. Excluding conversion to arthroplasty, the rate of reoperation was 2.3% (8/351 patients). The majority of reoperations were repeat hip arthroscopy for continued pain and/or labral tear identified on postoperative MRI. There were 3 additional reoperations: 1 for excision of HO, 1 irrigation and debridement for deep wound infection, and 1 lysis of adhesions. When including arthroplasty, the total reoperation rate increased to 20.8%.</p> |

F/U=follow-up; FABER=Flexion Abduction External Rotation; FADIR=Flexion Adduction Internal Rotation; FAI=Femoroacetabular Impingement; FAIS=Femoroacetabular Impingement Syndrome; GROC=Global Rate of Change; HADS=Hospital anxiety and depression scale; HAGOS=Copenhagen hip and groin outcome score; HOS=Hip Outcome Score; HOS-ADL=Hip Outcome Score Activities of Daily Living; iHOT=international Hip Outcomes Tool; ITT=intention to treat; MCID=Minimally clinically important difference; MCS=mental component score; mHHS=modified Hip Harris Score; mm=millimeters; MRA=Magnetic Resonance Arthrogram; MRI=Magnetic Resonance Imaging; NAHS=Non-arthritic hip score; NPS=Numeric Pain Scale; NR=not reported; OA=osteoarthritis; PCS=physical component score; PT=physical therapy; QOL=quality of life; RCT=randomized controlled trial; ROB=risk of bias; SD=standard deviation; VAS=visual analogue scale

## 2.9 Medicare and Representative Private Insurer Coverage Policies

Currently there are no national or local coverage determinations or policies for The Centers for Medicare and Medicaid Services (CMS) regarding the surgical treatment of FAI syndrome. Coverage policies are consistent for surgical treatment, either open or arthroscopic, of FAI syndrome for selected bell-weather payers. The payers will provide coverage for surgical intervention as long as certain patient conditions are met. In order to provide a more comprehensive review, recommendations from EviCore, a medical benefits management company, have been included as well. Table 4 provides an overview of policy decisions.

**Table 4. Overview of payer technology assessments and policies for hip surgery procedures for FAI.**

| Payer (year)                                     | Search Dates  | Evidence Base Available  | Policy   | Rationale /comments  |
|--|---|--|--|--|
| <b>National Coverage Policies</b>                |   |  |  |  |
| Centers for Medicare and Medicaid Services (CMS) | NA  | NA   | No national or local coverage determinations   | NA   |
| <b>Representative Private Insurers</b>           |   |  |  |  |
| United Healthcare (2019)                         | Hayes Medical Technology Literature Search: 2008 to 2016 PubMed: March 2017 to May 2018 | 35 publications*; 19 SRs, 1 RCT, 2 comparative cohorts, 11 case series, 1 consensus statement, 1 guideline | <b>Surgical treatment for femoroacetabular impingement (FAI) syndrome is proven and medically necessary when the following criteria are met:</b> <ul style="list-style-type: none"> <li>• Pain unresponsive to non-surgical management (e.g., restricted activity, nonsteroidal anti-inflammatory drugs)</li> <li>• Moderate-to-severe symptoms typical of FAI (persistent hip or groin pain that limits activity and is worsened by bending of the joint such as squatting or prolonged sitting)</li> <li>• Positive impingement sign (i.e., sudden pain on 90 degree hip flexion with adduction and internal rotation or extension and external rotation)</li> <li>• Imaging studies (X-rays, MRI or CT scans) confirming FAI (e.g., pistol-grip deformity, alpha angle greater than 50 degrees, coxa profunda, and/or acetabular retroversion)</li> <li>• Do not have advanced osteoarthritis (i.e., Tönnis grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge grade III or IV)</li> </ul> | NR   |
| Aetna (2018)                                     | NR  | NR (but 106 references cited as forming the  | Aetna considers femoro-acetabular surgery, open or arthroscopic, for the treatment of hip  | <b>Note:</b> Iliopsoas tendon release surgery and capsular release |

| Payer (year) | Search Dates | Evidence Base Available | Policy  | Rationale /comments  |
|--------------|--------------|-------------------------|---|--|
|              |              | basis of the policy)    | <p>impingement syndrome medically necessary for persons who fulfil all the following criteria:</p> <ul style="list-style-type: none"> <li>• Diagnosis of definite femoro-acetabular impingement defined by appropriate imaging studies (X-rays, MRI or CT scans), showing cam impingement (alpha angle greater than 50 degrees), pincer impingement (acetabular retroversion or coxa profunda) (center edge angle greater than or equal to 40 degrees), or pistol grip deformity (nonspherical femoral head shape); and</li> <li>• Moderate to severe symptoms typical of FAI (hip or groin pain that is worsened by flexion activities (e.g., squatting or prolonged sitting) that significantly limits activities, with duration of at least 6 months where diagnosis of FAI has been made as above; and</li> <li>• Positive impingement sign with sudden pain on 90 degree hip flexion with adduction and internal rotation or extension and external rotation; and</li> <li>• Failure to respond to all available conservative treatment options including activity modification (e.g., restriction of athletic pursuits and avoidance of symptomatic motion),</li> <li>• pharmacological intervention (e.g., nonsteroidal anti-inflammatory drugs [NSAIDS]), injections of local anesthetics into the joint) and physiotherapy; and</li> <li>• Member is 15 years of age or older or skeletally mature (as indicated by epiphyseal closure); and</li> <li>• Absence of advanced osteoarthritis change on pre-operative Xray (Tonnis grade 2 or more) or severe cartilage injury (Outerbridge grade III or IV); and</li> <li>• Absence of joint space narrowing on plain radiograph of the pelvis. Joint space is not less than 2 mm wide anywhere along the source; and</li> <li>• Member does not have generalized joint laxity especially in diseases connected with hypermobility of the</li> </ul> | <p>surgery are considered integral to the primary procedure and not separately reimbursable.</p> <p><b>Notes:</b> For purposes of this policy, Aetna will consider the official written report of complex imaging studies (e.g., CT, MRI, myelogram). If the operating surgeon disagrees with the official written report, the surgeon should document that disagreement. The surgeon should discuss the disagreement with the provider who did the official interpretation, and there should also be a written addendum to the official report indicating agreement or disagreement with the operating surgeon.</p> |

| Payer (year)   | Search Dates | Evidence Base Available      | Policy   | Rationale /comments |
|--|--------------|------------------------------|--|---------------------|
|  |              |                              | <p>joints, such as Marfan syndrome and Ehlers-Danlos syndrome; and</p> <ul style="list-style-type: none"> <li>Member does not have osteogenesis imperfecta.</li> </ul> <p>Aetna consider surgery for FAI impingement experimental and investigational for all other indications.</p> <p>Aetna considers capsular plication experimental and investigational for the treatment of FAI because there is insufficient evidence regarding the effectiveness of this approach.</p>  |                     |
| Blue Cross<br>Blue Shield of<br>North Carolina<br>(BCBSNC)<br>(2018) | NR           | NR (but<br>references cited) | <p><b>BCBSNC will provide coverage for Surgery for Femoroacetabular Impingement when it is determined to be medically necessary because the criteria and guidelines shown below have been met:</b></p> <p><b>Age</b></p> <ul style="list-style-type: none"> <li>Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older).</li> </ul> <p><b>Symptoms</b></p> <ul style="list-style-type: none"> <li>Moderate-to-severe hip pain worsened by flexion activities (e.g., squatting or prolonged sitting) that significantly limits activities; AND</li> <li>Unresponsive to conservative therapy for at least 3 months (including activity modifications, restriction of athletic pursuits and avoidance of symptomatic motion); AND</li> <li>Positive impingement sign on clinical examination (pain elicited with 90 degrees of flexion and internal rotation and adduction of the femur).</li> </ul> <p><b>Imaging</b></p> <ul style="list-style-type: none"> <li>Morphology indicative of cam or pincer-type FAI, e.g., pistol-grip deformity, femoral head neck offset with an alpha angle greater than 50 degrees, a positive wall sign, acetabular retroversion (over coverage with crossover sign), coxa profunda or protrusion, or damage of the acetabular rim; AND</li> </ul> | NR                  |

| Payer (year) | Search Dates | Evidence Base Available | Policy  | Rationale /comments |
|--------------|--------------|-------------------------|---|---------------------|
|              |              |                         | <ul style="list-style-type: none"> <li>• High probability of a causal association between the FAI morphology and damage, e.g., a pistol-grip deformity with a tear of the acetabular labrum and articular cartilage damage in the anterosuperior quadrant; AND</li> <li>• No evidence of advanced osteoarthritis, defined as Tönnis grade II or III, or joint space of less than 2 mm; AND</li> <li>• No evidence of severe (Outerbridge grade IV) chondral damage.</li> </ul> <p>Treatment of FAI is considered <b>investigational</b> in all other situations.</p>  |                     |
| Cigna (2014) | NR           | NR                      | <p><b>Cigna covers open or arthroscopic hip surgery, including labral repair with or without grafting, for femoroacetabular impingement (FAI) syndrome as medically necessary when ALL of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• moderate-to-severe persistent hip or groin pain that limits activity and is worsened by flexion activities (e.g., squatting or prolonged sitting)</li> <li>• pain unresponsive to medical management (e.g., restricted activity, nonsteroidal anti-inflammatory drugs)</li> <li>• positive impingement sign (i.e., sudden pain on 90 degree hip flexion with adduction and internal rotation or extension and external rotation)</li> <li>• radiographic confirmation of FAI (e.g., pistol-grip deformity, alpha angle greater than 50 degrees, coxa profunda, and/or acetabular retroversion)</li> <li>• absence of <b>BOTH</b> of the following: <ul style="list-style-type: none"> <li>-Tönnis grade 2 osteoarthritis (i.e., small cysts in femoral head or acetabulum, increasing narrowing of joint space, moderate loss of sphericity of femoral head)</li> <li>-Tönnis grade 3 osteoarthritis (i.e., large cysts, severe narrowing or obliteration of joint space, severe deformity of femoral head, avascular necrosis)</li> </ul> </li> </ul> | NR                  |

| Payer (year)   | Search Dates | Evidence Base Available   | Policy  | Rationale /comments  |
|----------------|--------------|---|---|--|
|                |              |   | <p><b>Cigna does not cover EITHER of the following for the treatment of femoroacetabular impingement (FAI) syndrome because each is considered experimental, investigational or unproven:</b></p> <ul style="list-style-type: none"> <li>• capsular plication</li> <li>• anterior inferior iliac spine (AIIS)/subspine impingement decompression</li> </ul>   |  |
| Regence (2019) | NR           | NR (but references are provided; and it is stated that no RCTs were identified) | <p><b>I. Open surgical treatment of femoroacetabular impingement (FAI) may be medically necessary in skeletally mature patients when all of the following criteria (A-E) are met:</b></p> <p>A. Moderate-to-severe hip pain that is worsened by flexion activities (e.g., squatting or prolonged sitting) that significantly limits activities</p> <p>B. Unresponsive to conservative therapy for at least 3 months or clinical documentation that conservative therapy is contraindicated (e.g., history of falls due to mechanical instability of hip joint). Conservative therapy for FAI must include documented activity modification to avoid symptoms and physical therapy, unless this aggravates symptoms.</p> <p>C. Positive impingement sign on clinical examination (i.e., pain elicited with 90 degrees of flexion and internal rotation and adduction of the femur)</p> <p>D. All of the following criteria must be met:</p> <ol style="list-style-type: none"> <li>1. Imaging (conventional x-rays, MRI, MRI arthrogram) documents morphology indicative of cam-type or pincer-type FAI (See Policy Guidelines).</li> <li>2. No evidence of advanced osteoarthritis, defined as Tonnis grade II or III, or joint space of less than 2 mm, except when there is mechanical instability</li> </ol> | <p>There is enough research to show that surgical treatment of femoroacetabular impingement can improve pain and function in some patients. Therefore, this surgery may be considered medically necessary for patients who meet the policy criteria.</p> <p>For patients that do not meet the policy criteria, surgical treatment of femoroacetabular impingement is considered not medically necessary because the procedure is not considered clinically effective or appropriate for these individuals. Capsular plication, capsular repair, labral reconstruction,</p> |

| Payer (year) | Search Dates | Evidence Base Available | Policy  | Rationale /comments   |
|--------------|--------------|-------------------------|---|---|
|              |              |                         | <p>3. No evidence of severe (Outerbridge grade IV) chondral damage.</p> <p>E. Requested procedures must be consistent with the anatomical abnormalities documented.</p> <p><b>II. Arthroscopic treatment of femoroacetabular impingement (FAI) may be medically necessary in skeletally mature patients when all of the following criteria (A-E) are met:</b></p> <p>A. Moderate-to-severe hip pain that is worsened by flexion activities (e.g., squatting or prolonged sitting) that significantly limits activities</p> <p>B. Unresponsive to conservative therapy for at least 3 months or clinical documentation that conservative therapy is contraindicated (e.g., history of falls due to mechanical instability of hip joint). Conservative therapy for FAI must include documented activity modification to avoid symptoms and physical therapy, unless this aggravates symptoms.</p> <p>C. Positive impingement sign on clinical examination (i.e., pain elicited with 90 degrees of flexion and internal rotation and adduction of the femur)</p> <p>D. All of the following criteria must be met:</p> <ol style="list-style-type: none"> <li>1. Imaging (conventional x-rays, MRI, MRI arthrogram) documents morphology indicative of cam-type or pincer-type FAI (See Policy Guidelines).</li> <li>2. No evidence of advanced osteoarthritis, defined as Tonnis grade II or III, or joint space of less than 2 mm, except when there is mechanical instability</li> <li>3. No evidence of severe (Outerbridge grade IV) chondral damage.</li> </ol> <p>E. Requested procedures must be consistent with the anatomical abnormalities documented.</p> | <p>iliotibial band windowing, trochanteric bursectomy, abductor muscle repair, iliopsoas tenotomy, and similar incidental procedures performed during surgical treatment of FAI are considered components of and incidental to the FAI procedure.</p> |

| Payer (year)  | Search Dates | Evidence Base Available | Policy  | Rationale /comments |
|---|--------------|-------------------------|---|---------------------|
|   |              |                         | III. Open or arthroscopic treatment of FAI is considered not medically necessary when Criteria I. and II. above are not met. Note that capsular plication, capsular repair, labral reconstruction, iliotibial band windowing, trochanteric bursectomy, abductor muscle repair, and/or iliopsoas tenotomy, when performed at the time of any FAI surgery, would be considered a component of and incidental to the FAI procedure.  |                     |
| <b>Management Organizations/Benefits Coordination Group</b> |              |                         |   |                     |
| Evicore (2019)  | NR           | NR                      | <p>Hip surgery, either arthroscopic or open surgery, is considered medically necessary for ANY of the following clinical situations:</p> <p>Femoroacetabular Impingement (FAI) when an individual has ALL of the following criteria:</p> <ul style="list-style-type: none"> <li>• Groin-dominant hip pain that is worsened by flexion (e.g., squatting or prolonged sitting) and significantly limits activities</li> <li>• Positive anterior impingement sign (i.e., groin-dominant hip pain with forced hip flexion, adduction, and internal rotation) on physical examination</li> <li>• Limited passive hip internal rotation on physical examination</li> <li>• Unresponsive to at least three (3) months of provider-directed non-surgical treatment which must include an image-guided diagnostic/therapeutic intra-articular hip injection to which there was not a negative response</li> <li>• ANY of the following radiographic findings to confirm FAI (Refer to <a href="#">MS-24: Hip</a> for advanced imaging indications for FAI): <ul style="list-style-type: none"> <li>- Alpha angle greater than 55 degrees</li> <li>- Pistol-grip deformity</li> <li>- Decrease of femoral head-neck offset</li> <li>- Acetabular retroversion (i.e., crossover sign, ischial spine sign)</li> <li>- Coxa profunda</li> </ul> </li> <li>• Documented presence of EITHER of the following:</li> </ul> | NR                  |



| Payer (year) | Search Dates | Evidence Base Available | Policy   | Rationale /comments |
|--------------|--------------|-------------------------|--|---------------------|
|              |              |                         | <ul style="list-style-type: none"> <li>- Tönnis grade 0 osteoarthritis (i.e., no signs of osteoarthritis)</li> <li>- Tönnis grade 1 osteoarthritis (i.e., sclerosis of the joint with slight joint space narrowing and osteophyte formation, and no or slight loss of femoral head sphericity)</li> <li>• Documented absence of BOTH of the following:               <ul style="list-style-type: none"> <li>- Tönnis grade 2 osteoarthritis (i.e., small cysts in femoral head or acetabulum with moderate joint space narrowing and moderate loss of femoral head sphericity)</li> <li>- Tönnis grade 3 osteoarthritis (i.e., large cysts in the femoral head or acetabulum, severe joint space narrowing or obliteration of the joint space, and severe deformity and loss of sphericity of the femoral head)</li> </ul> </li> </ul> |                     |

CT=computed tomography; F/U=follow-up; FABER=Flexion Abduction External Rotation; FADIR=Flexion Adduction Internal Rotation; FAI=Femoroacetabular Impingement; FAIS=Femoroacetabular Impingement Syndrome; GROC=Global Rate of Change; HADS=Hospital anxiety and depression scale; HAGOS=Copenhagen hip and groin outcome score; HOS=Hip Outcome Score; HOS-ADL=Hip Outcome Score Activities of Daily Living; iHOT=international Hip Outcomes Tool; ITT=intention to treat; MCID=Minimally clinically important difference; MCS=mental component score; mHHS=modified Hip Harris Score; mm=millimeters; MRA=Magnetic Resonance Arthrograph; MRI=Magnetic Resonance Imaging; NAHS=Non-arthritis hip score; NPS=Numeric Pain Scale; NR=not reported; OA=osteoarthritis; PCS=physical component score; PT=physical therapy; QOL=quality of life; RCT=randomized controlled trial; ROB=risk of bias; SD=standard deviation; VAS=visual analogue scale

\* The study states 16 studies were found via the Hayes Medical Technology Literature search and 3 more were found by the PubMed search, but they cite many more than that in their evidence base.

## 3 The Evidence

### 3.1 Methods of the Systematic Literature Review

#### 3.1.1 Objectives

The aim of this report is to update the 2011 HTA on Hip Surgery Procedures for the Treatment of Femoroacetabular Impingement Syndrome (FAIS) by systematically reviewing, critically appraising and analyzing new research evidence comparing the safety and efficacy of operative procedures for the treatment of FAI/FAIS compared to non-operative treatments. Information on case definition/diagnostic criteria for FAI/FAIS and validated outcomes measures from the original report were updated as contextual questions.

#### 3.1.2 Contextual Questions

1. Is there updated information published subsequent to the 2011 report regarding a consistent or agreed upon case definition for FAI/FAIS?
2. Are there additional/new validated outcomes measurement instruments used for evaluation of function or pain in FAIS patients in the updated evidence base? Is there information on clinically meaningful improvement for new validated measures used in the evidence base?

#### 3.1.3 Research Key Questions

1. What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with non-operative for FAI/FAIS? Including consideration of short-term ( $\leq 5$  years) intermediate-term ( $> 5$  years to  $< 10$  years) and long-term ( $\geq 10$  years) outcomes.
2. What is the evidence of the safety of hip surgery for FAI/FAIS compared with non-operative treatment?
3. What is the evidence that hip surgery for FAI/FAIS compared with non-operative treatment has differential efficacy or safety in subpopulations (e.g. age, sex, psychological or psychosocial comorbidities, baseline characteristics, deformity type, degree of osteoarthritis or cartilage damage, provider type, payer type)?
4. What is the cost-effectiveness of surgery for FAI/FAIS compared with non-operative treatments in the short and long term?

#### 3.1.4 Inclusion/Exclusion Criteria

Table 5 below for a summary of the inclusion and exclusion criteria. Briefly, included studies met the following requirements with respect to participants, intervention, comparators, outcomes, and study design:

- **Population:** Adults and children undergoing primary/initial treatment for FAI (symptomatic or asymptomatic).
- **Intervention:** Operative treatment for FAI/FAIS (open, arthroscopic or combination).
- **Comparators:** The focus was on non-operative treatment (may include, but not limited to, exercise, rehabilitation and manual therapies, activity modification, NSAIDs, injections, etc.); comparisons of surgical interventions (e.g. open vs. arthroscopic, labral repair vs. labral

debridement) were included for completeness and to provide information regarding safety primarily.

- **Outcomes:**

- Primary Clinical outcomes:**

- Functional outcome (validated patient- and clinician-reported hip scores, validated activities of daily living)
    - Pain (validated measures)
    - Conversion to THA

- Secondary or indirect (intermediate) outcomes:**

- Range of motion (intermediate)
    - Return to work or activity
    - Quality of life
    - Progression to arthritis

- Safety outcomes:**

- Complications/adverse events (peri-operative or longer-term)
    - Revision surgery
    - Additional/subsequent surgery (other than THA)
    - Heterotopic ossification
    - Trochanteric nonunion
    - Failure of labral re-fixation
    - Nerve damage
    - Mortality

- Economic outcomes:**

- Long term and short term comparative cost-effectiveness measures

- **Studies:** The focus was on high quality (low risk of bias) comparative studies (e.g., randomized controlled trials, comparative cohort studies with concurrent controls) for Key Questions 1-3. Case series with  $\geq 40$  patients that were designed specifically to evaluate safety or comprehensive systematic reviews specifically on safety were considered for inclusion. Case series focused on safety with fewer patients were considered for rare outcomes. No restrictions were placed on case series in pediatric or adolescent populations. For Key Question 3, RCTs that stratified on baseline patient characteristics and evaluated effect modification were included. Full, comparative, formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies) were sought for Key Question 4; studies using modeling may be used to determine cost-effectiveness.

Table 5. Summary of inclusion and exclusion criteria.

| Study Component     | Inclusion  | Exclusion  |
|---------------------|--|--|
| <b>Population</b>   | <ul style="list-style-type: none"> <li>Patients undergoing primary/initial treatment for FAI (any age, symptomatic or asymptomatic)</li> </ul>   | <ul style="list-style-type: none"> <li>Congenital hip dysplasia, slipped capital femoral epiphysis, Legg-Calve-Perthes</li> <li>Studies including &lt;80% FAI/FAIS patients</li> <li>Patients presenting for revision surgery</li> </ul>                                     |
| <b>Intervention</b> | <ul style="list-style-type: none"> <li>Operative treatment for FAI/FAIS (open, arthroscopic or combination)</li> </ul>   |  |
| <b>Comparator</b>   | <ul style="list-style-type: none"> <li>Focus:               <ul style="list-style-type: none"> <li>Simulated surgery</li> <li>Non-operative care (may include, but not limited to, exercise, rehabilitation and manual therapies, activity modification, NSAIDs, injections, etc.)</li> </ul> </li> <li>Others: Comparison of surgical interventions (e.g. open vs. arthroscopic)</li> </ul>   | <ul style="list-style-type: none"> <li>Matrix-induced autologous chondrocyte implant (MACI)</li> <li>Autologous matrix-induced chondrogenesis (AMIC)</li> </ul>  |
| <b>Outcomes</b>     | <p><b>Primary</b></p> <ul style="list-style-type: none"> <li>Functional outcome (validated patient- and clinician-reported hip scores, validated activities of daily living)</li> <li>Pain (validated measures)</li> <li>Conversion To THA (“continuing” or “subsequent intervention” that is not THA will be reported in the safety section)</li> </ul> <p><b>Secondary</b></p> <ul style="list-style-type: none"> <li>Range of motion (intermediate)</li> <li>Return to work or activity</li> <li>Quality of life</li> <li>Progression to arthritis</li> </ul> <p><b>Harms/Safety:</b></p> <ul style="list-style-type: none"> <li>Complications/adverse events (peri-operative or longer-term)</li> <li>Revision surgery</li> <li>Heterotopic ossification</li> <li>Trochanteric nonunion</li> <li>Failure of labral re-fixation</li> <li>Nerve damage</li> <li>Mortality</li> </ul> | <ul style="list-style-type: none"> <li>Non-clinical outcomes</li> </ul>  |
| <b>Timing</b>       | <ul style="list-style-type: none"> <li>Short- (≤5 years), intermediate- (&gt;5 years to &lt;10 years) and long-term (≥10 years)</li> </ul>   |  |
| <b>Study Design</b> | <ul style="list-style-type: none"> <li>High quality (low risk of bias) comparative studies (e.g., randomized controlled trials, prospective observational studies) will be considered for questions 1-3. The report will focus on comparative studies.</li> <li>Case series in adults with ≥ 40 patients that are designed specifically to evaluate safety or comprehensive systematic reviews specifically on safety will be considered for inclusion. Case series focused on safety with fewer patients</li> </ul>   | <ul style="list-style-type: none"> <li>Non-clinical studies</li> <li>Case reports</li> <li>Case series in adults designed specifically for safety with &lt;40 patients</li> <li>Case series not specifically designed to evaluate safety</li> <li>Imaging studies</li> </ul> |

| Study Component    | Inclusion   | Exclusion   |
|--------------------|---|---|
|                    | <p>may be considered for rare outcomes. Case series in children will be considered if no comparative studies are available.</p> <ul style="list-style-type: none"> <li>• Full economic studies for question 4</li> </ul>  | <ul style="list-style-type: none"> <li>• Studies comparing simultaneous vs. staged bilateral surgery, differences in suture techniques, iliopsoas lengthening vs. not, traditional vs. extra-articular techniques</li> </ul>  |
| <b>Publication</b> | <ul style="list-style-type: none"> <li>• Studies published in English in peer reviewed journals, technology assessments or publically available FDA reports</li> <li>• Studies published subsequent to the 2011 report</li> <li>• For question 4 full, formal economic analyses (e.g., cost-effectiveness, cost-utility studies) published in English in a peer reviewed journal</li> </ul> | <ul style="list-style-type: none"> <li>• Abstracts, editorials, letters</li> <li>• Duplicate publications of the same study that do not report different outcomes or follow-up times</li> <li>• Single reports from multicenter trials</li> <li>• White papers</li> <li>• Narrative reviews</li> <li>• Articles identified as preliminary reports when full results are published in later versions</li> <li>• Incomplete economic evaluations such as costing studies</li> </ul> |

FAIS = femoroacetabular impingement syndrome; NSAIDs = non-steroidal anti-inflammatory drugs; THA = total hip arthroplasty.

### 3.1.5 Data Sources and Search Strategy

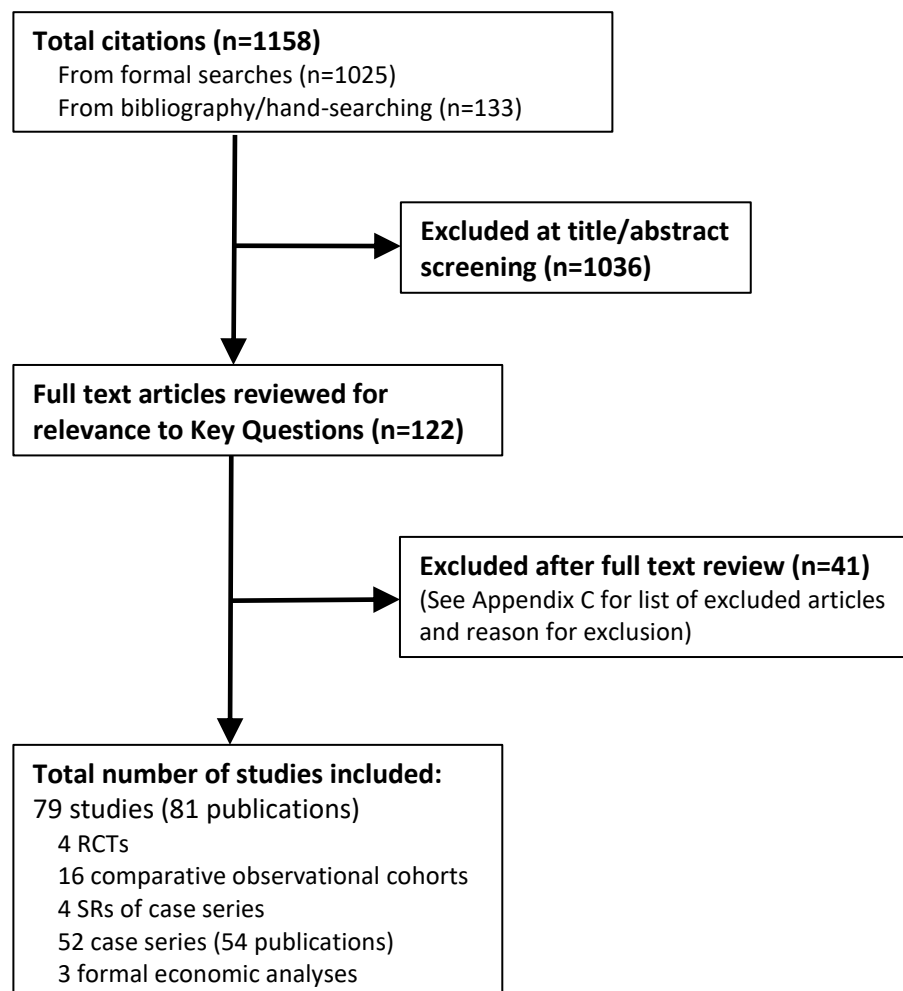
We searched electronic databases from April 1, 2011 to May 14, 2019 to identify publications assessing operative and non-operative treatments for FAIS that had been published since the original report. A formal, structured systematic search of the peer-reviewed literature was performed across a number of databases including PubMed, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews (see Appendix B for full search strategy) to identify relevant peer reviewed literature as well as other sources (ClinicalTrials.gov, ECRI Guidelines Trust, Center for Reviews and Dissemination Database) to identify pertinent clinical guidelines and previously performed assessments. Additional details on the search strategy conducted for clinical guidelines can be found in Appendix H. We also hand searched the reference lists of relevant studies and the bibliographies of systematic reviews. Results from searches done for the two signal update reports done for this topic in 2014 and 2018 were also reviewed for relevant publications.

The clinical studies included in this report were identified using the algorithm shown in Appendix A. The process involves four stages. The first stage of the study selection process consisted of the comprehensive electronic search and bibliography review. We then screened all possible relevant articles using titles and abstracts in stage two. This was done by two individuals independently. Those articles that met a set of *a priori* retrieval criteria were included for full-text review. We excluded conference abstracts, non-English-language articles, duplicate publications that did not report different data or follow-up times, white papers, narrative reviews, preliminary reports, and incomplete economic

evaluations. Any disagreement between screeners that were unresolved resulted in the article being included for the next stage. Stage three involved retrieval of the full text articles remaining. The final stage of the study selection algorithm consisted of the review and selection of those studies using a set of *a priori* inclusion criteria, again, by two independent investigators. Discrepancies were resolved through discussion and if necessary adjudicated by a third investigator. A list of excluded articles along with the reason for exclusion is available in Appendix C.

Consistent with the 2011 report, we focused on comparative studies evaluating operative versus non-operative treatments. Comparative studies that provide a direct comparison of treatments in the same underlying patient population are considered, indirect comparisons of case series were not considered. Studies which compared different surgical approaches or techniques for the treatment of FAIS were included for completeness only and to provide information regarding safety primarily.

**Figure 2. CONSORT diagram – flow of studies**



RCTs = randomized controlled trials; SRs = systematic reviews.

### 3.1.6 Data Extraction

Reviewers extracted the following data from the clinical studies: study design, country, sample size, inclusion and exclusion criteria, study population characteristics, follow-up time, study funding and conflicts of interest, treatment characteristics (e.g., surgical approach and pathologies addressed, components of non-operative care), type of FAI (e.g. cam, pincer, or mixed), study outcomes and adverse events. For economic studies, data related to sources used, economic parameters and perspectives, results, and sensitivity analyses were abstracted. An attempt was made to reconcile conflicting information among multiple reports presenting the same data. Detailed study and patient characteristics and results are available in Appendix F.

### 3.1.7 Quality Assessment: Risk of Bias, QHES evaluation & Overall Strength of Evidence,

The method used by Aggregate Analytics, Inc. (AAI) for assessing the quality of evidence of individual studies as well as the overall strength of evidence (SOE) for each primary outcome from comparative studies are based on criteria and methods established in the Cochrane Handbook for Systematic Reviews of Interventions,<sup>83</sup> precepts outlined by the Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group,<sup>10,68,71,72</sup> and recommendations made by the Agency for Healthcare Research and Quality (AHRQ).<sup>1</sup> Economic studies were evaluated according to The Quality of Health Economic Studies (QHES) instrument developed by Ofman et al. in conjunction with consideration of epidemiologic principles that may impact findings.<sup>152</sup> Systematic reviews included as primary evidence were assessed using the AMSTAR tool.<sup>188,189</sup> Based on these quality criteria, each comparative study chosen for inclusion for a Key Question was given a RoB (or QHES) rating; details of each rating are available in Appendix E.

Standardized, pre-defined guidelines were used to determine the RoB (or QHES) rating for each study included in this assessment. Criteria are detailed in Appendix D. Risk of bias was assessed for RCTs and comparative cohort studies. For comparative cohort studies, loss to follow-up (including differential loss to follow-up) and control for potential confounding are generally the primary sources of bias. Risk of bias was not assessed for case series (single arm studies); all case series were considered to be at high risk of bias. No formal risk of bias assessment was done for studies related to new outcomes measures included in Contextual Question 1. General risk of bias was assessed for systematic reviews and studies of diagnostic accuracy and reliability included for Contextual Question 2.

The SOE for all *primary* health outcomes was assessed by two researchers following the principles for adapting GRADE (Grades of Recommendation Assessment, Development and Evaluation)<sup>10,71,72</sup> as outlined by the Agency for Healthcare Research and Quality (AHRQ).<sup>1</sup> The SOE was based on the highest quality evidence available from comparative studies for a given outcome. In determining the strength of body of evidence regarding a given outcome, the following domains were considered:

- **Risk of bias:** the extent to which the included studies have protection against bias
- **Consistency:** the degree to which the included studies report results that are similar in terms of effect sizes, range and variability.
- **Directness:** describes whether the evidence is directly related to patient health outcomes or comparisons of interventions are direct (head to head).
- **Precision:** describes the level of certainty surrounding the effect estimates.
- **Publication or reporting bias:** is considered when there is concern of selective publishing or selective reporting. This is difficult to assess particularly for nonrandomized studies.

When assessing the SOE for studies performing subgroup analysis, we also considered whether the subgroup analysis was preplanned (*a priori*) and whether a test for homogeneity or interaction was done.

Bodies of evidence consisting of RCTs are initially considered as High SOE. In general, the GRADE and AHRQ methodologies initially consider nonrandomized studies as Low SOE as such studies typically are at higher risk of bias due to lack of randomization and inability of investigators to control for critical confounding factors

The SOE could be downgraded based on the limitations described above. There are also situations where studies (particularly observational studies) could be upgraded if the study had large magnitude of effect (strength of association) or if a dose-response relationship is identified and there are no downgrades for the primary domains listed above and confounding is not a concern. Publication and reporting bias are difficult to assess, particularly with fewer than 10 RCTs and for observational studies.<sup>15,185</sup> Publication bias was unknown in all studies and thus this domain was eliminated from the strength of evidence tables. The final SOE was assigned an overall grade of high, moderate, low, or insufficient, which are defined as follows:

- High - Very confident that effect size estimates lie close to the true effect for this outcome; there are few or no deficiencies in the body of evidence; we believe the findings are stable.
- Moderate – Moderately confident that effect size estimates lie close to the true effect for this outcome; some deficiencies in the body of evidence; we believe the findings are likely to be stable but some doubt remains.
- Low – Limited confidence that effect size estimates lie close to the true effect for this outcome; major or numerous deficiencies in the body of evidence; we believe that additional evidence is needed before concluding that findings are stable or that the estimate is close to the true effect.
- Insufficient – We have no evidence, are unable to estimate an effect or have no confidence in the effect estimate for this outcome; OR no available evidence or the body of evidence has unacceptable efficiencies precluding judgment.

Similar methods for determining the overall quality (strength) of evidence related to economic studies have not been reported, thus the overall strength of evidence for outcomes reported in Key Question 5 was not assessed.

Primary outcomes for this report were function (validated patient- and clinician-reported hip scores), pain (validated measures), conversion to total hip arthroplasty (THA) and adverse events. Strength of evidence (SOE) was assessed for these primary outcomes only. For efficacy, only results for the comparison of operative versus non-operative treatment were assessed for SOE and details of other outcomes are provided in the full report. SOE was not assessed for efficacy or effectiveness outcomes from studies comparing surgery to surgery. For safety, all study types were included in SOE to provide an overall view of surgery-related complications. The results and SOE focus on the highest quality of evidence available. Where RCTs or higher quality evidence were available, these were used to assess the overall strength of evidence. In the absence of RCTs, the highest quality comparative observational studies were used to assess overall SOE. Evidence for effectiveness outcomes consisting of case series alone was considered insufficient as conclusions regarding comparative effectiveness are not possible in the absence of a comparison with alternative treatments in groups of patients from the same underlying



patient populations. For safety, evidence from RCTs, comparative surgery cohorts and case series were all considered in the determination of SOE.

We compared overall conclusions and findings as reported in the previous report with findings in this update to the extent possible based on general qualitative concepts of AHRQ guidance on signal updates for systematic reviews<sup>146</sup>, primarily based on the Ottawa Method.<sup>191,192</sup> Individual studies included in the prior report were not extensively evaluated by AAI. Considerations included:

- Comparison of the general quality of evidence of included comparative effectiveness studies on primary outcomes.
- Comparison of comparators used.
- Assessment of whether new evidence constitutes a major change in the evidence based on existence of opposing findings or major changes in effectiveness short of opposing findings based on the highest quality of evidence available (preferably from high quality systematic reviews or pivotal RCTs). Substantial changes in effect size (e.g.  $\geq 50\%$ ) or changes in statistical significance beyond “borderline” changes (e.g. borderline p-values of 0.4 to 0.06) across studies of comparable quality were considered.
- Assessment of whether new evidence suggests substantial harm wherein risk of harm outweighs benefits.
- Assessment of whether new evidence provides high quality data on clinically important expansion of treatment (e.g. to new subgroups of patients) or clinically important caveat.

### 3.1.8 Analysis

Evidence was summarized qualitatively and quantitatively. In the absence of adjusted effect size estimates, for dichotomous outcomes, crude risk ratios (RR) and 95% confidence intervals (CI) were calculated using either STATA<sup>196</sup> or Rothman Episheet<sup>2</sup>, particularly for harms, if differences between treatments appeared to approach statistical significance for primary outcomes/harms only. For instances with fewer than five observations per cell, exact methods were employed. These effect estimates cannot control for confounding. Where effect estimates that were adjusted for confounding were reported by study authors, they were preferred and reported. Risk differences were not calculated for observational studies as causality cannot be inferred. Meta-analyses were conducted as appropriate in order to summarize data from multiple studies and to obtain more precise and accurate estimates. For continuous variables, differences in mean follow-up scores between treatments were analyzed to determine mean differences as an effect size. Methods for calculating the standard deviations and for imputing missing standard deviations followed the recommendations given in The Cochrane Handbook 7.7. Meta-analyses were conducted using STATA 14.0 (StataCorp, College Station Texas) and Profile Likelihood estimates were reported when available. In the case of non-convergence with Profile Likelihood, the DerSimonian and Laird estimates were reported.

Outcomes are detailed in the evidence tables in the appendices and/or the body of the report. Summary tables for case series are also found in the appendices.

## 4 Results

### 4.1 Contextual Questions

#### 4.1.1 Contextual Question 1

Is there updated information published subsequent to the 2011 report regarding a consistent or agreed upon case definition for FAI/FAIS? What is the evidence of reliability and validity of these case definitions?

**Key points and comparison to 2011 report:**

- The 2016 Warwick International Agreement provides expert consensus on the definition, diagnosis and general treatment options for FAIS. A 2019 consensus-based best practice guideline (Lynch, 2019) provides recommendations for patient evaluation and care before during and following hip arthroplasty for FAI as well as contraindications for arthroplasty to help decrease practice variability through all three stages and builds on the Warwick Agreement. Both documents acknowledge the paucity of high quality prospective and comparative studies on which to base FAIS diagnosis and treatment recommendations.
- The Warwick agreement recommends that diagnosis of femoroacetabular impingement syndrome (FAIS) be based on the triad of patient history, clinic tests for impingement and imaging findings. None of the criteria are pathognomonic for FAIS.
- Subsequent to the 2011, no high quality prospective accuracy studies specific to the diagnosis of FAI/FAIS as a distinct entity (versus FAI with labral tear) based on recommendations in the Warwick Agreement using surgery as a referent were identified. The agreement notes that there are not agreed upon thresholds for imaging diagnosis and that symptoms and clinical tests may not be specific to FAI. Thus, the findings from the 2011 report are generally still valid with regard case definition that includes hip/groin pain and positive impingement test and that evidence is very low (insufficient) for case definition, diagnostic accuracy of specific symptoms, clinical tests and imaging parameters and for the reliability for FAI criteria.

Table 6 below summarizes findings from the 2011 report and this update.

**Table 6. Summary comparison of findings from 2011 and 2019 reports regarding case definition and diagnostic criteria**

| 2011 Report<br>SOE: VERY LOW<br>(Insufficient)   | 2019 Report<br>(SOE: not formally assessed for contextual questions)  |
|--|---|
| <p><b>Case definition</b></p> <ul style="list-style-type: none"> <li>The most consistent case definition of FAI (cam or mixed) as defined by inclusion/exclusion criteria in prospective studies of treatment effectiveness includes hip/groin pain, positive clinical impingement test, and an <math>\alpha</math>-angle &gt;50-55°</li> </ul>  | <ul style="list-style-type: none"> <li><b>2016 Warwick Agreement</b> (expert consensus) defines FAI syndrome (FAIS) as a triad of symptoms, clinical signs and imaging findings. This emphasizes that symptoms, clinical signs and relevant imaging findings must all be present for diagnosis to distinguish it from “asymptomatic FAI” or “radiological FAI” that may be more descriptive of hip morphology versus a clinical disorder. The agreement does not specify thresholds for radiographic parameters.</li> <li><b>Inclusion/exclusion criteria</b> across 4 included RCTs most consistently define FAIS (regardless of morphologic type) based on inclusion/exclusion criteria across the RCTs includes hip or groin pain (assuming that “symptomatic” means pain was present) and positive imaging signs; one RCT noted the absence of agreed upon diagnostic thresholds</li> <li><b>Surgical criteria/indications:</b> Systematic reviews (SR) suggest a lack of consensus and substantial inconsistency regarding specific indications or criteria for surgical treatment of FAIS. A 2019 consensus-based best practice guideline alludes to general selection criteria for surgical candidates and list contraindications to surgery</li> </ul>  |
| <p><b>Diagnostic accuracy and reliability</b></p> <ul style="list-style-type: none"> <li>There is no evidence that the diagnosis of FAI can be obtained from clinical exam in one small study. One clinical test, the impingement sign, had a positive and negative predictive value of 86% and 79% in one study where the prevalence of FAI was 50%; however, in another study, the reliability of the impingement sign was only moderate.</li> <li>Even though the <math>\alpha</math>-angle showed moderate to high interobserver reliability in several studies, it had poor diagnostic value in identifying FAI. Other imaging tests assessing abnormalities of the femur and acetabulum</li> </ul> | <p><b>Diagnostic criteria</b></p> <ul style="list-style-type: none"> <li>High quality prospective studies on the accuracy of diagnostic criteria described in the agreement for FAIS compared with surgical findings were not identified. The evidence base cited in studies identified is of poor quality. None of the criteria described are pathognomonic for FAI or FAIS.</li> <li><b>2016 Warwick Agreement</b> specifies that the triad of symptoms, clinical signs and imaging findings must <b>all</b> be present to diagnose FAIS, but acknowledge that criteria are imprecise and their utility unclear. Consensus recommendations regarding criteria include: <ul style="list-style-type: none"> <li><b>Symptoms:</b> Pain is the primary symptom, usually in hip or groin, but may be reported in lateral hip, anterior thigh, buttock, knee, and lower back, lateral and posterior thigh; typically motion-related or position-related.</li> <li><b>Clinical Tests:</b> FADIR impingement test and impingement testing to reproduce patient’s pain, ROM evaluation (including internal rotation in flexion), FABER distance; should also assess gait, single leg control, muscle tenderness. Image-guided anesthetic injection may help distinguish sources of hip pain.</li> <li><b>Imaging:</b> Morphologic assessment with plain radiographs and to rule out other painful conditions. Cross-sectional imaging (CT, MR, MRA) to further assess morphology and associated labral or chondral pathology (particularly if surgery is considered). The panel did not recommend precise diagnostic values for any common measures to define morphologies in routine clinical practice indicating FAIS is a complex interaction, during motion, between the acetabulum and femoral neck.</li> </ul> </li> <li><b>Accuracy (surgery referent) and reliability of symptoms and clinical tests:</b> <ul style="list-style-type: none"> <li>One systematic review and one retrospective study suggest that impingement tests may be sensitive but not specific for FAIS.</li> </ul> </li> </ul> |

| 2011 Report<br>SOE: VERY LOW<br>(Insufficient)  | 2019 Report<br>(SOE: not formally assessed for contextual questions)   |
|---|--|
| had variable degrees of reliability, but no others were tested for diagnostic validity. | <ul style="list-style-type: none"> <li>○ The retrospective study found that groin pain was the most sensitive (87%) and specific symptom (100%); most combinations of groin pain, impingement tests and FABER distance were sensitive (&gt;90%), but specificity was 0%</li> <li>○ Overall raw agreement for most clinical tests in one institution was substantial (58% to 99%).</li> <li>○ No prospective studies comparing the accuracy of diagnostic hip injection with surgical findings in patients with FAIS were identified</li> <li>● <b>Accuracy of imaging (surgery referent)</b> <ul style="list-style-type: none"> <li>○ Specific to FAI diagnosis, one SR reports sensitivities ranging from 71% to 91% for MRI/MRA and CT across 3 individual studies with specificities ranging from 60% to 89% using various criteria. Sensitivity (66%) and specificity (65%) of ultrasound were low. Pre-test FAIS prevalence was high; all tests impacted posttest probabilities to varying degrees; all but one study was retrospective. Another SR reported that most poor quality studies supported the use of various radiographic parameters for diagnosis of pincer-type FAI, higher quality studies were inconclusive.</li> <li>○ Two SRs suggest that MRI, MRA and CTA are useful for diagnosing labral and chondral pathology in FAIS patients. (See report)</li> </ul> </li> <li>● <b>Reliability of imaging</b> <ul style="list-style-type: none"> <li>○ Across four studies, interrater reliability varied by radiographic parameter, reader specialty and patient population, ranging from slight agreement (<math>\kappa = 0.06</math>) to substantial agreement (<math>\kappa</math> or ICC &gt;0.61); agreement was most frequently fair to moderate across most parameters and diagnostic determination of FAI suggesting that interpretation is subjective.</li> </ul> </li> </ul> |

CT= computed tomography; CTA=computed tomography arthrography; FABER=flexion adduction external rotation test; FADDIR=flexion-adduction-internal rotation impingement test; FAI=Femoroacetabular Impingement; IR=internal rotation; LR=Likelihood ratio; MRA=magnetic resonance arthrogram; MRI=magnetic resonance imaging; NPV=negative predictive value; NR=not reported; SR= systematic review; US=ultrasound; vs.= versus

## Detail

The 2011 report found very low (insufficient) evidence regarding agreed upon criteria for case-definition or specific diagnostic criteria. New evidence does not substantially change over conclusions from the 2011 report or impression of evidence quality. (Table 6) The strategy to answer this question for this update review included a limited literature search with a primary focus on consensus documents, guidelines and high quality systematic reviews containing information published subsequent to the 2011 report. We attempted to focus on the highest quality prospective studies or systematic reviews of such studies that assessed the validity of usual practices for FAI diagnosis using patients' symptoms, clinical exam and imaging results either in combination or individually and focused on visual inspection at the time of surgery as a reference standard for comparison against the test. We sought to summarize the reliability of commonly used clinical tests and imaging. In keeping with the methods from the 2011 report this was combined with the consideration of the inclusion/exclusion criteria of studies comparing operative and nonoperative treatment for FAI/FAIS.

Subsequent to the 2011 report, the publication of a 2016 expert consensus statement, the Warwick International Agreement,<sup>44,65,123</sup> on the diagnosis and management of FAI and 2019 consensus-based

best-practice guideline (BPG) by Lynch, et. al. on arthroscopic treatment of FAI<sup>123</sup> have been published. The Warwick Agreement provides expert consensus on the definition, diagnosis and general treatment options for FAI. The 2019 BPG provides recommendations for patient evaluation before during and following hip arthroplasty for FAI to help decrease practice variability through all three stages of care and builds on the Warwick Agreement.

The Warwick Agreement was developed by an international, multidisciplinary group of clinicians, academics and one patient based on selected systematic reviews and seminal literature (explicit inclusion/exclusion criteria or critical appraisal process not described). A meeting in 2016 led to expert consensus recommendations regarding a definition of FAI syndrome, diagnostic criteria and treatment as well as a description of prognosis, important outcomes and recommendations for future research.

**Warwick Agreement Definition:** FAI syndrome is a motion-related clinical disorder of the hip with a triad of symptoms, clinical signs and imaging findings. It represents symptomatic premature contact between the proximal femur and the acetabulum.

The consensus definition of FAI *syndrome* (FAIS) reflects the panel’s synthesis of previous definitions and descriptions with an emphasis on the importance of patient symptoms to distinguish it from “asymptomatic FAI” or “radiological FAI” that may be more descriptive of hip morphology versus a clinical disorder; individuals with cam or pincer morphology may not be symptomatic.

**Diagnosis:** The Warwick agreement specifies that the triad of symptoms, clinical signs and imaging findings must all be present to diagnose FAIS. The symptoms, clinical signs and imaging features are not pathognomonic for FAIS however. Table 7.

**Table 7. Summary of Warwick Agreement: Diagnosis of FAI syndrome (FAIS)**

| Diagnostic component  | Criterion/Recommendations  | Comments  |
|-----------------------|--|---|
| <b>Symptoms</b>       | <ul style="list-style-type: none"> <li>• Motion or position-related hip or groin pain</li> <li>• Possible pain in back, buttocks or thigh</li> <li>• Restricted ROM, clicking, locking, catching, stiffness, giving way may be described by patients</li> </ul>  | <ul style="list-style-type: none"> <li>• Such pain may also be seen in a number of other conditions which may or may not arise from the hip joint</li> <li>• In most patients seeking treatment for FAIS, symptoms are often severe and limiting</li> </ul>   |
| <b>Clinical signs</b> | <ul style="list-style-type: none"> <li>• FADIR impingement test should be performed.; Positive test: must reproduce patient’s pain/rule out other causes capable of producing similar pain</li> <li>• Restricted ROM (especially internal rotation in flexion)</li> <li>• FABER distance (flexion abduction external rotation)</li> <li>• Abnormal movement patterns around hip, pelvis; examine gait, single leg control</li> </ul> | <ul style="list-style-type: none"> <li>• FADIR impingement test is sensitive, but not very specific (often not positive when FAIS is not the correct diagnosis)</li> <li>• Performance of tests in various environments is unknown</li> <li>• There is substantial variation in how clinicians apply and interpret tests</li> <li>• Abnormal movement patterns may be seen in other conditions</li> <li>• Evidence on ROM is contradictory</li> </ul> |
| <b>Imaging</b>        | <ul style="list-style-type: none"> <li>• AP radiograph of pelvis, lateral (orthogonal) femoral neck view; Identify morphologies, other pain sources</li> </ul>   | <ul style="list-style-type: none"> <li>• No specific diagnostic/radiographic measurements or thresholds recommended for the morphologies</li> </ul>   |

| Diagnostic component | Criterion/Recommendations   | Comments  |
|----------------------|---|---|
|                      | <ul style="list-style-type: none"> <li>• Cam: alpha angle (<math>\alpha</math>-angle)</li> <li>• Pincer: cross-over sign and center edge angle</li> <li>• Cross-sectional imaging (CT, MR) appropriate to further assess hip morphology, associated labral and cartilage lesions</li> <li>• MRI important if surgery is being considered</li> </ul> | <ul style="list-style-type: none"> <li>• Identification of cam or pincer morphology alone does not constitute diagnosis of FAI; a substantial proportion of the general population may have these morphologies</li> <li>• Radiographs moderately sensitive but are specific for identifying typical morphology</li> </ul> |
| <b>Other testing</b> | <ul style="list-style-type: none"> <li>• Diagnostic injection: Image-guided anesthetic injection may help distinguish sources of hip pain</li> </ul>  | <ul style="list-style-type: none"> <li>• Pain relief “supports” diagnosis of FAIS if other criteria are met.</li> <li>• Pain relief may also be seen in patients with labral tear and chondral abnormalities in the absence of FAI</li> </ul>   |

### Validation and diagnostic accuracy

We focused on systematic reviews and studies of diagnostic accuracy/validity providing data on the primary Warwick diagnostic criteria/recommendations, with preferential inclusion of prospective studies if available. The primary reference standard for the diagnosis of FAIS should be arthroscopic or open surgery to verify presence of pathology.

Three systematic reviews evaluating<sup>173,174,183</sup> and presenting diagnostic accuracy data of clinical tests or imaging compared with surgery were identified and summarized; all provided pooled estimates for diagnostic accuracy measures (Table 8). An additional review<sup>175</sup> did not report diagnostic accuracy data and is summarized qualitatively below. Most studies included in the systematic reviews were retrospective and considered at high risk of bias. In addition, one study describing the diagnostic accuracy of patient symptoms and clinical tests alone and in combination versus surgical findings was identified and included even though it was retrospective. Table 8. Studies reporting on quantification of intra-articular damage were excluded as they are not specific to the diagnosis of FAI.

#### *Patient symptoms and clinical tests*

One good quality (low risk of bias) systematic review reported<sup>173</sup> on the accuracy of FADDIR and flexion-internal rotation (flexion IR) tests compared with surgery. Included studies were mostly retrospective and all were considered at high risk of bias. Sensitivity was high for both tests (99%, 95% CI 98%, 100% for FADDIR, 96%, 95%CI 81%, 99% flexion IR) but specificity was poor (5%, 95% CI 1%, 18% and 25%, 95%CI 1%, 81% respectively) compared with surgery and posttest probabilities were similar to pre-test probabilities. Populations of included studies were of patients with high disease probability.

One retrospective study at high risk of bias reported on the diagnostic accuracy of various patient symptoms<sup>203</sup> and clinical tests alone and in combination compared with surgery. Patients with at least one imaging finding correlated with intra-articular hip pathology but no signs of hip OA and who agreed to arthroscopy were included. All but one had intra-articular hip pathology (98.7%) and most (76%) were diagnosed as having FAI with concomitant labral pathology. (Table 8) With the exception of groin pain as the primary pain location (87%, 95%CI 77%, 93% sensitivity), all other patient history/symptoms had

very poor sensitivity (22% to 57%). Specificity was 100% for all symptoms/history features except for perceived stiffness. With regard to physical tests, the highest sensitivities were reported for AIT (91%, 95%CI 82%, 96%), FABER (81%, 95%CI 70%, 88%) and the Fitzgerald test (specific to labral tear, 72%, 95%CI 61%, 82%); specificities for AIT and FABER were 0% (95%CI 0% to 95%) and 33% (95%CI 2%, 97%) for the Fitzgerald Test. All combinations of patient history/symptoms and physical tests yielded high sensitivity (>90%), but still resulted in low specificity (0%-33%).

### *Imaging*

No new prospective diagnostic accuracy studies specific to the diagnosis of FAI or FAIS comparing specific radiographic parameters with surgery were identified.

Two systematic reviews of diagnostic accuracy primarily assessing the use of MRI or MRA were identified<sup>174,183</sup> and summarized in Table 8. Most of the included studies focused on the identification of labral and/or chondral pathology in conjunction with FAIS, not on the specific diagnosis of FAI morphology or FAIS. The extent to which some of these imaging modalities are routinely used (e.g. CTA, MRA) or widely available (e.g. 3.0T direct MRI) is unclear.

One systematic review<sup>174</sup> at low risk of bias presented limited data specifically on imaging diagnosis of FAI, with more studies evaluating labral tear. Inclusion criteria for the review were hip pain suspected to be related to FAI or ALT (labral tear), at least one imaging sign and/or intra-articular injection for FAI/LT diagnosis, use of surgery as a gold standard and score of 10 or higher on the QUADA tool. Across included studies, populations were highly selected and had high pre-test probabilities of FAI with or without labral tear. Authors conclude that these factors, in conjunction with the wide confidence intervals limit the generalizability of the findings. They identified four studies describing imaging specific to the diagnosis of FAIS<sup>174</sup>, but only one was considered prospective.<sup>208</sup> The focus of that study was on use of sequential CT imaging in various hip positions (e.g. extension, flexion) to identify impingement location to facilitate surgical management and did not provide diagnostic accuracy for FAI diagnosis. Of the other three studies, two used MRA (1.5 T and 3.0T) and the last used a cross-table lateral view. All studies used different FAI definitions and data on sensitivity and specificity were not presented for any of the four FAI diagnostic studies. Across the four studies, pre-test FAI probability was high and calculated to be 74% (95% CI 51%, 81%). Based on authors' calculations for each of the imaging methods, positive test results increased the probability of a true positive and negative test results increased the probability of no FAI in these highly selected patient populations. (Table 8)

The same systematic review included 22 studies evaluating diagnosis of acetabular labral tear (ALT) in conjunction with FAI with magnetic resonance imaging (MRI), magnetic resonance arthrography (MRA), computed tomography arthrography (CTA) and ultrasound. All but four studies were retrospective. Across studies, again the pre-test probability of ALT was high (81% (95%CI 72%, 91%). CTA appeared to have the strongest diagnostic accuracy. MRA, both 1.5T and 3.0T, appeared to have good sensitive and specificity for diagnosis of ALT with 1.5T conventional MRI and ultrasound being least sensitive and specific (Table 8). Across studies, authors conclude that for diagnosis of ALT, positive findings increased the probability that a tear was present from a minimal to small degree for MRI, MRA and ultrasound and to a moderate degree for CTA. Negative findings on MRI and ultrasound decreased the probability of ALT to only a minimal degree, a small to moderate degree for MRA and to a moderate degree for CTA.

Another systematic review<sup>183</sup> at moderately low risk of bias evaluated the diagnostic accuracy of conventional MRI, direct MRA and indirect MRA compared with surgery (open or arthroscopic) to detect labral and chondral pathology in persons with FAIS. All 12 studies were at high risk of bias related to patient selection and surgery was done with knowledge of imaging findings. In general, the findings from this review for conventional MRI and MRA are consistent with those in the Reiman 2017 review: MRA appears to do well for the diagnosis of labral pathology. In the Saied review, conventional and direct MRI were both sensitive for the detection of labral and chondral pathology with direct MRA being somewhat less specific. Pooled results suggest that direct MRA may have the best accuracy for detection of both labral and chondral pathology compared with conventional MRI. (Table 8).

The fourth systematic review<sup>175</sup> evaluated evidence for diagnosis of pincer-type FAI for imaging modalities and radiographic signs and reported only qualitative analyses. Diagnostic accuracy data (e.g. sensitivity, specificity) were not provided. Of 44 included studies, only six (14%) were of consecutive patients with application of a universally applied “gold” standard of surgical information (Level 2 diagnostic study) implying high risk of bias (Level 3 or 4) for the majority of studies and only five studies were prospective. Plain AP pelvis radiographs were most commonly used (33/44 studies) but most studies didn’t specify whether they were taken in a supine or standing position. While most poor quality studies (Level 4) supported the use of the crossover sign, posterior wall sign, ischial spine sign, central-edge angle for diagnosis of pincer-type FAI, higher quality studies (Level 2, 3) were inconclusive. Authors conclude that there is not strong evidence to support the use of any specific radiographic marker for diagnosis of pincer-type FAI.

#### *Diagnostic injections:*

No prospective studies comparing the accuracy of diagnostic hip injection with surgical findings were identified. One of the imaging systematic reviews<sup>174</sup> described the impact of positive and negative results for diagnostic injection from an older (2004) single study reporting<sup>22</sup> on diagnostic injections. While a positive response to injection did little to shift the post-test probability of pathology (from 80% to 83%), a negative result shifted the posttest probability 21% (from 20% to 41%).



Table 8. Summary of diagnostic accuracy evidence

| Author (year)<br>Search<br>Quality                                | Evidence<br>Base<br>Available<br>(quality)  | Reference<br>Standard(s) | Diagnosis<br>Tests<br>(studies, N)   | Sensitivity<br>% (95%CI)                                    | Specificity<br>% (95%CI)                               | Other Outcomes<br>(95%CI)   | Comments and<br>Authors' Primary<br>Conclusions   |
|---|---|--------------------------|--|---|--|---|---|
| <b>SR: Clinical tests</b>   |   |                          |  |   |  |   |   |
| Reiman<br>(2015)<br><br>Search<br><br>AMSTAR<br>score: Low<br>ROB | 9 studies of<br>FAI/ALT in<br>pooled<br>analysis<br>reported<br>here; 2 were<br>prospective;<br>all high risk of<br>bias based<br>on QUADAS | MRA<br>Surgery           | <b>Pooled results</b><br>(#studies, #<br>patients, referent)<br>a. FADDIR (n= 4,<br>N=188, MRA)<br>b. FADDIR (n=4,<br>N=319, surgery)<br>c. Flexion IR<br>(n=2,N=27,<br>surgery) | a. 94%(90%, 97%)<br>b. 99% (98%, 100%)<br>c. 96% (81%, 99%) | a. 9% (2%, 23%)<br>b. 5% (1%, 18%)<br>c. 25% (1%, 81%) | a. Pretest= 84%,<br>posttest=83%; PPV<br>83% (77%, 89%);<br>LR+1.02(0.96,<br>1.08);LR-, 0.45 (0.19,<br>1.09);<br>b. Pretest and<br>posttest=90%; PPV<br>90% (89%, 90%); LR+<br>1.04 (0.97, 1.1); LR-,<br>0.14 (0.02, 0.9)<br>c. Pretest=87%,<br>posttest=90%;PPV<br>90%(73%, 98%);LR+<br>1.28(0.72, 2.27); LR-,<br>0.15(0.01, 1.99) | <b>Conclusion:</b> Due to<br>poor study quality and<br>biased sampling of<br>patients with high<br>disease probability,<br>tests do not provide<br>significant value in<br>altering probability of<br>disease. FADDIR and<br>Flex-IR are supported<br>by data as valuable<br>screening tests.<br>However, data<br>supporting them are<br>from retrospective<br>studies at high risk of<br>bias. Little difference<br>in pre vs. post-test<br>probabilities. |
| <b>SR: Radiograph or other Imaging</b>                            |   |                          |  |   |  |   |   |
| Reiman<br>(2017)<br><br>Search<br><br>AMSTAR<br>score: Low<br>ROB | 25 imaging<br>studies for<br>FAI/ALT*<br><br>FAI Only (4<br>studies);   | Surgery                  | <b>FAI diagnosis: #<br/>studies (N)</b><br>a. Cross-table<br>lateral Xray; 1<br>(N=84)<br>b. 1.5T MRA;<br>1(N=41)  | <b>FAI diagnosis NR</b>                                     | <b>FAI diagnosis NR</b>                                | <b>FAI diagnosis:</b><br>Pre-test FAI probability<br>(4 studies) 74% (95%CI<br>51%-91%)<br>a. + test ↑ probability<br>of FAI dx 41% (from<br>46% to 87%; (-) test<br>↑ odds of not  | <b>Conclusions:</b><br>Populations had high<br>pre-test probabilities<br>(high prevalence). For<br>ALT, + findings ↑<br>probability of tear a<br>minimal to small<br>degree for MRI, MRA,   |

| Author (year)<br>Search<br>Quality | Evidence<br>Base<br>Available<br>(quality)            | Reference<br>Standard(s) | Diagnosis<br>Tests<br>(studies, N)  | Sensitivity<br>% (95%CI)   | Specificity<br>% (95%CI)   | Other Outcomes<br>(95%CI)  | Comments and<br>Authors' Primary<br>Conclusions   |
|------------------------------------|---|--------------------------|---|--|--|--|---|
|                                    | ALT (22<br>studies); only<br>4 prospective<br>studies |                          | c. 3.0 T MRA;<br>1(N=36)<br>d. 4D-CT; 1(N=30)<br><br><b>Pooled results; ALT<br/>diagnosis; #<br/>studies (N)</b><br>a. 1.5T MRI; 4<br>(n=181)<br>b. 3.0T MRI; 2<br>(n=133)<br>c. 1.5T MRA; 12<br>(n=517)<br>d. 3.0T MRA; 4<br>(n=185)<br>e. CTA; 4 (n=125)<br>f. US; 2 (n=50) | <b>Pooled results; ALT<br/>diagnosis</b><br>a. 71% (62%, 78%)<br>b. 72% (62%, 80%)<br>c. 88% (85%, 92%)<br>d. 89% (82%, 95%)<br>e. 91% (83%, 96%)<br>f. 66% (48%, 81%) | <b>Pooled results; ALT<br/>diagnosis</b><br>a. 60% (35%, 82%)<br>b. 76% (57%, 89%)<br>c. 59% (50%, 68%)<br>d. 79% (61%, 92%)<br>e. 89% (74%, 97%)<br>f. 65% (38%, 86%) | having FAI 35%<br>(from 54% to 89%)<br>b. + test, probability of<br>true + ↑ 15% (from<br>83% to 98%); (-) test<br>probability of true (-<br>) ↑ 64% (from 17% to<br>81%)<br>c. + test, probability of<br>true + ↑ 6% (from<br>72% to 78%); (-) test<br>probability of true (-<br>) ↑ 47% (from 28% to<br>75%)<br>d. anterior<br>impingement, + test,<br>probability of true +<br>↑ 8% (from 90% to<br>98%); (-) test<br>probability of true (-<br>) ↑ 56% (from 10% to<br>75%); for posterior<br>impingement + test,<br>probability of true +<br>↑ 20 (from 70% to<br>98%) and (-) test<br>probability of true (-<br>) ↑ 61% (from 30% to<br>91%)<br><br><b>ALT Pooled results;</b><br>Pre-test probability<br>81% (95%CI 72%, 91%) | US, moderate degree<br>for CT); negative<br>findings ↓ probability<br>of ALT to minimal<br>degree with MRI, US,<br>small to moderate<br>degree for MRA and<br>moderate for CTA.<br>Generalizability<br>limited by high pre-<br>test prevalence, wide<br>CIs and study selection |

| Author (year)<br>Search<br>Quality | Evidence<br>Base<br>Available<br>(quality) | Reference<br>Standard(s) | Diagnosis<br>Tests<br>(studies, N) | Sensitivity<br>% (95%CI) | Specificity<br>% (95%CI) | Other Outcomes<br>(95%CI)   | Comments and<br>Authors' Primary<br>Conclusions |
|------------------------------------|--|--------------------------|------------------------------------|--------------------------|--------------------------|---|---|
|                                    |  |                          |                                    |                          |                          | <p><b>ALT diagnosis; pre to posttest probability for + test (95%CI)</b></p> <p>a. Pre=90%, Post=95% (88% to 98%)</p> <p>b. Pre=76%, Post= 90% (81% to 95%)</p> <p>e. Pre=76%, Post= 88% (85% to 90%)</p> <p>f. Pre=75%, Post=93% (85% to 97%)</p> <p>g. Pre=70%, Post=95% (87% to 98%)</p> <p>h. Pre=67%, Post= 79% (60% to 92%)</p> <p><b>Pooled results; ALT diagnosis; pre to posttest probability for (-) test (95%CI)</b></p> <p>a. Pre=10%,Post=19% (10% to 31%)</p> <p>b. Pre=24%,Post= 46% (32% to 60%)</p> <p>c. Pre=24%, Post= 63% (54% to 71%)</p> <p>d. Pre=75%, Post=93% (85% to 97%)</p> <p>e. Pre=30%, Post=81% (65% to 91%)</p> <p>f. Pre=23%, Post= 48% (27% to 68%)</p> |   |

| Author (year)<br>Search<br>Quality                                      | Evidence<br>Base<br>Available<br>(quality)   | Reference<br>Standard(s) | Diagnosis<br>Tests<br>(studies, N)  | Sensitivity<br>% (95%CI)   | Specificity<br>% (95%CI)  | Other Outcomes<br>(95%CI)   | Comments and<br>Authors' Primary<br>Conclusions   |
|---|--|--------------------------|---|--|---|---|---|
|   |  |                          |   |  |   | <b>LR+/LR-</b><br>a. 1.18 (0.69-2.1)/<br>0.78 (0.43-1.4)<br>b. 2.03 (0.91-4.5)/<br>0.51 (0.35-0.73)<br>c. 1.91 (1.2-3.2)/<br>0.20 (0.11-0.35)<br>d. 3.21 (1.5-6.9)/<br>0.15 (0.07-0.31)<br>e. 6.28 (2.78-14.21)/<br>0.11 (0.06-0.21)<br>f. 1.86 (0.94-3.7)/<br>0.56 (0.32-0.99) |   |
| Saied (2017)<br>SR<br>Search<br><br>AMSTAR<br>score:<br>Moderate<br>ROB | 12 studies for<br>meta-<br>analyses;<br>Most at high<br>risk of bias<br>related to<br>subject<br>inclusion;<br>most<br>retrospective | Surgery                  | Chondral and labral<br>lesions in FAI<br>a. Conventional<br>MRI; Labral, 3<br>(n=90), chondral,<br>3 (n=90)<br>b. Direct MRA<br>Labral, 8 (N=NR),<br>chondral, 8<br>(N=NR)<br>c. Indirect MRA<br>Labral, 2 (N=NR),<br>chondral, 2<br>(N=NR) | a. Labral 86% (76%,<br>94%); Chondral<br>76% (65%, 85%)<br>b. Labral 91% (88%,<br>94%); Chondral<br>75% (69%, 80%)<br>c. Labral not<br>calculable;<br>Chondral 72%<br>(47%, 90%) | a. Labral 83% (36%,<br>100%); Chondral<br>72% (57%, 84%)<br>b. Labral 58%<br>(48%, 68%);<br>Chondral 87%<br>(79%, 92%)<br>c. Labral not<br>calculable;<br>Chondral 92%<br>(62%, 100%) |   | Author conclusions:<br>MRI, dMRA and iMRA<br>are useful for<br>diagnosis of labral and<br>chondral pathology in<br>FAI with superior<br>accuracy for dMRA.<br>Accuracy was lower<br>for the detection of<br>chondral lesions<br>compared to that for<br>labral lesions. |

| Author (year)<br>Search<br>Quality                         | Evidence<br>Base<br>Available<br>(quality)   | Reference<br>Standard(s) | Diagnosis<br>Tests<br>(studies, N)  | Sensitivity<br>% (95%CI)  | Specificity<br>% (95%CI)   | Other Outcomes<br>(95%CI)   | Comments and<br>Authors' Primary<br>Conclusions  |
|--|--|--------------------------|---|---|--|---|--|
| <b>Individual study: History and clinical tests</b>        |  |                          |   |   |  |   |  |
| Tijssen<br>(2017)<br>Retrospective<br>High Risk of<br>Bias | N= 77 (79<br>hips); Intra-<br>articular<br>pathology<br>n=78;<br>Patients with<br>pre-op PT<br>screening<br>scheduled for<br>arthroplasty<br><br>Age 37 years<br>(SD 10.9) <br>groin pain<br>87%<br>Sports 82%<br>Symptom<br>duration 3.2<br>years<br><br>89% (70/79)<br>hips had<br>labral<br>pathology | Surgery<br>(arthroscopy) | <b>FAI and/or labral<br/>tear</b><br><br><b>Patient history</b><br>a. Groin 1° pain<br>location<br>b. Clicking<br>c. Giving way<br>d. Locking<br>e. Perceived<br>stiffness<br>f. Perceived<br>mobility<br>restriction<br><br><b>Physical Tests</b><br>a. AIT<br>b. FABER<br>c. RSLR<br>d. Scourt†<br>e. Fitzgerald test†<br><br><b>Combined<br/>parameters</b><br>a. Groin pain +<br>AIT + FABER +<br>Fitzgerald†<br>b. Groin pain +<br>AIT + FABER | <b>Patient history</b><br>a. 87% (77%, 93%)<br>b. 57% (45%, 68%)<br>c. 28% (19%, 40%)<br>d. 26% (17%, 37%)<br>e. 40% (29%, 52%)<br>f. 22% (14%, 33%)<br><br><b>Physical Tests</b><br>a. 91% (82%, 96%)<br>b. 81% (70%, 88%)<br>c. 21% (13%, 32%)<br>d. 5% (35%, 65%)<br>e. 72% (61%, 82%)<br><br><b>Combined<br/>parameters</b><br>a. 97% (90%, 100%)<br>b. 97% (90%, 100%)<br>c. 95% (86%, 98%)<br>d. 97% (90%, 100%)<br>e. 97% (90%, 100%)<br>f. 91% (81%, 96%)<br>g. 97% (90%, 100%)<br>h. 97% (90%, 100%)<br>i. 93% (85%, 98%)<br>j. 91% (81%, 96%) | <b>Patient history</b><br>a. 100% (5%,<br>100%)<br>b. 100% (31%,<br>100%)<br>c. 100% (5%,<br>100%)<br>d. 100% (5%, 1%)<br>e. 0% (0%, 95%)<br>f. 100% (5%,<br>100%)<br><br><b>Physical Tests</b><br>a. 0% (0%, 95%)<br>b. 0% (0%, 95%)<br>c. 0% (0%, 95%)<br>d. Infinity<br>e. 33% (2%, 87%)<br><br><b>Combined<br/>parameters</b><br>a. 0% (0%, 69%)<br>b. 0% (0%, 95%)<br>c. 0% (0%, 69%)<br>d. 0% (0%, 69%)<br>e. 0% (0%, 95%)<br>f. 33% (2%, 87%)<br>g. 0% (0%, 69%)<br>h. 0% (0%, 95%)<br>i. 0% (0%, 69%)<br>j. 0% (0%, 69%) | <b>LR+/LR-<br/>Patient history</b><br>a. Infinity/<br>0.13 (0.07, 0.23)<br>b. Infinity/<br>0.43 (0.34, 0.56)<br>c. Infinity/<br>0.72 (0.62, 0.83)<br>d. Infinity/<br>0.74 (0.65, 0.85)<br>e. 0.40 (0.3, 0.52)/<br>Infinity<br>f. Infinity/<br>0.78 (0.7, 0.88)<br><br><b>Physical Tests</b><br>a. 0.91 (0.85, 0.98)/<br>Infinity<br>b. 0.81 (0.72, 0.9)/<br>Infinity<br>c. 0.21 (0.14, 0.33)/<br>Infinity<br>d. Infinity/Infinity<br>e. 1.08 (0.48, 2.45)/<br>0.83 (0.16, 4.41)<br><br><b>Combined parameters</b><br>a. 0.97 (0.94–1.01)/<br>Infinity<br>b. 0.97 (0.94–1.01)/<br>Infinity | Author conclusions: In<br>clinical practice<br>absence of groin as<br>main location of pain<br>combined with a<br>negative FABER test or<br>the combination of a<br>negative AIT and a<br>negative FABER test<br>are suggested to rule<br>out the diagnosis of<br>symptomatic FAI<br>and/or labral<br>pathology.<br><br>This was a small<br>retrospective study in<br>a highly selected<br>population.<br>Sensitivities were high<br>for many physical<br>tests, but confidence<br>intervals were often<br>wide. Sensitivities<br>were also high for<br>combined parameters.<br>For both physical tests<br>and combined<br>parameters the<br>specificity was 0% for<br>most. |

| Author (year)<br>Search<br>Quality | Evidence<br>Base<br>Available<br>(quality) | Reference<br>Standard(s) | Diagnosis<br>Tests<br>(studies, N)  | Sensitivity<br>% (95%CI) | Specificity<br>% (95%CI) | Other Outcomes<br>(95%CI)  | Comments and<br>Authors' Primary<br>Conclusions |
|------------------------------------|--|--------------------------|---|--------------------------|--------------------------|--|---|
|                                    |  |                          | c. Groin pain +<br>AIT +<br>Fitzgerald†<br>d. Groin pain +<br>FABER +<br>Fitzgerald†<br>e. Groin pain +<br>FABER<br>f. Groin pain +<br>Fitzgerald†<br>g. AIT + FABER +<br>Fitzgerald†<br>h. AIT + FABER<br>i. AIT +<br>Fitzgerald†<br>j. FABER +<br>Fitzgerald† |                          |                          | c. 0.95 (0.9–1.0)/<br>Infinity<br>d. 0.97 (0.94–1.01)/<br>Infinity<br>e. 0.97 (0.94–1.01)/<br>Infinity<br>f. 1.36 (0.61–3.04)/<br>0.28 (0.04–2.07)<br>g. 0.97 (0.94–1.01)/<br>Infinity<br>h. 0.97 (0.94–1.01)/<br>Infinity<br>i. 0.93 (0.88–0.99)/<br>Infinity<br>j. 0.91 (0.85–0.98)/<br>Infinity |   |

AIT=Anterior Impingement test; ALT=Acetabular Labral Tear; ALT = acetabular labral tear; AMSTAR=A Measurement Tool to Assess Systematic Reviews; CI=confidence interval; CTA=computed tomography arthrography; FABER=flexion adduction external rotation test; FADDIR=flexion-adduction-internal rotation impingement test; FAI=Femoroacetabular Impingement; IR=internal rotation; LR=Likelihood ratio; MRA=magnetic resonance arthrogram; MRI=magnetic resonance imaging; NPV=negative predictive value; NR=not reported; PPV=positive predictive value; PT=physical therapy; ROB=risk of bias; RSLR=resisted straight leg test; SD=standard deviation; US=ultrasound; vs.= versus

\*For inclusions study patient must have suspected hip pain related to FAI/ALT, have had ≥1 imaging and/or intraarticular injection for diagnosis and QUADAS score of ≥10.

†Test only applicable in labral pathology.

## Reliability

Summarization of reliability studies focused on suggested Warwick diagnostic criteria/recommendations that are likely most common in clinical practice. Studies of new techniques (e.g. 3D prediction models, computer assisted assessment) or new classifications for determining FAI, OA, were excluded as were studies of the reliability of labral tear assessment and categorization. Based on Landis and Koch<sup>109</sup> categories, kappa values between 0.01-0.2 represents slight agreement; 0.21-0.40 fair; 0.41-0.60 moderate and 0.61-0.80 represents substantial agreement. Similar ranges applied to the interpretation of interclass correlation coefficients.

### *Patient symptoms and clinical tests*

One study evaluated interrater reliability for various clinical hip tests used in diagnosis of FAIS.<sup>166</sup> (Table 9) but reported only raw overall agreement; the sample size was small (n=12 patients, 24 hips). Seven patients (11 hips) reported hip pain in at least one hip in the previous 12 months. Clinicians were blinded to patient history. Raw interrater reliability across two rheumatologists and seven physiotherapists was generally high (<60%) but authors did not account for the role of chance agreement (e.g. use of kappa).

**Table 9. Summary of inter-rater reliability coefficients for hip tests commonly utilized in diagnosing FAIS**

|   | Ratzlaff 2013 (ROB = moderately low)   |
|---|--|
| <b>Patient Population<br/>(N, normal, FAI, dysplasia)</b> | N = 12 subjects; some with symptomatic FAI-confirmed hips and some with pain-free healthy hips.  |
| <b>Test Condition<br/>(#observers, other)</b>             | 2 rheumatologist and 7 physiotherapists with varying degrees of experience in musculoskeletal practice and examination of the hip joint for FAI. |
| Examination   | Overall raw agreement (95%CI)  |
| Log roll test, pain                                       | 0.99 (0.96–1.00)   |
| FABER test, pain  | 0.84 (0.75–0.95)   |
| Hip IR, pain  | 0.84 (0.74–0.96)   |
| Posterior impingement test                                | 0.81 (0.69–0.94)   |
| Flexion 120°/adduction/IR pain                            | 0.78 (0.68–0.92)   |
| Anterior impingement test                                 | 0.76 (0.66–0.91)   |
| Flexion 90°/adduction/compression pain                    | 0.70 (0.59–0.87)   |
| Flexion 120°/adduction/compression pain                   | 0.69 (0.61–0.85)   |
| Flexion 90°/adduction/IR ROM                              | 0.67 (0.60–0.83)   |
| Flexion 120°/adduction/IR ROM                             | 0.58 (0.52–0.75)   |

95%CI=95% confidence interval; FABER=flexion, abduction, and external rotation; IR=internal rotation; ER=external rotation; ROB=Risk of Bias; ROM=range of motion.

## Imaging

Four studies published subsequent to the 2011 HTA reported on interrater reliability for various FAI imaging parameters. (Table 10) One was rated as moderately low risk of bias<sup>8</sup>, one as low<sup>201</sup> and one as high risk of bias<sup>124</sup>. One study was in adolescents was at moderately high risk of bias.<sup>87</sup> Two studies (moderately low risk of bias) also reported on intra-rater reliability related to imaging.<sup>8,167</sup>

Across the reliability studies, interrater reliability varied by radiographic parameter, reader specialty and patient population. Reliability ranged from slight agreement ( $\kappa = 0.06$ ) to substantial agreement ( $\kappa$  or ICC  $> 0.61$ ), although agreement was most frequently fair to moderate across a high proportion of the parameters evaluated suggesting that interpretation is subjective. Table 10.

One study (Ayeni) evaluated intra-rater reliability for radiologists and surgeons separately on 51 AP and frog-leg radiographs.<sup>8</sup> Readers evaluated common radiographic parameter reported for identification of FAI morphology as well as providing and determination for whether findings were consistent with FAI, the specific morphology (e.g. cam, pincer) and on the adequacy of films. Films were read on two occasions 4 weeks apart. While there was general consistency within each provider group, there was variability between the two provider groups which was substantial for some parameters. There was also variability with specialty group between 1<sup>st</sup> and 2<sup>nd</sup> readings that also seemed dependent on the radiographic parameter. Interrater reliability for consensus ratings across the two groups showed a lower level of agreement and agreement was most generally fair to moderate for most parameters assessed. Table 11. Of note, consensus agreement was only fair for determination that findings were consistent with FAI, pistol-grip deformity was well as for pincer lesions and some characteristics used to evaluate them (e.g. posterior wall sign, ischial spine sign) while there was more often moderate to substantial agreement for cam morphology, alpha angle and size of alpha angle. Agreement on what a may be the best radiographic views was slight as rated by surgeons but fair to moderate when rated by radiologists.

In another study (high risk of bias), a group of 39 of orthopedic surgeons with varying levels of experience with FAI and hip preservation ranging from trainees to high volume hip preservation surgeons were asked to evaluate radiographs from 10 patients as part of a professional meeting.<sup>124</sup> Patient history and clinical findings were also provided. After making initial diagnoses and parameter assessments, additional information from CT and/or MR was provided and participants again provided final diagnoses and assessments. Agreement across experience levels was fair for all factors for initial diagnoses except for the crossover sign which was moderate agreement which was largely influenced by the substantial agreement among trainee participants; the addition of CT and/or MR findings didn't impact the overall agreement. Agreement within the high-volume surgeon group was generally fair to moderate (except for slight agreement on posterior wall sign) and changed from fair to substantial for determining type of FAI and dysplasia after consideration of additional information from CT or MRI. There was only fair overall agreement regarding Tönnis angle and grade. Table 11.

A third study at low risk of bias included 53 patients with FAIS (based on clinical and imaging criteria) and cam morphology and 53 asymptomatic volunteers.<sup>201</sup> The study's purpose was to compare alpha angle measurements between the different groups and develop potential threshold values. Two musculoskeletal radiologists, blinded to clinical data, evaluated alpha angle determined in five different planes from 1.5T MRI images. Authors report substantial overlap in alpha angle between FAIS patients



and volunteers. Interrater reliability was moderate to substantial across all planes in FAIS and ranged from fair to substantial in asymptomatic volunteers depending on the plane.

One retrospective study in 177 adolescents at moderately high risk of bias was identified.<sup>87</sup> The primary purpose was to evaluate differences in hip morphology between male and female patients undergoing hip arthroscopy. Alpha angle, lateral center-edge angle and Tönnis angle were measured from preoperative plain radiographs and MRI scans using published criteria. Authors do not report that the three raters, which included a musculoskeletal radiologist, an orthopedic surgery resident and a fourth year medical student were blinded to each other's conclusions. For alpha angle there was moderate agreement for measurement based on radiographs but substantial agreement when it was based on MRI. For lateral central-edge angle there was substantial agreement for measurements taken from both imaging modalities. There was also substantial agreement regarding Tönnis angle evaluated via radiographs. Authors do not provide reliability information based on sex, but report that there are distinct differences between males and females on both pre-operative imaging and surgical inspection. Male patients and greater mean alpha angle (which authors state as severe cam-type deformity) and were more likely to have evidence of chondral damage at the time of surgery compared with female patients.

One of the systematic reviews reporting on diagnostic accuracy<sup>174</sup> for labral tear also reported intra and intra-rater reliability for included studies. All studies were read by musculoskeletal radiologists. Only one study was prospective. Across six studies contained in that review and published since the 2011 report, interrater reliability for diagnosis of labral tear was substantial for 3.0T MRI (2 studies  $\kappa$  range 0.65 to 0.88), 3.0T MRA (2 studies  $\kappa$  range 0.81 to 0.95) and CTA (2 studies  $\kappa$  range 0.64 to 0.92). For 1.5T MRI, agreement ranged from fair to moderate (2 studies,  $\kappa$  range 0.27 to 0.58) and from slight to moderate for ultrasound (1 study  $\kappa$  range 0.05 to 0.51). Three of the included studies reported on intra-rater reliability for diagnosis of labral tear using different modalities. While reliability was substantial for 1.5T MRA (0.95 (95%CI 0.87, 1.0) and for CTA (ICC 0.92-1.0), it was only moderated for ultrasound ( $\kappa$  = 0.44-0.56).

**Table 10. Summary of inter-rater reliability coefficients for imaging commonly described in diagnosing FAIS**

|   | <b>Ayeni 2014<br/>(ROB = Moderately Low)</b>  | <b>Malviya 2016<br/>(ROB = High)</b>  | <b>Sutter 2012<br/>(ROB = Low)</b>  | <b>Hooper 2016<br/>(ROB = Moderately High)</b>   |
|---|---|---|---|--|
| <b>Patient Population<br/>(N, normal, FAI,<br/>dysplasia)</b> | N = 51 consecutive symptomatic patients with unilateral hip pain and broad spectrum of FAI pathologies  | N= 10 patients;   | N= 106; n=53 Cam FAI w/symptoms; n=53 asymptomatic volunteers                                 | N=177 adolescents undergoing arthroscopy   |
| <b>Test Condition<br/>(#observers, other)</b>                 | 3 orthopedic surgeons, 3 radiologists; films read independently on 2 occasions 4 weeks apart; assessments based on uniform definitions; unclear whether readers had knowledge of clinical tests | 39 orthopedic surgeons with varying levels of experience were presented with history/clinical findings with X-ray films             | 2 musculoskeletal radiologists blinded to clinical data independently analyzed                | 1 fellowship-trained musculoskeletal radiologist; 1 orthopedic surgery resident; 1 fourth-year medical student |
| <b>Images</b>   | 51 masked AP and frog-leg lateral films were in standardized format   | 10 patients' films presented for initial diagnosis, additional investigations (e.g. MRI, CT) presented to determine final diagnosis | MRI (enhanced in FAI patients, not in volunteers); focus on alpha angle from different planes | Plain radiographs and MRI scans  |

| <b>Agreement measure</b>                        | <b>ICC (95% CI) *</b>  |   |  | <b>Kappa (K)*†</b> |             |          |          |            | <b>ICC*</b>    |                   | <b>ICC (95%CI)*</b> |
|---|--|---|--|--------------------|-------------|----------|----------|------------|----------------|-------------------|---------------------|
|   | <b>Surgeons</b>  | <b>Radiologists</b>                                   | <b>Consensus</b>   | <b>A</b>           | <b>B</b>    | <b>C</b> | <b>D</b> | <b>All</b> | <b>FAI pts</b> | <b>Volunteers</b> | <b>Consensus</b>    |
| <b>Findings c/w FAI or<br/>Diagnosis of FAI</b> | T1: <b>0.72</b><br>(0.52, 0.84)<br>T2: <b>0.70</b><br>(0.52, 0.82) | T1: 0.59 (0.35, 0.76)<br>T2: <b>0.74</b> (0.59, 0.84) | T1: 0.33 (−0.17, 0.62)<br>T2: 0.15 (−0.50, 0.51)             | <b>0.67</b>        | <b>0.62</b> | 0.56     | 0.59     | 0.6        | ---            | ---               | ---                 |
| <b>Cam morphology</b>                           | T1: <b>0.74</b><br>(0.57, 0.84)<br>T2: <b>0.62</b><br>(0.39, 0.77) | T1: 0.54 (0.27, 0.73)<br>T2: <b>0.69</b> (0.50, 0.81) | T1: <b>0.78</b> (0.61, 0.87)<br>T2: <b>0.74</b> (0.54, 0.85) | ---                | ---         | ---      | ---      | ---        | ---            | ---               | ---                 |
| <b>Pistol-grip morphology</b>                   | T1: <b>0.78</b><br>(0.63, 0.87)<br>T2: <b>0.81</b><br>(0.70, 0.89) | T1: 0.60 (0.35, 0.76)<br>T2: <b>0.75</b> (0.60, 0.85) | T1: 0.27 (−0.28, 0.58)<br>T2: 0.35 (−0.14, 0.63)             | ---                | ---         | ---      | ---      | ---        | ---            | ---               | ---                 |
| <b>Pincer lesion</b>                            | T1: 0.42<br>(0.11, 0.64)<br>T2: 0.28<br>(−0.15, 0.56)              | T1: 0.39 (0.00, 0.65)<br>T2: 0.20 (−0.31, 0.53)       | T1: 0.30 (−0.23, 0.60)<br>T2: −0.10 (−0.92, 0.37)            | ---                | ---         | ---      | ---      | ---        | ---            | ---               | ---                 |
| <b>Mixed FAI</b>                                | T1: <b>0.62</b><br>(0.38, 0.77)                                    | T1: <b>0.62</b> (0.39, 0.77)                          | T1: <b>0.67</b> (0.42, 0.81)                                 | ---                | ---         | ---      | ---      | ---        | ---            | ---               | ---                 |

| Agreement measure  | ICC (95% CI) *   |  |  | Kappa (K)*†  |              |              |                     |            | ICC*   |  | ICC (95%CI)*   |
|--|--|--|--|--------------|--------------|--------------|---------------------|------------|--|--|--|
|  | T2: 0.35<br>(-0.04, 0.61)  | T2: 0.34 (-0.06, 0.60)                                 | T2: 0.57 (0.25, 0.76)  |              |              |              |                     |            |  |  |  |
| Type of FAI<br>Type after CT/MR  | -----  | -----  | -----  | 0.12<br>0.35 | 0.23<br>0.21 | 0.4<br>0.53  | 0.29<br><b>0.75</b> | 0.3<br>0.4 | ---  | ---  | ---  |
| Dysplasia<br>After CT/MR   | -----  | -----  | -----  | 0.3<br>0.11  | 0.42<br>0.48 | 0.36<br>0.42 | 0.45<br><b>0.65</b> | 0.3<br>0.3 | ---  | ---  | ---  |
| Cross-over sign  | T1: 0.55<br>(0.29, 0.72)<br>T2: 0.48<br>(0.17, 0.69)               | T1: <b>0.67</b> (0.48, 0.80)<br>T2: 0.18 (-0.31, 0.51) | T1: 0.44 (0.01, 0.68)<br>T2: 0.60 (0.30, 0.77)               | <b>0.88</b>  | 0.59         | 0.57         | 0.43                | 0.6        | ---  | ---  | ---  |
| Posterior wall sign  | T1: 0.49<br>(0.21, 0.69)<br>T2: 0.14<br>(-0.37, 0.48)              | T1: <b>0.69</b> (0.51, 0.81)<br>T2: 0.16 (-0.33, 0.49) | T1: 0.39<br>(-0.07, 0.65)<br>T2: 0.34<br>(-0.16, 0.62)       | 0.36         | 0.28         | 0.23         | 0.17                | 0.23       | ---  | ---  | ---  |
| Ischial spine sign   | T1: <b>0.75</b><br>(0.60, 0.85)<br>T2: <b>0.73</b><br>(0.56, 0.83) | T1: <b>0.65</b> (0.44, 0.79)<br>T2: 0.59 (0.35, 0.76)  | T1: 0.40<br>(-0.06, 0.66)<br>T2: <b>0.65</b> (0.39, 0.80)    | 0.8          | 0.45         | 0.49         | 0.52                | 0.5        | ---  | ---  | ---  |
| α angle  | T1: <b>0.77</b><br>(0.58, 0.88)<br>T2: <b>0.81</b><br>(0.69, 0.89) | T1: <b>0.73</b> (0.50, 0.86)<br>T2: 0.62 (0.31, 0.80)  | T1: 0.55 (0.21, 0.74)<br>T2: 0.47 (0.07, 0.70)               | ---          | ---          | ---          | ---                 | ---        | ---  | ---  | Radiographs: 0.56 (0.43, 0.67)<br>MRI: <b>0.65</b> (0.56, 0.73)        |
| α angle; planes (MR)<br>a. Anteroinferior<br>b. Anterior<br>c. Anterosuperior<br>d. Superior<br>e. Posterosuperior | -----  | -----  |  | ---          | ---          | ---          | ---                 | ---        | <b>a. 0.68</b><br><b>b. 0.817</b><br>c. 0.531<br><b>d. 0.748</b><br>e. 0.560 | a. 0.370<br><b>b. 0.625</b><br><b>c. 0.741</b><br>d. 0.490<br>e. 0.235 | ---  |
| Size of α angle  | T1: <b>0.66</b><br>(0.44, 0.80)<br>T2: <b>0.69</b><br>(0.51, 0.82) | T1: 0.47 (0.07, 0.72)<br>T2: 0.59 (0.30, 0.78)         | T1: <b>0.70</b> (0.48, 0.83)<br>T2: <b>0.82</b> (0.61, 0.90) | ---          | ---          | ---          | ---                 | ---        | ---  | ---  | ---  |
| Central edge angle   | -----  | -----  | -----  | 0.54         | 0.45         | 0.44         | 0.49                | 0.44       | ---  | ---  | Radiographs: <b>0.73</b> (0.52, 0.84)<br>MRI: <b>0.74</b> (0.67, 0.80) |

| Agreement measure            | ICC (95% CI) *   |  |   | Kappa (K)*† |      |      |             |      | ICC* | ICC (95%CI)*                                |
|------------------------------|--|--|---|-------------|------|------|-------------|------|------|---|
| <b>Offset ratio</b>          | T1: <b>0.64</b><br>(0.40, 0.79)<br>T2: <b>0.80</b><br>(0.67, 0.88) | T1: <b>0.69</b> (0.49, 0.82)<br>T2: <b>0.69</b> (0.46, 0.83) | T1: 0.31<br>(-0.22, 0.60)<br>T2: 0.45 (0.04, 0.69)        | ---         | ---  | ---  | ---         | ---  | ---  | ---   |
| <b>Size of offset ratio</b>  | T1: <b>0.69</b><br>(0.50, 0.82)<br>T2: 0.50<br>(0.21, 0.70)        | T1: 0.31 (-0.22, 0.63)<br>T2: -0.04<br>(-0.74, 0.41)         | T1: 0.51 (0.14, 0.72)<br>T2: <b>0.70</b> (0.47, 0.83)     | ---         | ---  | ---  | ---         | ---  | ---  | ---   |
| <b>Coxa profunda</b>         | T1: <b>0.68</b><br>(0.48, 0.81)<br>T2: <b>0.69</b><br>(0.51, 0.82) | T1: 0.39 (0.02, 0.63)<br>T2: 0.26 (-0.18, 0.55)              | T1: <b>0.63</b> (0.35, 0.79)<br>T2: 0.27<br>(-0.28, 0.59) | ---         | ---  | ---  | ---         | ---  | ---  | ---   |
| <b>Acetabular protrusion</b> | T1: 0.26<br>(-0.14, 0.54)<br>T2: 0.26<br>(-0.18, 0.55)             | T1: 0.28 (-0.16, 0.57)<br>T2: 0.00 (-0.59, 0.40)             | T1: 0.55 (0.21, 0.74)<br>T2: -0.06<br>(-0.86, 0.39)       | ---         | ---  | ---  | ---         | ---  | ---  | ---   |
| <b>Fem head sphericity</b>   | -----  | -----  | -----   | 0.34        | 0.49 | 0.4  | 0.48        | 0.4  | ---  | ---   |
| <b>Rotation</b>              | -----  | -----  | -----   | 0.12        | 0.29 | 0.59 | <b>0.65</b> | 0.41 | ---  | ---   |
| <b>Tönnis angle</b>          | -----  | -----  |   | 0.14        | 0.2  | 0.49 | 0.39        | 0.3  | ---  | ---   |
| <b>Tönnis grade</b>          |  |  |   | 0.27        | 0.3  | 0.49 | 0.46        | 0.4  |      | Angle from Radiographs: 0.63<br>(0.43-0.70) |
| <b>Best view</b>             | T1: -0.10<br>(-0.072, 0.33)<br>T2: 0.00<br>(-0.59, 0.40)           | T1: 0.33 (-0.07, 0.60)<br>T2: 0.57 (0.31, 0.74)              | T1: -0.29<br>(-1.26, 0.27)<br>T2: 0.00<br>(-0.75, 0.43)   | ---         | ---  | ---  | ---         | ---  | ---  | ---   |
| <b>Film adequacy</b>         | ---  | ---  | ---   | -0.02       | 0.26 | 0.23 | 0.3         | 0.2  | ---  | ---   |

AP=anteroposterior; CT=computed tomography; FAI=Femoroacetabular Impingement; ICC=intraclass correlation coefficient; MRI=magnetic resonance imaging; ROB=Risk of Bias

\*Boldface indicates kappa or ICC ≥ 0.61 suggesting at least good agreement or kappa of 0.61 to 0.80 indicating substantial agreement; values between 0.01-0.2 represents slight agreement; 0.21-0.40 fair; 0.41-0.60 moderate

† Group definitions: A= orthopedic trainees, n=5; B= hip surgeons with no/limited experience with hip preservation surgery, n= 9; C = hip surgeons with experience in hip preservation, n=22; D = high volume hip preservation surgeons, n=10.

**Table 11. Summary of intra-rater reliability coefficients for imaging commonly described in diagnosing FAIS**

|   | <b>Ayeni 2014 (ROB = Moderately Low)</b>  |                          | <b>Ratzleff 2016 (ROB = Moderately Low)</b>  |
|---|---|--------------------------|--|
| <b>Patient Population (N, normal, FAI, dysplasia)</b> | N = 51 consecutive symptomatic patients with unilateral hip pain and broad spectrum of FAI pathologies  |                          | N=50; n=40 randomly selected from IMPAKT-HiP study and n = 10 with clinically, imaging, and arthroscopically confirmed FAI; 42% had hip pain in past 12 months   |
| <b>Test Condition (#observers, other)</b>             | 3 orthopedic surgeons, 3 radiologists; films were standardized format, read independently, 2 occasions 4 weeks apart; assessments based on uniform definitions; unclear whether readers had knowledge of clinical tests |                          | One 3 <sup>rd</sup> year medical student trained by musculoskeletal radiologist; Clinical and demographic information blinded then 49 hips randomized, read by radiologist and student then were re-read by student 8 weeks later in new randomized order. |
| <b>Images</b>   | 51 masked AP and frog-leg lateral films were in standardized format   |                          | AP-Pelvis (weight-bearing), bilateral Dunn projections(supine)   |
| <b>Agreement measure</b>                              | <b>ICC (95% CI)*</b>  |                          | <b>Kappa or ICC*</b>   |
|   | <b>Surgeons</b>   | <b>Radiologists</b>      |  |
| <b>Overall diagnosis</b>                              |   |                          | <b>K=0.58, PABAK=0.76</b>  |
| <b>Findings c/w FAI</b>                               | 0.41 (-0.08, 0.67)  | 0.25 (-0.32, 0.75)       |  |
| <b>Cam morphology</b>                                 | <b>0.86</b> (0.76, 0.92)  | <b>0.72</b> (0.50, 0.84) |  |
| <b>Pistol-grip morphology</b>                         | 0.01 (-0.73, 0.44)  | <b>0.68</b> (0.44, 0.82) |  |
| <b>α angle &gt;50.5°</b>                              | 0.19 (-0.43, 0.54)  | 0.42 (-0.01, 0.67)       | <b>&gt;55° ICC=0.97,</b>   |
| <b>Size of α angle</b>                                | <b>0.84</b> (0.72, 0.91)  | <b>0.91 (0.84, 0.95)</b> |  |
| <b>Offset ratio &lt;0.17</b>                          | 0.40 (-0.06, 0.66)  | <b>0.71</b> (0.49, 0.83) |  |
| <b>Size of offset ratio</b>                           | <b>0.82</b> (0.68, 0.90)  | -0.04 (-0.82, 0.41)      |  |
| <b>Pincer lesion</b>                                  | <b>0.70</b> (0.48, 0.83)  | -0.13 (-0.98, 0.36)      |  |
| <b>Cross-over sign</b>                                | 0.29 (-0.25, 0.59)  | 0.26 (-0.30, 0.58)       | K=0.58   |
| <b>Posterior wall sign</b>                            | 0.20 (-0.40, 0.54)  | 0.48 (0.08, 0.70)        |  |
| <b>Ischial spine sign</b>                             | 0.55 (0.20, 0.74)   | <b>0.80</b> (0.65, 0.89) |  |
| <b>Coxa profunda</b>                                  | 0.02 (-0.72, 0.44)  | 0.52 (0.16, 0.73)        |  |
| <b>Acetabular protrusion</b>                          | 0.10 (-0.57, 0.49)  | -0.03 (-0.81, 0.41)      |  |
| <b>Mixed FAI</b>                                      | 0.15 (-0.49, 0.52)  | 0.45 (0.04, 0.69)        |  |
| <b>Best view</b>                                      | 0.00 (-0.75, 0.43)  | 0.20 (-0.40, 0.54)       |  |
| <b>Central edge angle &gt;40</b>                      |   |                          | <b>ICC=0.87</b>  |

AP=anteroposterior; CI=confidence interval; FAI=Femoroacetabular Impingement; ICC=intraclass correlation coefficient; IMPAKT-HiP=Investigations of Mobility, Physical Activity and Knowledge Translation in Hip Pain; PABAK=prevalence and bias adjusted kappa; ROB=risk of bias

\*Boldface indicates ICC≥0.61 suggesting at least good agreement or kappa of 0.61 to 0.80 indicating substantial agreement.

### Consensus-Based Best Practice Guideline

The Lynch 2019 BPG<sup>123</sup> was based on a systematic review<sup>138</sup> conducted to assess risk factors and outcomes related to arthroscopic management of FAI and a survey of 24 questions administered to the

development group of 15 hip arthroscopists. The systematic review is briefly summarized in the background to this report; briefly the review consisted of 29 surgical studies, most of which were retrospective (26 were case series) and 2 biomechanical studies. It was performed by a subset of authors involved in the BPG. Recommendations for pre-operative care include assessment of factors that may lead to poor arthroscopy outcomes. Diagnostic criteria for FAI/FAIS are not described; general selection criteria for surgical candidates are alluded to in the pre-operative recommendations, however. Contraindications to surgery are listed with intraoperative recommendations. Preoperative recommendations include:

- Patient education regarding FAI (components or content not described)
- Standard minimum 3 month duration of conservative care is recommended
  - To include trials of rest and NSAIDs, activity modification and physical therapy; no opioids
  - Less than full duration of conservative care is permitted for professional or out-of-season athletes, patients with no or marginal improvement with PT (as assessed by surgeon and PT), those with surgery on contralateral side and those with high baseline mental health status (VR 12)
- Assessment of joint parameters for proceeding with surgery prior to completion of conservative care including high alpha angle, low Tönnis grade, large cam-type or combined deformity in the absence of osteoarthritic changes and large ROM limitations with pain
- MRI in the setting of previous hip scope with intra-articular pain

Contraindications to arthroscopy include joint space narrowing ( $< 2\text{mm}$  anywhere along the lateral and/or medial source or OA, Tönnis grade  $\leq 2$ , and pain not localized to the hip or out of proportion due to psychological issue. Obesity and severe femoral retro or anteversion with gait abnormality are also listed as contraindications but hypermobility and skeletal immaturity are not.

### **Inclusion criteria of included RCTs**

As in the 2011 report, we compared inclusion/exclusion criteria of clinical trials as they allude to criteria that define a subpopulation of patients thought to have the condition and who are potential candidates for surgery, thus providing a form of case definition. RCTs, which are prospective, were chosen because retrospective studies only have available those criteria that were collected at baseline while prospective studies are able to state up front all the criteria that best identifies the FAI(S) population.

Table 12 summarizes the inclusion/exclusion criteria across the three included RCTs comparing arthroscopy with non-operative care<sup>66,125,153</sup> and the one included RCT comparing labral repair versus labral debridement in persons undergoing arthroscopy for FAIS<sup>106</sup>. The most consistent case definition of FAIS (regardless of morphologic type) based on inclusion/exclusion criteria across the RCTs includes hip or groin pain (assuming that “symptomatic” means pain was present) and positive imaging signs. Regarding imaging signs, three trials report use of alpha angle (varying thresholds) and/or lateral center edge angle and/or positive cross over sign. One trial reported qualitative imaging assessment noting the absence of agreed upon diagnostic thresholds.<sup>153</sup> While all RCTs allude to use of clinical tests for diagnosis, only one specified use of a specific test.<sup>125</sup>

**Table 12. Summary of clinically-related inclusion/exclusion criteria for included RCTs**

|                                      | Griffin 2018<br>[UK FASHION trial]  |               | Mansell 2018   |              | Palmer 2019<br>[FAIT trial]   |               | Krych 2013  |                                 |
|--------------------------------------|---|---------------|--|--------------|---|---------------|---|---------------------------------|
|                                      | Arthroscopy<br>(n=171)  | PT<br>(n=177) | Arthroscopy<br>(n=40)  | PT<br>(n=40) | Arthroscopy (n=112)   | PT<br>(n=110) | Arthroscopic<br>labral repair<br>(n=18)   | Labral<br>debridement<br>(n=18) |
| <b>INCLUSION CRITERIA</b>            |   |               |  |              |   |               |   |                                 |
| <b>Age</b>                           | ≥16 years   |               | 18-60 years  |              | 18-60 years   |               | ≥18 years, female   |                                 |
| <b>Pain</b>                          | “Hip pain”; may also have symptoms of clicking, catching or giving way  |               | Self-reported anterior hip or groin pain and pain reproduced with passive or active flexion                |              | “symptomatic”   |               | “symptomatic”   |                                 |
| <b>Type of FAI</b>                   | Cam, pincer or mixed (see imaging criteria below)   |               | Cam, pincer, or mixed† (see imaging criteria below)  |              | Cam, pincer or mixed (see imaging criteria below)                                 |               | Pincer or mixed (see imaging criteria below)  |                                 |
| <b>Failed conservative treatment</b> | NR  |               | Yes – failed 6 weeks of conservative management (NSAIDs, profile, patient education and exercise handouts) |              | NR  |               | NR  |                                 |
| <b>Failed previous PT</b>            | Unclear§  |               | No (see exclusion criteria)  |              | No (see exclusion criteria)   |               | NR  |                                 |
| <b>Positive impingement</b>          | Unclear – clinical examination performed (specifics not reported)   |               | Yes – positive FADIR test  |              | Unclear – FAI confirmed clinically (specifics not reported)                       |               | Yes – specifics not reported  |                                 |
| <b>Positive imaging sign</b>         | Yes – alpha angle >55° and/or a lateral center edge angle of >40° or a positive crossover sign on AP radiograph   |               | Yes – alpha angle >50° and/or positive crossover sign (on CT, radiograph and MRI)                          |              | Unclear – via qualitative assessment of imaging only (radiograph and MRI)**       |               | Yes – positive cross over sign and prominent ischial spine sign; coxa profunda; acetabular protrusion; or pincer divot at femoral head-neck junction on AP radiograph; with or without alpha angle >45° on oblique radiograph |                                 |
| <b>Intra-articular injection</b>     | NR  |               | Yes – Subjective relief of pain after intra-articular injection  |              | NR  |               | Yes – in most patients  |                                 |
| <b>Other</b>                         | <ul style="list-style-type: none"> <li>• Able to give informed consent</li> <li>• Treating surgeon believed patient was likely to benefit from hip arthroscopy</li> </ul> |               | <ul style="list-style-type: none"> <li>• Tricare beneficiaries</li> </ul>                                  |              | <ul style="list-style-type: none"> <li>• Able to give informed consent</li> </ul> |               | <ul style="list-style-type: none"> <li>• Presence of labral tear/pathology was required on MRI</li> </ul>   |                                 |

|                           | Griffin 2018<br>[UK FASHION trial]   |               | Mansell 2018  |              | Palmer 2019<br>[FAIT trial]   |               | Krych 2013   |                                 |
|---------------------------|--|---------------|---|--------------|---|---------------|--|---------------------------------|
|                           | Arthroscopy<br>(n=171)   | PT<br>(n=177) | Arthroscopy<br>(n=40)   | PT<br>(n=40) | Arthroscopy (n=112)   | PT<br>(n=110) | Arthroscopic<br>labralrepair<br>(n=18)   | Labral<br>debridement<br>(n=18) |
| <b>EXCLUSION CRITERIA</b> |  |               |   |              |   |               |  |                                 |
| <b>Preexisting OA</b>     | Tönnis >1 or <2mm superior joint space narrowing   |               | Joint space narrowing <2mm  |              | Kellgren–Lawrence≥2††   |               | Yes – Tönnis grade ≥2  |                                 |
| <b>Hip dysplasia</b>      | No   |               | No  |              | center-edge angle <20°  |               | Yes  |                                 |
| <b>Previous surgery‡‡</b> | shape-changing surgery, open or arthroscopic   |               | Yes   |              | Yes   |               | Yes  |                                 |
| <b>Previous PT</b>        | No   |               | Yes, within prior 6 months  |              | Yes, within prior 12 months   |               | NR   |                                 |
| <b>Other</b>              | <ul style="list-style-type: none"> <li>History of previous hip injury (e.g., acetabular fracture, hip dislocation, or femoral neck fracture)</li> <li>History of hip pathology (e.g., Perthes’ disease, slipped upper femoral epiphysis, or avascular necrosis)</li> </ul> |               | <ul style="list-style-type: none"> <li>Concurrent systemic disease that may affect the condition</li> <li>Pending litigation/workmen’s compensation</li> <li>Moving within following 6 months</li> <li>Clearing lumbar spine reproduces patient’s hip symptoms</li> </ul> |              | <ul style="list-style-type: none"> <li>Medical conditions that prevent surgical intervention</li> <li>Contraindications to MRI</li> </ul> |               | <ul style="list-style-type: none"> <li>Evidence of a Wiberg lateral center edge angle &lt;25°</li> </ul> |                                 |

AP = anterior-posterior; FAI = femoroacetabular impingement; MRI = magnetic resonance imaging; OA = osteoarthritis; PT = physical therapy.

§Authors state that they intended to recruit a cohort of typical patients with FAI deemed suitable for arthroscopic surgery; this included patients who may have already received a course of physiotherapy.

\*\*No quantitative assessment was performed; Authors state the following: “Owing to the absence of agreed diagnostic thresholds and to improve generalizability of our study findings, we did not use quantitative imaging measurements as inclusion criteria for this study. Instead, surgeons qualitatively assessed hip morphology to diagnose FAI.”

††Of those randomized, osteoarthritis of Kellgren Lawrence grade 0/1/unknown was present in 80%/15%/5%.

‡‡To symptomatic hip.



### **Surgical indications/criteria**

The Warwick Agreement acknowledges that there is no high-level evidence to support the definitive treatment of FAIS and that conservative care, rehabilitation and surgery may play a role in different patients. The panel further suggests that decision making should employ a multidisciplinary group that has access to and knowledge about all of the options. No specific criteria or indications for surgery for FAIS are described. Authors do, however, indicate that it is rarely indicated to offer surgery to persons with an asymptomatic cam or pincer morphology.

There appears to be a lack of consensus and substantial inconsistency regarding specific indications or criteria for surgical treatment of FAIS across the literature. One older systematic review<sup>9</sup> of indications used by clinicians to address FAI with surgical dislocation (N= 15 studies, 12 were case series) reported that pain and the impingement sign were the most common clinical criteria for surgery and that the most common radiologic criteria were derived from MRI/MRA versus plain radiographs and included description of labral tears and cartilage damage. A more recent scoping review<sup>160</sup> of 108 studies reported that only 56% of studies identified followed the Warwick Agreement consensus of using a combination of symptoms, clinical signs and diagnostic imaging for FAIS diagnosis. Across the studies reporting on the triad, the most commonly reported criteria were  $\geq 6$  months of hip pain, decreased hip flexion and internal rotation, positive impingement sign,  $\alpha$ -angle  $> 50^\circ$  and a positive cross-over sign. Only 44% described previous failure of non-operative or physiotherapist led rehabilitation as part of surgical decision making. The most common criterion for FAIS surgery was related to imaging evidence (92%) and only 12% of studies reported use of diagnostic intra-articular injection as an FAIS diagnostic criterion.

#### **4.1.2 Contextual Question 2**

**What are the expected treatment outcomes of hip surgery for FAI? Are there validated instruments related to hip surgery outcomes? Has clinically meaningful improvement in outcomes been defined in FAI?**

Key Points:

- New studies for the Tönnis system for grading OA showed only slight to fair interrater reliability and fair to moderate for intrarater reliability. By contrast another study reported substantial interobserver reliability for the Kellgren Lawrence grading system.
- Four new functional outcomes measures were used RCTs included in this update: iHOT-33 and iHOT-12, HAGOS, HOOS and OHS and in general appear to be valid and have good reliability.
- Updated MCIDS were identified for some outcomes measures compared with the prior report.

**Table 13. Comparison of findings from the 2011 and 2019 reports**

| KQ 2, 2011 Report<br>SOE: VERY LOW (Insufficient)   | Contextual questions #2, 2019 Report<br>(SOE: not formally assessed for contextual questions)   |
|---|---|
| <p><u>Patient- and clinician reported outcomes</u></p> <ul style="list-style-type: none"> <li>• The Tönnis classification is often used to determine the extent of osteoarthritis in the hip. There were no studies found that assessed its validity. Reliability was tested in only one study and intra- and interobserver reliability in that study was moderate.</li> <li>• Seven hip outcomes measures were used commonly in FAI patients. Three have undergone psychometric analysis in FAI (HOS-D, M-WOMAC) or young hip-pain (HOS, NAHS) patient populations.</li> <li>• Only one, the Non-arthritic Hip Score (NAHS), of the three instruments was adequately tested for validity, and it was performed in a young hip-pain patient population.</li> <li>• Reliability was inadequately tested for all three instruments.</li> <li>• 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. The MCID has not been defined for any other outcome measures in FAI or young hip-pain patients.</li> </ul> | <p><u>Patient- and clinician reported outcomes</u></p> <ul style="list-style-type: none"> <li>• Two new studies found interrater reliability for the Tönnis classification to be slight to fair and intrarater reliability ranged from fair to moderate. Both conclude that reproducibility is not adequate. No validation studies in FAI patients were identified.</li> <li>• For the Kellgren Lawrence grading system from one general, population-based study reported substantial interobserver reliability. Construct validity and predictive validity for future THA were considered good.</li> <li>• Four additional hip measures were used in RCTs included in the update report: iHOT-33 and iHOT-12, HAGOS, HOOS and OHS.</li> <li>• In FAI patients, OHS demonstrated good construct validity without notable floor or ceiling effects as well as high internal consistency, internal and external responsiveness and ability to discriminate between patients. An MCID of 5.22 points was reported by different authors for adults undergoing THA.</li> <li>• A prospective longitudinal study in 50 young adults undergoing arthroscopy for FAI, labral lesion or chondroplasty (or combination) and 50 healthy age-matched adults evaluated the psychometric properties of the HAGOS, HOOS, HOS, i-HOT-33 and mHHS. Content validity for HOOS, HAGOS, and iHOT-33 and all measures were able to detect differences between the study groups. None demonstrated floor effects. Responsiveness was considered adequate for mHHS, HOOS and iHOT-33.</li> <li>• Updated MCIDs in patients with hip pain and/or hip related procedures for measures are as follows: (see report for other measures) <ul style="list-style-type: none"> <li>○ iHot-33 for patients undergoing arthroscopy for FAIS: pediatric, 10.7 pts, adults 12.1 pts</li> <li>○ mHHS: pediatric patients undergoing arthroscopy for FAIS 9.7pts, adults, any arthroscopy 8 pts</li> <li>○ Adult arthroscopy patients: HAGOS-pain: 6 points, HAGOS-symptoms: 10 points, HAGOS-ADL: 9 points, HAGOS-sport: 9 points, HAGOS-physical activity: 1point, HAGOS- QOL: 9 points</li> <li>○ VAS pain (0-100 pts), adult arthroscopy patients: -15 points</li> </ul> </li> </ul> |

International Hip Outcome Tool (iHOT-33 & iHOT-12); Hip and Groin Outcome Score (HAGOS); Hip disability & osteoarthritis outcome score (HOOS); Oxford Hip Score (OHS); Hip Outcome Score (HOS)/ German version (HOS-D); Nonarthritic Hip Score (NAHS); Harris Hip Score (HHS); mHHS (modified HHS); Merle d'Aubigne Score (MAP); UCLA Activity Score; Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC-12)

The 2011 report contained substantial detail regarding the validity, reliability, and responsiveness of outcomes measured used by included studies and was part of the formal research questions and the interested reader should consult that report. For this 2019 report, the intention is to provide general context regarding basic aspects of validity, reliability and responsiveness for new measures reported across included RCTs based on a limited literature search. Information on the Kellgren Lawrence system for assessing OA is also added for this update as some included studies used this for OA assessment.

The goals of FAIS surgery include preventing or delaying osteoarthritis (OA) of the hip and total hip arthroplasty in the long-term, and improving function and restoring activity in the short-term. With respect to osteoarthritis of the hip, this outcome was, most commonly reported using the Tönnis or Kellgren Lawrence grading system across studies included in this report.

The Tönnis classification system has four grades:

- Grade 0: No signs of OA
- Grade 1: Increased sclerosis, slight joint space narrowing, no or slight loss of head sphericity
- Grade 2: Small cysts, moderate joint space narrowing, moderate loss of head sphericity
- Grade 3: Large cysts, severe joint space narrowing, severe deformity of the head, or evidence of necrosis.

The Kellgren Lawrence

- Grade 0: No signs of OA
- Grade 1: Possible narrowing of joint space medially and possible osteophytes around the femoral head; or osteophytes alone
- Grade 2: Definite narrowing of joint space inferiorly, definite osteophytes, and slight sclerosis
- Grade 3: Marked narrowing of joint space, definite osteophytes, some sclerosis and cyst formation, and deformity of the femoral head and acetabulum
- Grade 4: Gross loss of joint space with sclerosis and cysts, marked deformity of femoral head and acetabulum and large osteophytes

With respect to identifying improved function and restoration of activity, patient- and clinician-reported functional outcomes measures are often employed.

### **Long-term outcomes, osteoarthritis**

The previous report found no study that sought to validate the Tönnis classification for hip osteoarthritis. None were identified for this update. The prior report provided information from one study on e intraobserver and interobserver reliability of the Tönnis classification in a series of 77 patients with diagnoses of cam, pincer, or combined FAI (n = 25), acetabular dysplasia (n = 27), or normal hips (n = 25). The combined intraobserver reliability (kappa value) was 0.60 (95% CI 0.54 to 0.66), and the interobserver reliability was 0.59 corresponding to moderate agreement.<sup>32</sup> Two additional studies assessing the intraobserver and interobserver reliability of the Tönnis classification were identified for this update.<sup>86,206</sup> In one series of 61 patients who were candidates for hip-preserving surgery (n=31) or asymptomatic with respect to the hip joint (n=30, the intraobserver reliability (kappa value) ranged from 0.364 to 0.397, and the interobserver reliability ranged from 0.173 to 0.397. In the

second study<sup>86</sup> (n=49) in patients with FAI, the average intraobserver reliability of the Tönnis classification was moderate ( $\kappa = 0.472$ ), and the interobserver reliability was fair ( $\kappa = 0.287$ ). All three studies<sup>32,86,206</sup> concluded that good reproducibility of the Tönnis grading system of osteoarthritis had not been demonstrated, and Valera et al.<sup>206</sup> suggested that its routine use in therapeutic decision-making for conservative hip surgery should be reconsidered.

The Kellgren Lawrence grading system has been used in studies included in this report and information on its validity and reliability are therefore included in this update. One older study evaluating the Kellgren Lawrence system and minimal joint space (MJS) was identified but did not describe individuals with FAI. The study sampled 3595 subjects from the Rotterdam study, a prospective population-based longitudinal cohort who had baseline and follow-up radiographs.<sup>172</sup> Construct validity was assessed based on the ability to identify patients with clinical hip OA symptoms and predictive validity was based on prediction of THA at follow-up. Reliability was also assessed. For construct validity, significant associations between both the Kellgren-Lawrence  $\geq 2$  and MJS  $\leq 2.5$  mm and hip pain based on estimates adjusted for MBI and radiographic OA of the other hip. Similarly the Kellgren Lawrence grade was a significant predictor of THA at follow up. Interrater reliability across radiographic features varied. For Kellgren-Lawrence  $\geq 2$  it was considered substantial (kappa 0.68, 95%CI 0.44, 0.92).

#### Short-term outcomes, patient- and clinician-reported functional outcomes

The prior report identified seven commonly used functional patient- and clinician-reported hip outcomes measures that were used in the FAIS patient population. Since then, an additional four outcomes used in the FAIS patient population were identified, totaling eleven identified outcomes measures.

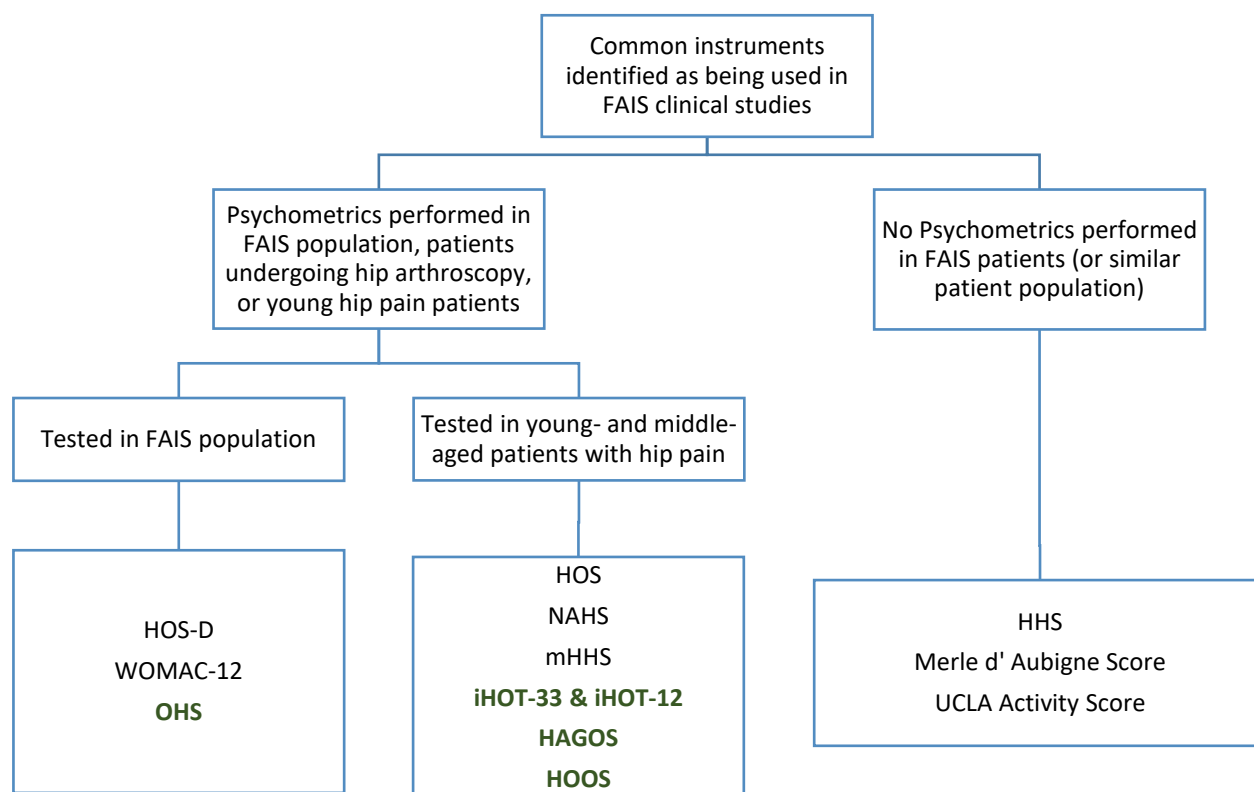
##### **Identified in 2011 report**

1. Hip Outcome Score (HOS)/ German version (HOS-D)
2. Nonarthritic Hip Score (NAHS)
3. Harris Hip Score (HHS)
4. mHHS (modified HHS)
5. Merle d'Aubigne Score (MAP)
6. UCLA Activity Score
7. Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC-12)

##### **Identified in 2019 update report**

1. International Hip Outcome Tool (iHOT-33 & iHOT-12)
2. Hip and Groin Outcome Score (HAGOS)
3. Hip disability & osteoarthritis outcome score (HOOS)
4. Oxford Hip Score (OHS)

Of these, three outcome measures have been tested for validity in FAIS patients: HOS-D, WOMAC-12, and OHS. In addition, six outcome measures have been tested for validity in young hip-pain populations: HOS, NAHS, iHOT-33/iHOT-12, HAGOS, HOOS, and mHHS. Three outcome measures have not been tested for validity in the FAIS patient population or another similar patient population. (Figure 3)

**Figure 3. Functional outcomes measures commonly reported in studies on FAIS patients**

Studies in green represent the four newly identified outcomes used in the FAIS patient population (i.e. studies included in the prior report did not use these outcomes).

FAIS = Femoroacetabular Impingement Syndrome; HAGOS = Hip and Groin Outcome Score; HHS = Harris Hip Score; HOOS = Hip disability & osteoarthritis outcome score; HOS = Hip Outcome Score; HOS-D = Hip Outcome Score German version; iHOT = international Hip Outcome Tool; mHHS = modified Hip Harris Score; NAHS = Nonarthritic Hip Score; OHS = Oxford Hip Score; UCLA = University of California Los Angeles; WOMAC = Western Ontario & McMaster Universities Osteoarthritis Index

Of the three outcomes measures validated in the FAIS patient population, two were reported on in the previous report (HOS-D and WOMAC-12). Content validity was considered inadequate for HOS and WOMAC-12, primarily because patients were not involved in item selection; criterion validity was not tested for the same two instruments. Construct validity was demonstrated for the HOS/HOS-D, but was inadequately tested for the WOMAC-12 as no hypothesis was made as to expected differences in scores between patient groups. Reliability was inadequately tested for both outcomes measures at the time of the 2011 report.<sup>42</sup> An overview of validity, reliability and responsiveness evaluations for the new outcomes measures is found in Table 14.

**Table 14. Validity, reliability, and responsiveness of functional outcome measures**

| Outcome measure   | Patient population tested in  | Validity   | Reliability | Responsiveness |
|---|---|------------|-------------|----------------|
| <b>Measures included in prior report</b>  |   |            |             |                |
| <b>MA</b>   | Patients with coxarthrosis and candidates for total hip arthroplasty (N = 35) (59 years; 49% male)  | not tested | +           | not tested     |
|   | Patients with acetabular fracture (N = 450) (44 years; sex NR)  | +          | not tested  | not tested     |
|   | Patients undergoing total hip replacement (N = 61) (50 years; 33% male)   | +          | not tested  | –              |
| <b>HHS</b>  | Patients with total hip arthroplasty (N = 58) (71 years; 34% male)  | +          | +           | not tested     |
|   | Patients with total hip arthroplasty (N = 78) (62 years; 55% male)  | +          | –           | +              |
|   | Patients with hip osteoarthritis (N = 75) (72 years; 27% male)  | not tested | not tested  | +              |
|   | Patients with coxarthrosis and candidates for total hip arthroplasty (N = 35) (59 years; 49% male)  | not tested | +           | not tested     |
|   | Patients with total hip arthroplasty (N = 100) either cemented (n = 54) (71 years; 43% male) or uncemented (n = 46) (49 years; 50% male)                        | +          | not tested  | not tested     |
|   | Patients undergoing total hip replacement (N = 61) (50 years; 33% male)   | +          | not tested  | +              |
|   | Patients with acetabular fracture (N = 450) (44 years; sex NR)  | +          | not tested  | not tested     |
| <b>MHHS*</b>  | Patients with 1–2 total hip arthroplasties (≥ 1 year postop) (N = 36) (69 years; 31% male)  | +          | not tested  | not tested     |
| <b>2019 New outcomes measures reported in included RCTs (and update to HOS, MHHS)</b> |   |            |             |                |
| Kellgren-Lawrence (OA)  | General population from longitudinal cohort (N= 3583, age≥55 years old)   | +          | +           | not tested     |
| OHS   | Patients with FAI (N=126) and patients having THA (N=550)   | +          | +           | +              |
| iHOT-33   | Patients adults undergoing arthroscopy for FAI, labral lesion or chondroplasty or combination (n=50, 37 years) and 50 healthy age-matched adults (age 32 years) | +          | +           | +              |
| HAGOS   |   | +          | +           | +              |
| HOOS  |   | +          | +           | +              |
| HOS   |   | +          | +           | +              |
| MHHS  |   | +          | +           | +              |

MA= Merle d' Aubingne Score, MMHS= Modified Harris Hip Score FAIS = Femoroacetabular Impingement Syndrome; HAGOS = Hip and Groin Outcome Score; HHS = Harris Hip Score; HOOS = Hip disability & osteoarthritis outcome score; HOS = Hip Outcome Score; HOS-D = Hip Outcome Score German version; iHOT = international Hip Outcome Tool; mHHS = modified Hip Harris Score; NAHS = Nonarthritic Hip Score; OHS = Oxford Hip Score; UCLA = University of California Los Angeles; WOMAC = Western Ontario & McMaster Universities Osteoarthritis Index

\* The version of the MHHS that was validated omitted the public transportation question (worth 1 points). Thus the maximum number of points was 90 (versus 91 in the more commonly used mHHS), which was then converted to a scale of 0–100.

One new outcomes measure, OHS, has been validated in the FAIS patient population. Impellizzeri et al. 2015<sup>89</sup> conducted a prospective observational cohort comparing the psychometric properties of the OHS in a group of symptomatic patients undergoing either arthroscopy (52%) or mini-open surgery (52%) plus treatment of labral pathology for cam, localized pincer, or mixed-type FAI (n=165) versus a contemporaneous group of patients receiving THA for end-stage hip osteoarthritis (n=550). The HOS (ADL and Sport subscales) was used as the reference instrument for assessing construct validity and internal and external responsiveness; the global treatment outcome (GTO) was also used for assessing internal responsiveness. Patients completed questionnaires at baseline and 6 and 12 months post-surgery. Regarding construct validity in FAI patients the correlation between OHS and HOS-ADL and HOS- Sport scores was high ( $r = 0.84$  to  $0.84$  and  $r = 0.67$  to  $0.74$  respectively with no notable floor or ceiling effects >15% for HOS-sport or OHS at anytime point. ICC values for reproducibility were high (ICC =0.97) suggesting a good ability to discriminate between patients for cross-sectional evaluations. Authors also report high internal and external responsiveness and high internal consistency in FAI patients,

Overall there were six outcomes measures (HOS, NAHS, mHHS, iHOT-33/iHOT-12, HAGOS, HOOS) reported in included studies for either the 2011 or 2019 reports that have been tested for validity in young- to middle-aged patients with hip pain. Three of these outcomes (HOS, NAHS, mHHS) were evaluated in the previous report; reliability was considered to be inadequately tested in all three. Only the NAHS demonstrated content, criterion, and construct validity, but was inadequately evaluated for internal consistency, and reproducibility. Floor/ceiling measurements were not reached, and responsiveness and interoperability was not evaluated. All six measures have been subsequently evaluated in a prospective longitudinal study in young- to middle-age adults with hip and groin disability.<sup>100</sup> The study was conducted in 50 adult patients who had undergoing hip arthroscopy for FAI, labral lesion or chondroplasty or a combination thereof to evaluate the psychometric properties of the HAGOS, HOOS, HOS, i-HOT-33 and mHHS. A control group of 50 healthy age-matched adults was also included. The questionnaires were administered to the study group at baseline, between 3 and 14 days and between 9 and 12 months; the control group only completed the questionnaires at baseline. Authors report acceptable content validity for HOOS, HAGOS, and iHOT-33 and that all measures were able to detect differences between the study groups. Ceiling effects were noted for MHHS and ADL subscales for HOOS, HOS and HAGOS but floor effects were not observed for any measure. Reliability was considered excellent (ICC, 0.91-.097). Authors conclude that some psychometric properties of the MHHS, HOS and subscales for the HAGOS may be reduced in those undergoing hip arthroscopy suggesting that they may be less valuable for this population. MIC for all measures was <11 points of a possible 100 points.

The MCID for all patient and clinician reported outcomes measures can be found in Table 15.

**Table 15. Outcome measures for outcomes used in included studies**

| Outcome measure  | Assessed By | Components  | Score range | Interpretation                        | MCID   |
|--|-------------|---|-------------|---------------------------------------|--|
| <b>Functional Outcome Measures</b>                     |             |   |             |                                       |  |
| international Hip Outcome Tool (iHOT-33)               | Patient     | 33-item survey with questions relating to Symptoms and Functional Limitations, Sports and Recreational Activities, Job-Related Concerns and Lifestyle Concerns.   | 0-100       | Higher scores = increased QOL         | For pediatric patients undergoing hip arthroscopy for FAIS: 10.7 points <sup>150</sup><br><br>For adult patients undergoing hip arthroscopy for any condition: 6.1 points <sup>140</sup><br>10 points <sup>100</sup>   |
| Modified Harris Hip Score (mHHS)                       | Patient     | The mHHS score gives a maximum of 100 points. Pain receives 44 points, function 47 points, range of motion 5 points, and deformity 4 points. Function is subdivided into activities of daily living (14 points) and gait (33 points).       | 0-100       | Higher scores = increased function    | For pediatric patients undergoing hip arthroscopy for FAIS: 9.5 points <sup>150</sup><br><br>For adult patients undergoing hip arthroscopy for any condition: 8 points <sup>100</sup>  |
| Hip and Groin Outcome Score (HAGOS)                    | Patient     | Six separate subscales that are scored separately assessing Pain, Symptoms, Physical function in daily living, Physical function in Sport and Recreation, Participation in Physical Activities and hip and/or groin-related Quality of Life | 0-100       | Higher scores = no hip/groin problems | For adult patients undergoing hip arthroscopy for any condition <sup>100</sup> :<br>HAGOS-pain: 6 points<br>HAGOS-symptoms: 10 points<br>HAGOS-ADL: 9 points<br>HAGOS-sport: 9 points<br>HAGOS-physical activity: 1* point<br>HAGOS- QOL: 9 points             |
| Hip disability and osteoarthritis outcome score (HOOS) | Patient     | 26 items scored on a 5-point Likert scale. Subscale scores summed, then transformed to 0–100.   | 0-100       | Higher scores = no hip/groin problems | No published references when applied to FAIS.<br><br>For adult patients undergoing hip arthroscopy for any condition <sup>100</sup> :<br>HOOS-pain: 9 points<br>HOOS-symptoms: 10 points<br>HOOS-ADL: 6 points<br>HOOS-sport: 10 points<br>HOOS-QOL: 11 points |
| Oxford Hip Score (OHS)                                 | Patient     | 12-item survey that assesses pain, and function of the hip  | 12-60       | Higher scores = increased function    | No published references when applied to FAIS.  |



| Outcome measure  | Assessed By           | Components   | Score range  | Interpretation  | MCID   |
|--|-----------------------|--|--|---|--|
|  |                       | in relation to daily activities including walking, dressing, climbing the stairs, and sleeping. Each item has five possible responses.   |  |   | For adult patients undergoing THA: 5.22 points <sup>13</sup>   |
| Merle d' Aubingne Score  | Patient and Physician | The Merle d'Aubigné hip score includes the parameters pain, mobility, and ability to walk, with each rated from 0 to 6.  | <p>Addition of the scores for pain and mobility results in an absolute estimation of hip function (range, 0-12)</p> <p>Difference between preoperative and postoperative status (all three categories, with pain and walking ability multiplied by two before being added) (range, 0-30)</p> | <p>Lower scores = worse outcomes</p> <p>For estimation of hip function: higher scores = absolute</p> <p>For difference between pre- and post-operative scores:</p> <ul style="list-style-type: none"> <li>•Very great improvement: <math>\geq 12</math></li> <li>•Great improvement: 7-11</li> <li>•Fair improvement: 3-6</li> <li>•Failure: <math>\leq 2</math></li> </ul> | There are no reports of MCID for the Merle d' Aubingne Score that we are aware of.   |
| Hip Outcome Score (HOS-ADL & HOS-sport)                                | Patient               | Each item is graded on a 5-point Likert scale. The HOS consists of 2 sub scales, ADL and sports, which are scored separately: the total score is divided by the maximum possible score (based on the number of questions answered), and the result multiplied by 100 to obtain a percentage. | 0-100  | Higher scores = increased function  | <p>For adult patients undergoing hip arthroscopy for FAIS: HOS-ADL: 8.3 points<sup>151</sup> HOS-sport: 14.5 points<sup>151</sup></p> <p>For pediatric patients undergoing hip arthroscopy for FAIS: HOS-ADL: 9.8 points<sup>150</sup> HOS-sport: 12.1 points<sup>150</sup></p> <p>For adult patients undergoing hip arthroscopy for any condition: HOS-ADL: 9 points<sup>128</sup> HOS-sport: 6 points<sup>128</sup></p> <p>HOS ADL: 5 points<sup>100</sup> HOS-sport: 6 points<sup>100</sup></p> |
| Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) | Patient               | The WOMAC has a multi-dimensional scale comprising 24 items grouped into three dimensions: pain (5 items), stiffness (2 items), and  | 0-100  | Higher scores = worse health status   | No published references when applied to FAIS.  |

| Outcome measure                  | Assessed By | Components  | Score range | Interpretation                         | MCID   |
|----------------------------------|-------------|---|-------------|--|--|
|                                  |             | physical function (17 items). The test is scored on a Likert scale, and the final scores are standardized to a 0-100 scale.   |             |  | For adult patients undergoing THA for hip OA <sup>165</sup> :<br>WOMAC-pain: 21.38<br>WOMAC-function: 11.93<br>WOMAC-stiffness: 27.98      |
| Non-arthritis Hip Score (NAHS)   | Patient     | NAHS evaluates function with four domains: pain (5 items, 20 points), physical function (5 items, 20 points), mechanical symptoms (4 items, 16 points), and level of activity (6 items, 24 points). The final score is obtained by multiplying the total points by 1.25 | 0-100       | Higher scores = increased hip function | There are no reports of MCID for the NAHS score that we are aware of.  |
| Quality of Life Outcome Measures |             |   |             |  |  |
| EQ-5D-3L Index                   | Patient     | 5-dimension survey that assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The test also includes a VAS.  | 0-1         | Higher scores = increased QOL          | No published references when applied to FAIS, hip arthroscopy, or hip labral tears that we are aware of.                                   |
| SF-12                            | Patient     | A shorter version of the SF-36 Health Survey that uses 12 questions to measure functional health and well-being from the patient's point of view. Consists of two component scores; mental and physical.  | 0-100       | Higher scores = increased QOL          | No published references when applied to FAIS.<br><br>For patients with low back pain <sup>43</sup> :<br>SF-12-MCS: 3.77<br>SF-12-PCS: 3.29 |
| Pain Outcome Measures            |             |   |             |  |  |
| VAS                              | Patient     | Measures the amount of pain that a patient feels.   | 0-100       | Higher scores = worse pain             | For adult patients undergoing hip arthroscopy for FAIS: -15 points <sup>127</sup>  |

\*Authors state that it was very difficult to be certain of the validity of this finding because of the large ceiling effects and reduced capacity for change. Therefore they are not able to recommend the use of this subscale of the HAGOS.

## **4.2 Key Question 1: Efficacy and effectiveness**

### **4.2.1 Number of studies retained**

A total of 82 studies (across 84 publications) were identified that met inclusion criteria (

Table 16): four randomized controlled trials (RCTs),<sup>66,106,125,153</sup> 16 observational comparative cohorts,<sup>6,17,21,27,49,84,98,113,135,157, 169,170,179,184,209,215</sup> four systematic reviews (SRs) of case-series,<sup>16,40,139,178</sup> 52 case series (across 54 publications)<sup>14,23,24,26,28,30,38,39,41,46,50,53,60,69,73,77,80,85,91,102,111,115,122,129,133,136,143,148,149,154, 155,158,159,162,176,180,182,186,187,193,204,214</sup>, and three formal cost-effectiveness analyses.<sup>29,37,48,66,73,74,93,118,131,135,143,158,159,190,194,197,198</sup> A total of 14 studies were in pediatric populations and included one observational cohort comparing operative versus non-operative treatment<sup>157</sup>, 11 case series of arthroscopy<sup>23,24,39,41,53,69,115,122,133,162,204</sup> and 2 case series of open hip dislocation surgery<sup>149,193</sup>.

Consistent with the 2011 HTA, the focus of this update report is on the efficacy and effectiveness of operative versus non-operative treatment for FAIS. No RCTs and only one poor quality cohort that compared operative treatment versus non-operative historical controls was identified for the 2011 report. For this update, we identified five new studies comparing operative versus non-operative treatment, three RCTs<sup>66,106,125,153</sup> and two observational comparative cohorts (one of which was in adolescents).<sup>98,157</sup> Studies comparing different surgical approaches for the treatment of FAIS, as well as case series, are included for completeness only and to provide information related to safety primarily. All comparative studies were assessed individually for risk of bias; however, strength of evidence was not done for outcomes related to efficacy or effectiveness for any of the studies evaluating only surgical interventions.

**Table 16. Overview of included studies**

|   | No. of included studies (No. of publications, if applicable) |  |  |                      |                    |
|---|--|--|--|----------------------|--------------------|
|   | RCTs   | Comparative Cohorts  | Case Series  | SRs*                 | Economic Analyses† |
| <b>Key Question 1 (Efficacy/Effectiveness)</b>                            |  |  |  |                      |                    |
| Arthroscopic Surgery vs. Non-operative Treatment                          | 3 <sup>66,125,153</sup>                                      | 2 <sup>98,157</sup>  | 0  | 0                    | -----              |
| Surgery with Labral Repair/Reattachment vs. Labral Debridement/Resection  | 1 <sup>106</sup>   | 5 <sup>6,27,113,135,184</sup>                                  | 0  | 0                    | -----              |
| Arthroscopic Surgery vs. Open Surgical Dislocation                        | 0  | 5 <sup>17,49,170,179,215</sup>                                 | 0  | 0                    | -----              |
| Arthroscopic Surgery with Labral Detachment vs. without Labral Detachment | 0  | 1 <sup>169</sup>   | 0  | 0                    | -----              |
| Open Femoral Osteochondroplasty with Rim Trim vs. without Rim Trim        | 0  | 1 <sup>84</sup>  | 0  | 0                    | -----              |
| Additional included studies addressing KQ1                                | 0  | 0  | 25<br>(26) <sup>24,29,37,38,41,48,53,69,73,74,93,115,118,122,133,135,143,149,158,159,162,193,194,197,198,204</sup> | 2 <sup>139,178</sup> | -----              |
| <b>TOTAL</b>  | 4 <sup>66,106,125,153</sup>                                  | 14 <sup>6,17,27,49,84,98,113,135,157,169,170,179,184,215</sup> | 25<br>(26) <sup>24,29,37,38,41,48,53,69,73,74,93,115,118,122,133,135,143,149,158,159,162,193,194,197,198,204</sup> | 0                    | -----              |
| <b>Key Question 2 (Safety)</b>  |  |  |  |                      |                    |
| Arthroscopic Surgery vs. Non-operative Treatment                          | 3 <sup>66,125,153</sup>                                      | 0  | 0  | 0                    | -----              |
| Arthroscopic Surgery vs. Open Surgical Dislocation                        | 0  | 6 <sup>17,21,49,170,179,215</sup>                              | 0  | 0                    | -----              |
| Surgery with Labral Repair/Reattachment vs. Labral Debridement/Resection  | 0  | 3 <sup>27,113,135</sup>  | 0  | 0                    | -----              |
| Arthroscopic Surgery with Labral Detachment vs. without Labral Detachment | 0  | 2 <sup>169,209</sup>   | 0  | 0                    | -----              |
| Open Femoral Osteochondroplasty with Rim Trim vs. without Rim Trim        | 0  | 1 <sup>84</sup>  | 0  | 0                    | -----              |

|  | No. of included studies (No. of publications, if applicable) |  |  |                            |                         |
|--|--|--|--|----------------------------|-------------------------|
|  | RCTs   | Comparative Cohorts                                      | Case Series  | SRs*                       | Economic Analyses†      |
| Additional included studies addressing KQ2                       | 0  | 0  | 40<br>(42) <sup>14,23,24,28,30,38,41,46,50,53,60,69,73,77,80,85,91,102,111,115,122,129,133,136,143,148,149,154,155,158,159,176,180,182,186,187,193,204,214</sup> | 4 <sup>16,40,139,178</sup> | -----                   |
| TOTAL  | 3 <sup>66,125,153</sup>                                      | 12 <sup>17,21,27,49,84,113,135,169,170,179,209,215</sup> | 40<br>(42) <sup>14,23,24,28,30,38,41,46,50,53,60,69,73,77,80,85,91,102,111,115,122,129,133,136,143,148,149,154,155,158,159,176,180,182,186,187,193,204,214</sup> | 4 <sup>16,40,139,178</sup> | -----                   |
| <b>Key Question 3 (Differential Efficacy)‡</b>                   |  |  |  |                            |                         |
| Arthroscopic Surgery vs. Non-operative Treatment                 | 2 <sup>66,153</sup>  | 0  | 0  | 0                          | -----                   |
| <b>Key Question 4 (Economic)</b>                                 |  |  |  |                            |                         |
| Arthroscopic Surgery vs. Non-operative Treatment                 | -----  | -----  | -----  | -----                      | 3 <sup>66,131,190</sup> |
| <b>Total # of included studies: 79 studies (81 publications)</b> | <b>4</b>   | <b>16 (16)</b>   | <b>52 (54)</b>   | <b>4</b>                   | <b>3</b>                |

KQ = Key Question; RCT = randomized controlled trials; SRs = systematic reviews (including meta-analyses).

\*SRs of case series included for safety and for conversion to THA only.

†Only formal cost-effectiveness or cost-utility studies were considered.

‡For this key question, only RCTs that stratified on baseline patient characteristics and evaluated effect modification were considered.

#### 4.2.2 Operative vs. Non-operative Treatment

##### Studies included

A total of five studies were identified that compared operative versus non-operative treatment which included three RCTs comparing arthroscopy versus physical therapy in adults<sup>66,125,153</sup> and two observational cohort studies, one in adults<sup>98</sup> and one in adolescent athletes,<sup>157</sup> comparing arthroscopy versus different conservative management strategies (activity modification and non-steroidal anti-inflammatory drugs in the adult study and a formal PT program with or without intraarticular steroid injection in the adolescent study). Of note, one of the RCTs was conducted in a military population (Tricare beneficiaries) and had a high rate of crossover from the non-operative to the arthroscopy group.<sup>125</sup>

##### Summary of results

- One RCT reported that more arthroscopy patients compared with physical therapy (PT) patients achieved clinically important improvements in function according to the Hip Outcome Score Activities of Daily Living (HOS-ADL) subscale: minimal clinically important difference (MCID)  $\geq 9$  points (51% vs. 32%; RR 1.6, 95% CI 1.1 to 2.3) and final score  $> 87$  points (48% vs. 19%; RR 2.5, 95% CI 1.5 to 4.0) (SOE: low) short term (8 months).

- Improvement favoring arthroscopy versus PT was seen for function based on the International Hip Outcome Tool (iHOT-33) (3 RCTs; pooled MD 1.94 on a 0-100 scale, 95% CI 0.13 to 3.03,  $I^2=0\%$ ) and the HOS-Sport subscale (2 RCTs; pooled MD 10.98 on a 0-100 scale, 95% CI 5.67 to 16.30,  $I^2=0\%$ ) at 6 to 8 months; however, only the difference on the HOS-Sport subscale is likely clinically significant. (SOE: low)
- No clear difference between groups was seen for functional outcomes at any other timepoint measured: i-HOT-33 at 12 months (2 trials) and 24 months (1 trial), and no difference the HOS-ADL and HOS-Sport subscales at 12 and 24 months in one RCT. (SOE: low for the i-HOT-33 at 12 months; insufficient for the i-HOT-33 at 24 months and the HOS-ADL and -Sport subscales at both timepoints).
- Greater improvement in pain based on the Copenhagen hip and groin outcome score (HAGOS) was reported by patients who received arthroscopy versus PT at 8 months (adjusted MD 12.7, 95% CI 8.1 to 17.2) in one RCT; the difference may be clinically important, but the confidence interval is wide. This same trial found that fewer arthroscopy patients reported pain on hip flexion, hip adduction and the FABER test but there were no differences between groups on other assessments; clinical relevance of differences is unclear. (SOE: low).
- Across two RCTs, two patients (1.0%) in the arthroscopy groups compared with no patient who received PT required conversion to total hip arthroplasty (THA) over 12 and 24 months; sample size and follow-up likely impacted the ability to adequately capture this event (SOE: insufficient).
- Two observational studies at moderately high risk of bias, one in adults and one in adolescents, reported similar functional results between patients who went on to have arthroscopy versus those who received conservative care only based on the modified Harris Hip Score (2 studies), Non-Arthritic Hip Score (NAHS, 2 studies) and the Western Ontario and McMasters Osteoarthritis Index (1 study) at a mean of 27 months. In the study evaluating adolescent athletes, there was no difference between treatment groups (arthroscopy versus PT with or without steroid injection) in the proportion of patents who returned to sport.
- No comparative long-term evidence ( $\geq 5$  years) regarding comparative benefit of operative versus non-operative care was identified.
- The characteristics and frequency of non-operative care sessions varied across studies and in general, components of postoperative rehabilitation were not specified. The impact of these on results is unknown.

#### 4.2.2.1 **Randomized controlled trials**

Three trials that met inclusion criteria were identified which compared operative treatment with non-operative treatment for FAIS in adult populations.<sup>66,125,153</sup> The longest follow-up reported was 24 months (short term); no studies reported on long-term ( $\geq 5$  years) outcomes comparing operative versus non-operative treatment.

#### **Study characteristics**

##### *Inclusion criteria*

Age was restricted to 18 to 60 years in two trials<sup>125,153</sup>; in the third, patients at least 16 years old (with no upper limit on age) were eligible for enrollment.<sup>66</sup>

All patients had to be symptomatic with clinical and radiographic evidence of FAI. However, only the trial by Mansell et al.<sup>125</sup> stated specific criteria used to confirm a clinical diagnosis of FAI, which included a combination of all the following physical examination findings: self-reported pain in the anterior hip or groin, pain reproduced with passive or active flexion, a position FADIR (flexion, adduction, internal rotation) test and subjective relief of pain after intra articular injection. All types of FAI morphology were included (cam, pincer or mixed cam and pincer). Radiographic criteria differed somewhat across two of the trials, with the presence of cam-type FAI defined as an alpha angle greater than 55 degrees<sup>66</sup> or greater than 50 degrees.<sup>125</sup>; for pincer-type FAI, criteria in one trial<sup>66</sup> included a lateral center edge angle of greater than 40 degrees or a positive crossover sign on anteroposterior (AP) radiograph while the other specified only a positive crossover sign (on AP radiograph, CT or MRI).<sup>125</sup> In the third RCT by Palmer et al.,<sup>153</sup> no quantitative radiographic assessment was performed; instead the authors state the following: “Owing to the absence of agreed diagnostic thresholds and to improve generalizability of our study findings, we did not use quantitative imaging measurements as inclusion criteria for this study. Instead, surgeons qualitatively assessed hip morphology to diagnose FAI.” Only one trial required that patients had failed conservative medical management (i.e., 6 weeks of non-steroidal anti-inflammatory drugs, education, and exercise handouts)<sup>125</sup> and in two trials only patients who had not completed a standardized physical therapy program targeting FAI in the previous 6 months<sup>125</sup> or 12 months<sup>153</sup> were eligible (in order to counter selection bias towards patients who have failed prior intervention as reported by one trial<sup>153</sup>). Conversely, the third trial included patients who may have already failed a course of physical therapy; however, the authors did not provide information on how many patients this may have applied to.<sup>66</sup> For all inclusion criteria see Table 17.

#### *Exclusion criteria*

In all trials, patients with preexisting osteoarthritis (OA) and previous hip surgery were excluded. One trial also specifically excluded patients with hip dysplasia<sup>153</sup>. As stated above, two studies excluded patients who had undergone a physical therapy program within 6 or 12 months of enrollment.<sup>125,153</sup> For all exclusion criteria see Table 17.

#### *Patient characteristics*

Across the three RCTs, sample sizes ranged from 80 to 348 and the mean patient age was similar (31 to 36 years); males comprised the majority of the populations in two trials (59% and 61%)<sup>66,125</sup> but only 34% in the third trial,<sup>153</sup> Table 17. Symptom duration was a mean 3.2 years in one trial and in a second trial, 54% of patients reported symptoms for greater than 2 years prior to enrollment; the third trial did not report duration of symptoms.<sup>153</sup> In two RCTs, patients underwent treatment for primarily cam-type FAI (75% and 94%), followed by mixed-type and pincer-type; the third trial did not report the specific types of FAI in its population but it did not exclude any specific morphology.<sup>125</sup> In one trial, 8% of patients presented with bilateral hip symptoms; only the most symptomatic hip was assigned to treatment.<sup>66</sup> Patients were followed for a total of 8 months,<sup>153</sup> 12 months<sup>66</sup> and 24 months<sup>125</sup> in the three trials.

#### *Treatments*

Details of specific operative and non-operative treatments performed can be found in Table 18. All procedures were done via a standard arthroscopic approach and involved bone reshaping as well as repair or debridement of labral pathology in most cases; in the trial by Palmer et al., nine patients (9%) had only procedures to fix the labrum. Non-operative treatment involved individualized, supervised physical therapy programs in all trials, with a home therapy component in two trials,<sup>66,125</sup> though the specific therapy components varied across the trials. The number of sessions attended also varied with



most patients attending at least six sessions up to a total of 12 sessions. Sessions generally lasted 30 to 45 minutes with initial treatment session lasting longer.

### *Risk of bias*

Two RCTs were considered moderately low<sup>66,153</sup> and one was considered moderately high risk of bias.<sup>125</sup> In all trials outcomes were patient-reported and patients could not be blinded to the treatments received; additionally, in the trial rated moderately high risk of bias, loss-to follow-up and between group loss-to-follow-up were higher than acceptable and there was a high rate of crossover from non-operative treatment to arthroscopy.<sup>125</sup> For details related to risk of bias, see Appendix E.

**Table 17. Demographics and inclusion and exclusion criteria in RCT comparing operative versus non-operative treatment for FAI**

|  | Griffin 2018<br>[UK FASHION trial]   |                         | Mansell 2018   |                | Palmer 2019<br>[FAIT trial]                          |                          |
|--|--|-------------------------|--|----------------|--|--------------------------|
|  | Arthroscopy<br>(n=171)   | PT<br>(n=177)           | Arthroscopy<br>(n=40)  | PT<br>(n=40)   | Arthroscopy<br>(n=112)                               | PT<br>(n=110)            |
| Mean age   | 35 years   | 35 years                | 31 years   | 30 years       | 36 years   | 36 years                 |
| Male (%)   | 58%  | 64%                     | 65%  | 53%            | 34%  | 34%                      |
| Mean duration of symptoms                              | 3.1 years  | 3.3 years               | >2 years:<br>55%*  | >2 years: 53%* | NR   | NR                       |
| Cam/pincer/<br>mixed-type<br>FAI (%)                   | 75%/8%/17%   | 75%/8%/17%              | NR†  | NR†            | 93%/1%/6%  | 94%/0%/6%                |
| Hip laterality:<br>right/left (%)                      | 56%/44%‡   | 58%/42%‡                | 48%/52%  | 73%/27%        | 60%/40%  | 54%/46%                  |
| Median time from<br>random-<br>ization to<br>treatment | 122 days (IQR,<br>80–185)  | 37 days (IQR,<br>22–60) | NR   | NR             | 86 days (IQR,<br>5–435)                              | 44 days (IQR,<br>14–251) |
| <b>INCLUSION CRITERIA</b>                              |  |                         |  |                |  |                          |
| Age  | ≥16 years  |                         | 18–60 years  |                | 18–60 years  |                          |
| Type of FAI  | Cam, pincer or mixed<br>(see imaging criteria below)                               |                         | Cam, pincer, or mixed†<br>(see imaging criteria below)   |                | Cam, pincer or mixed<br>(see imaging criteria below) |                          |
| Pain   | Yes – “hip pain”; may also have<br>symptoms of clicking, catching<br>or giving way |                         | Yes – self-reported anterior hip<br>or groin pain and pain<br>reproduced with passive or<br>active flexion             |                | Yes – “symptomatic”                                  |                          |
| Failed<br>conservative<br>treatment                    | NR   |                         | Yes – failed 6 weeks of<br>conservative management<br>(NSAIDs, profile, patient<br>education and exercise<br>handouts) |                | NR   |                          |
| Failed<br>previous PT                                  | Unclear§   |                         | No (see exclusion criteria)  |                | No (see exclusion criteria)                          |                          |

|                           | Griffin 2018<br>[UK FASHION trial]  |               | Mansell 2018   |              | Palmer 2019<br>[FAIT trial]  |               |
|---------------------------|---|---------------|--|--------------|--|---------------|
|                           | Arthroscopy<br>(n=171)  | PT<br>(n=177) | Arthroscopy<br>(n=40)  | PT<br>(n=40) | Arthroscopy<br>(n=112)   | PT<br>(n=110) |
| Positive impingement      | Unclear – clinical examination performed (specifics not reported)   |               | Yes – positive FADIR test  |              | Unclear – FAI confirmed clinically (specifics not reported)  |               |
| Positive imaging sign     | Yes – alpha angle >55° and/or a lateral center edge angle of >40° or a positive crossover sign on AP radiograph   |               | Yes – alpha angle >50°and/or positive crossover sign (on CT, radiograph and MRI)   |              | Unclear – via qualitative assessment of imaging only (radiograph and MRI)**  |               |
| Intra-articular injection | NR  |               | Yes – Subjective relief of pain after intra-articular injection  |              | NR   |               |
| Other                     | <ul style="list-style-type: none"><li>• Able to give informed consent</li><li>• Treating surgeon believed patient was likely to benefit from hip arthroscopy</li></ul>  |               | <ul style="list-style-type: none"><li>• Tricare beneficiaries</li></ul>  |              | <ul style="list-style-type: none"><li>• Able to give informed consent</li></ul>  |               |
| EXCLUSION CRITERIA        |   |               |  |              |  |               |
| Preexisting OA            | Yes – Tonnis grade >1 or <2mm of superior joint space on an AP radiograph   |               | Yes – joint space narrowing <2mm   |              | Yes – Kellgren–Lawrence grade ≥2††   |               |
| Hip dysplasia             | No  |               | No   |              | Yes, center-edge angle <20 degrees   |               |
| Previous surgery‡‡        | Yes (shape-changing surgery, open or arthroscopic)  |               | Yes  |              | Yes  |               |
| Previous PT               | No  |               | Yes, within prior 6 months   |              | Yes, within prior 12 months  |               |
| Other                     | <ul style="list-style-type: none"><li>• History of previous hip injury (e.g., acetabular fracture, hip dislocation, or femoral neck fracture)</li><li>• History of hip pathology (e.g., Perthes’ disease, slipped upper femoral epiphysis, or avascular necrosis)</li></ul> |               | <ul style="list-style-type: none"><li>• Other concurrent systemic disease that may affect the condition</li><li>• Pending litigation/workmen’s compensation</li><li>• Will be moving within following 6 months</li><li>• Clearing the lumbar spine reproduces the patient’s hip symptoms</li><li>• Inability to provide informed consent</li><li>• Unable to speak or write in English</li></ul> |              | <ul style="list-style-type: none"><li>• Medical conditions that prevent surgical intervention</li><li>• Contraindications to MRI</li></ul> |               |

AP = anterior-posterior; CT = computed tomography; FAI = femoroacetabular impingement; IQR = interquartile range; MRI = magnetic resonance imaging; NSAIDs = non-steroidal anti-inflammatory drugs; OA = osteoarthritis; PT = physical therapy.

\*The duration of symptoms in those who actually underwent surgery differed between groups: only 14.3% of the no-surgery group had symptoms >2 years compared with 62.1% of the surgery group.

†Given radiographic inclusion criteria all types of FAI were eligible; authors other state that patients were required to have a clinical diagnosis of FAI and/or labral pathology but do not provide proportions of patients with specific FAI types.

‡6% (11/171) of arthroscopy and 10% (18/177) of non-operative patients had bilateral hip symptoms; only the most symptomatic hip was randomly assigned to treatment and followed up.

§Authors state that they intended to recruit a cohort of typical patients with FAI deemed suitable for arthroscopic surgery; this included patients who may have already received a course of physiotherapy.

\*\*No quantitative assessment was performed; Authors state the following: “Owing to the absence of agreed diagnostic thresholds and to improve generalizability of our study findings, we did not use quantitative imaging measurements as inclusion criteria for this study. Instead, surgeons qualitatively assessed hip morphology to diagnose FAI.”

††Of those randomized, osteoarthritis of Kellgren Lawrence grade 0/1/unknown was present in 80%/15%/5%.

‡‡To symptomatic hip.

**Table 18. Treatment Details for RCTs of Surgery vs. Non-operative Treatment**

|  | <b>Griffin 2018<br/>N=348<br/>[UK FASHION trial]</b>  | <b>Mansell 2018<br/>N=80</b>   | <b>Palmer 2019<br/>N=222<br/>[FAIT trial]</b>  |
|--|---|--|--|
| <b>ARTHROSCOPY, n (%)</b>                              | n=171 randomized;<br>142* treated   | n=40 randomized; 65<br>treated†  | n=99   |
| Femoral Osteochondroplasty                             | ----  | ----   | 66 (67%)   |
| Femoral Osteoplasty †                                  | 105 (74%)   | ----   | ----   |
| Femoroplasty   | ----  | X  | ----   |
| Acetabular Osteochondroplasty                          | ----  | ----   | 5 (5%)   |
| Acetabular Osteoplasty ‡                               | 8 (6%)  | ----   | ----   |
| Acetabuloplasty  | ----  | X  | ----   |
| Femoral and Acetabular<br>Osteochondroplasty           | ----  | ----   | 19 (19%)   |
| Femoral and Acetabular<br>Osteoplasty **               | 26 (18%)  | ----   | ----   |
| Labral Procedure Only                                  | ----  | ----   | 9 (9%)   |
| Labral Repair  | 35 (25%)  | X  | 70 (71%)   |
| Labral Debridement                                     | 57 (40%)  | X  | 25 (25%)   |
| Labral Resection                                       | 5 (4%)  | ----   | ----   |
| Labral Thermal Shrinkage                               | 29 (20%)  | ----   | ----   |
| No Labral Procedure                                    | ----  | ----   | 4 (4%)   |
| Microfracture  | 21 (15%)  | ----   | 9 (9%)   |
| Chondroplasty  | 29 (20%)  | ----   | ----   |
| Chondral Debridement                                   | 10 (7%)   | ----   | ----   |
| Operation time (mins.), median<br>(range)              | ----  | X††  | 55, IQR 45-80 (22-160)   |
| Number of post-surgery PT-<br>sessions, median (range) | ----  | X  | 4, IQR 2.5-6 (1-14)  |
| <b>PHYSICAL THERAPY</b>                                | n=177 randomized;<br>168 treated‡‡  | N=40 randomized,<br>14 treated   | n=96   |
| Individualized   | Yes   | Yes  | Yes  |
| Supervised   | Yes   | Yes  | Yes  |
| Home-therapy component                                 | Yes   | Yes  | NR   |
| Therapy components                                     | (1) assessment of pain,<br>function, and range of<br>hip motion;<br>(2) patient education;<br>(3) progressive<br>exercise | (1) joint mobilizations<br>(2) mobilization with<br>motion<br>(3) therapeutic exercise<br>(4) soft tissue mobility<br>(5) stretching | (1) muscle strengthening<br>to improved core stability<br>and movement control;<br>(2) encouraged to avoid<br>impingement positions<br>(extremes of hip flexion, |

|  | Griffin 2018<br>N=348<br>[UK FASHION trial]                                       | Mansell 2018<br>N=80   | Palmer 2019<br>N=222<br>[FAIT trial]   |
|--|---|--|--|
|  | (4) help with pain relief when pain prevents performance of the exercise program§ | (6) motor control exercises<br>(7) hip mobilization<br>(8) other treatment interventions implemented at the discretion of the physical therapist | abduction, internal rotation)          |
| Number of sessions attended            | ≥6: 64% (n=100)<br>Range, 6-10  | 12 sessions  | Median 6 (IQR 4-8);<br>Range, 1-8      |
| Duration of first session (mins.)      | NR  | 45   | Median 60 (IQR 60-60);<br>Range, 30-95 |
| Duration of follow-up sessions (mins.) | Mean 30 (SD 11)§§   | 45   | Median 30 (IQR 30-30);<br>Range, 20-60 |

IQR=Interquartile range; NR=not reported; PT=physical therapy

\*144 patients (of 171) received their surgery within 12 months of randomisation. Operation notes were available for review in 142 patients.

†Surgery involved one or more of the following procedures that are marked with an X.

‡cam only resection

‡pincer only resection

§Could include one X-ray or ultrasound-guided intra-articular steroid injection

\*\*combined cam and pincer resection

††Typical surgery time is approximately 2 h in duration; surgery time may fluctuate up to 60 min depending on the complexity of the surgery ‡‡14 of 168 received most or all of the personalised hip therapy sessions and then went on to receive hip arthroscopy per their request. 9 patients received no treatment.

§§With the first assessment and treatment session usually lasting longer.

## ***Efficacy Results***

All analyses are based on intention-to-treat (ITT) analyses unless otherwise indicated.

## **Primary Outcomes**

### **Function**

Only one RCT<sup>153</sup> reported the proportion of patients who achieved a clinically meaningful improvement in function; based on the Hip Outcomes Score Activities of Daily Living (HOS-ADL) subscale more patients who received arthroscopy compared with PT achieved a minimal clinically important difference (MCID) of at least 9 points, but the effect size was small and approached the null value of 1 (51% vs. 32%; risk ratio [RR] 1.6, 95% confidence interval [CI] 1.1 to 2.3), and a patient acceptable symptom state (PASS), i.e. a score of >87 points (48% vs. 19%; RR 2.5, 95% CI 1.5 to 4.0), at 8 months post-randomization.

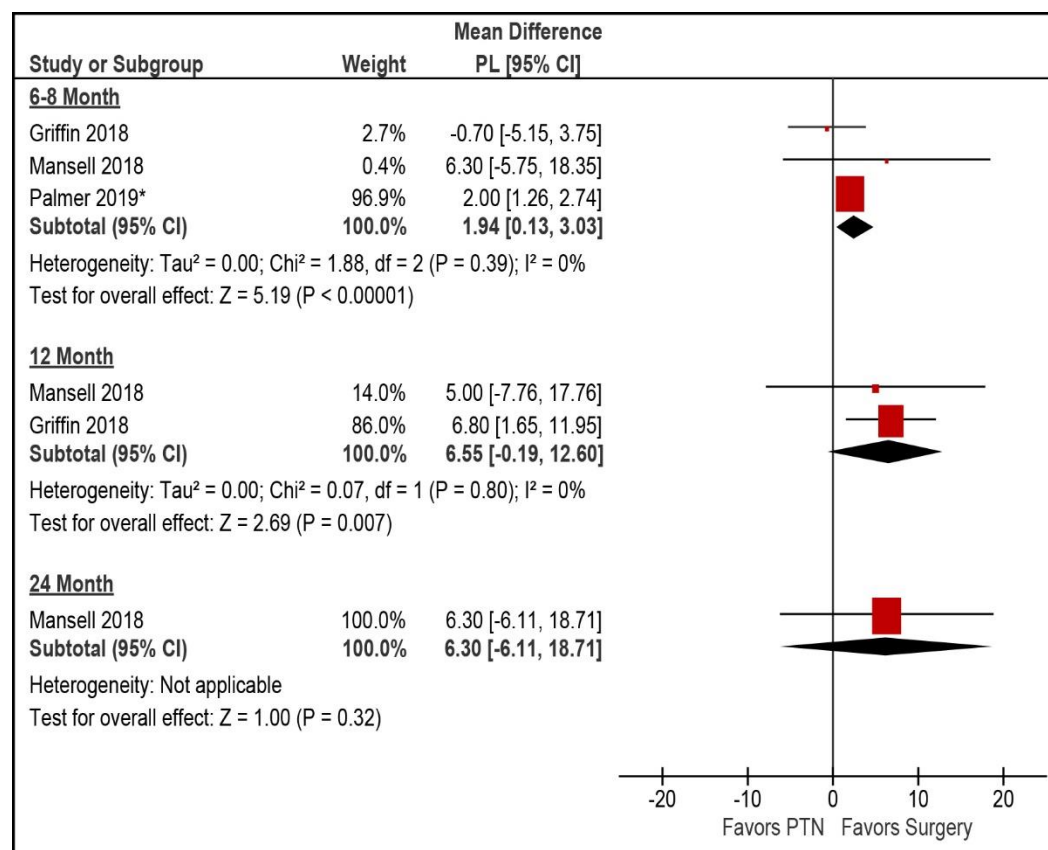
All three RCTs reported mean scores at follow-up. At 6 to 8 months (short-term), the pooled estimate showed statistically significant improvement in function favoring arthroscopy versus PT based on the International Hip Outcome Tool (iHOT-33) (3 RCTs; pooled mean difference [MD] 1.94 on a 0-100 scale, 95% CI 0.13 to 3.03,  $I^2=0\%$ ),<sup>66,125,153</sup> (Figure 4) and the HOS-Sport subscale (2 RCTs; pooled MD 10.98 on a 0-100 scale, 95% CI 5.67 to 16.30,  $I^2=0\%$ )<sup>125,153</sup> (Figure 5); however, only the difference on the HOS-Sport subscale is likely clinically significant. No difference between groups was seen for the HOS-ADL subscale (scale 0-100) when data were pooled (2 RCTs; pooled MD 6.26, 95% CI -6.52 to 16.96,  $I^2=77\%$ ),<sup>125,153</sup> possibly due to large statistical heterogeneity (Figure 6); individually, the bigger trial did find a statistically significant difference between groups at 8 months favoring arthroscopy which may be

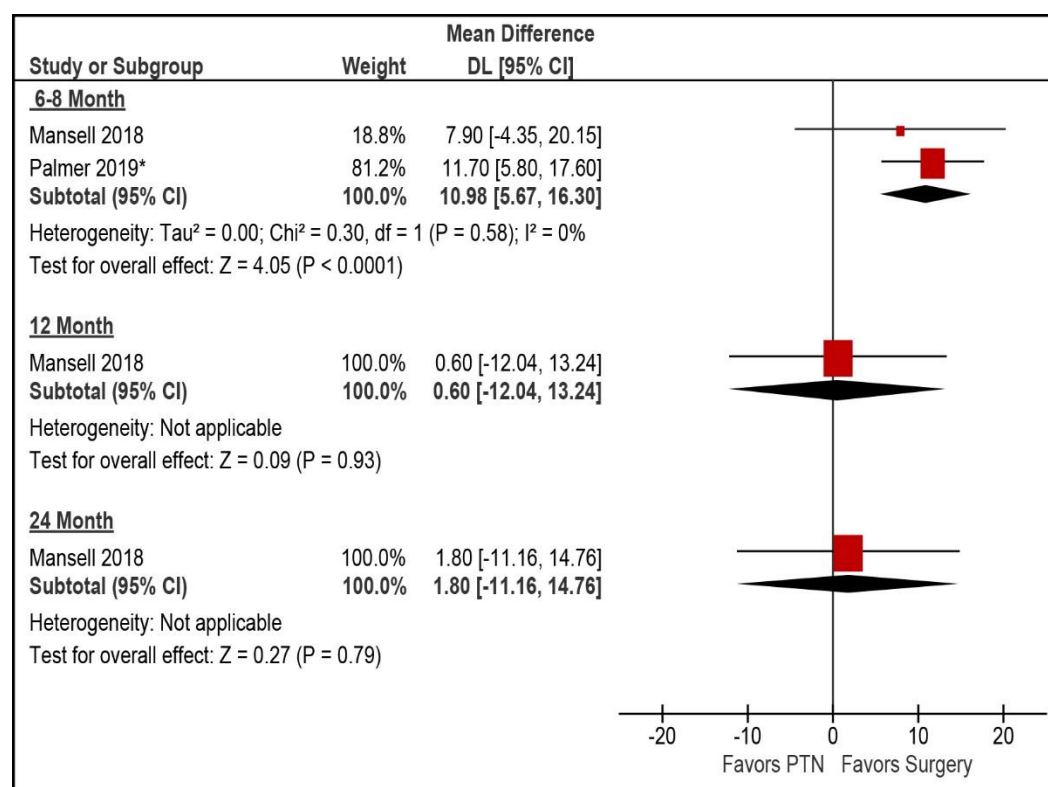
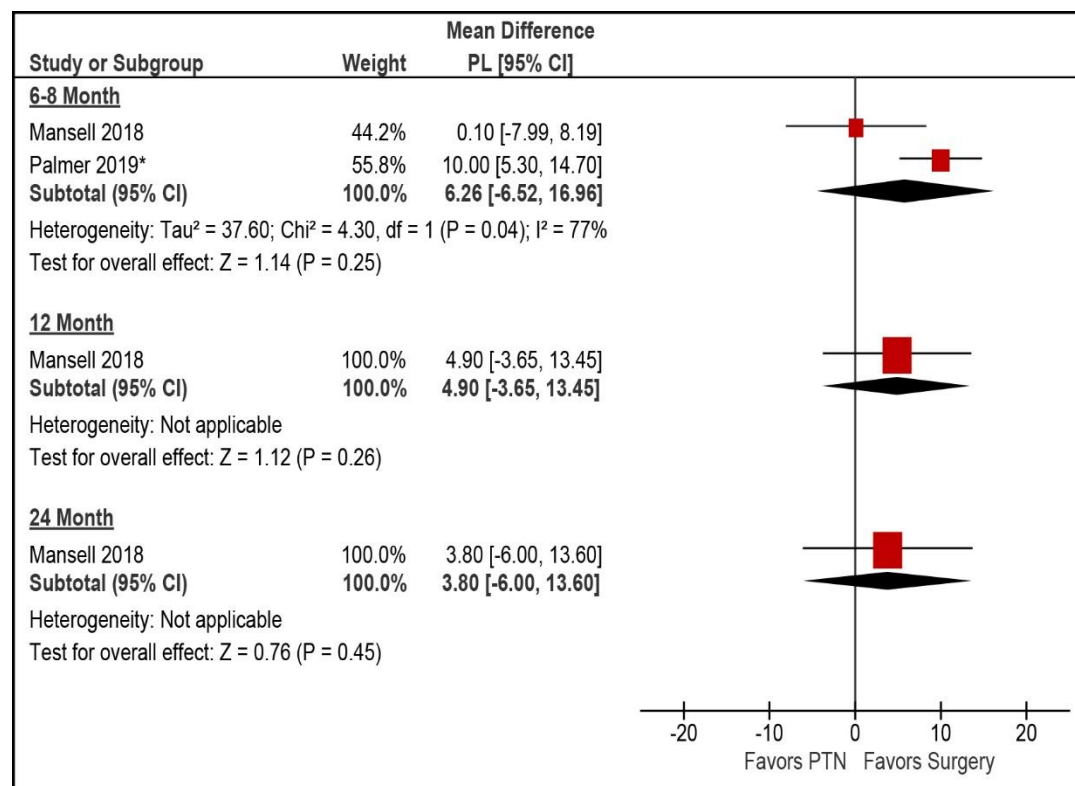
clinically meaningful (MD 10.0, 95% CI 5.30 to 14.70).<sup>153</sup> One trial<sup>153</sup> reported a variety of other functional measures at 8 months and found that arthroscopy resulted in greater improvement compared with PT on all of them, some of which may be clinically meaningful (Table 19).

At 12 months, no clear difference between groups was seen across two trials reporting the iHOT-33 (pooled MD 6.55, 95% CI –0.19 to 12.6  $I^2=0\%$ )<sup>66,125</sup> (Figure 4); the larger of the two trials<sup>66</sup> reached statistical significance favoring arthroscopy but the clinical relevance of the difference is unclear. In one smaller trial,<sup>125</sup> there was no difference at 12 months between arthroscopy versus PT on the HOS-ADL (MD 4.90, 95% CI –3.65 to 13.45) and HOS-Sport (MD 0.60, 95% CI –12.04 to 13.24) subscales (Figure 5 and Figure 6).

Only the smaller RCT<sup>125</sup> reported outcomes at 24 months and found no statistical difference between groups in any functional measure evaluated: i-HOT-33 (MD 6.30, 95% CI –6.11 to 18.71), HOS-ADL subscale (MD 3.80, 95% CI –6.00 to 13.60), and the HOS-Sport subscale (MD 1.80, 95% CI –11.16 to 14.76), Figure 4, Figure 5, Figure 6. Of note, this trial had an extremely high rate of crossover (70%) from PT to arthroscopy by a mean of 7 months post-randomization affecting the power of the study and therefore limiting the ability to draw definitive conclusions; a sensitivity analysis evaluating patients as-treated found similar results as the ITT analysis.

**Figure 4. Function: results across RCTs for the i-HOTT-33.**



**Figure 5. Function: results across RCTs for the HOS-Sport subscale.****Figure 6. Function: results across RCTs for the HOS-ADL subscale.**

## Pain

Two RCTs reported on short-term pain though their methods of measurement differed.

One RCT<sup>153</sup> found that patients who underwent arthroscopy reported greater improvement in pain at 8 months post-randomization compared with those who received PT according to the Copenhagen hip and groin outcome score (HAGOS) pain subscale (adjusted MD 12.7; 95% CI 8.1 to 17.2) and the PainDetect measure (which is a measure of neuropathic pain) (adjusted MD –2.1, 95% CI –4 to –0.2) after adjusting for baseline scores, sex, age at randomization, and time from randomization. In this same trial, fewer patients in the arthroscopy group had pain on flexion (47% vs. 66%; RR 0.72, 95% CI 0.56 to 0.93), adduction (31% vs. 46%; RR 0.67, 95% CI 0.46 to 0.97), and during the FAbER test, i.e., flexion, abduction and external rotation, at 8 months (44% vs. 62%; RR 0.71, 95% CI 0.53 to 0.94) but there were no statistical differences between groups on the other clinical hip assessment tests (Table 19).

A second RCT<sup>125</sup> reported prescription opiate pain medication use at 24 months and found no difference between groups on any metric analyzed (Table 19); confidence intervals were very wide.

## Total hip arthroscopy (THA)

Across two RCTs,<sup>66,125</sup> a total of two patients (1 in each trial) required conversion to THA both of which had received arthroscopy: 1.0% (2/203) versus 0% (0/160) following PT only over follow-up periods of 12 and 24 months. The difference between groups was not statistically significant; follow-up may not have been long enough to adequately capture this outcome. Additionally, sample sizes may not have been sufficient to identify this.

**Table 19. Function and pain outcomes not included in meta-analyses from RCTs comparing arthroscopy vs. physiotherapy for FAIS**

| Author, year<br>F/U length                      | Outcome*                                      | Arthroscopy vs. Physiotherapy<br>MD or RR (95% CI)†, no. patients |                                |
|---|---|---|--------------------------------|
| Function  |   |   |                                |
| Palmer 2019<br>(N=222)<br><br>F/U: 8<br>months‡ | HOS-ADL, % achieving:<br><br>MCID (≥9 points) | RR 1.6 (1.1 to 2.3)   | n=51/100 (51%) vs. 28/88 (32%) |
|   | PASS (HOS-ADL score >87 points)               | RR 2.5 (1.5 to 4.0)   | n=48/100 (48%) vs. 17/88 (19%) |
|   | Patient-expected improvement                  | RR 2.1 (1.2 to 3.8)   | n=31/100 (31%) vs. 13/88 (15%) |
|   | OHS (12-60)                                   | adj. MD 5.3 (3.2 to 7.5)  | n=92 vs. 87                    |
|   | NAHS (0-100)                                  | adj. MD 11.2 (6.8 to 15.7)  | n=91 vs. 78                    |
|   | UCLA (0-10)                                   | adj. MD 0.6 (0.1 to 1.0)  | n=92 vs. 88                    |
|   | HAGOS – ADL subscale (0-100)                  | adj. MD 11.6 (6.7 to 16.6)  | n=92 vs. 88                    |
|   | HAGOS – Sport subscale (0-100)                | adj. MD 13.1 (7.0 to 19.1)  | n=92 vs. 88                    |
|   | HAGOS – PA subscale (0-100)                   | adj. MD 14.6 (7.2 to 22.0)  | n=91 vs. 88                    |
|   | HAGOS – Symptoms subscale (0-100)             | adj. MD 13.3 (8.1 to 18.6)  | n=92 vs. 88                    |



| Author, year<br>F/U length                      | Outcome*  | Arthroscopy vs. Physiotherapy<br>MD or RR (95% CI)†, no. patients |                               |
|---|---|---|-------------------------------|
| Pain  |   |   |                               |
| Palmer 2019<br>(N=222)<br><br>F/U: 8<br>months‡ | HAGOS – Pain subscale (0-100)                     | adj. MD 12.7 (8.1 to 17.2)  | n=92 vs. 88                   |
|   | PainDetect (0-35)                                 | adj. MD -2.1 (-4 to -0.2)   | n=61 vs. 62                   |
|   | Hip assessment tests:                             |   |                               |
|   | Pain on flexion (%)                               | RR 0.72 (0.56 to 0.93)  | n=46/97 (47%) vs. 56/85 (66%) |
|   | Pain on extension (%)                             | RR 0.64 (0.38 to 1.1)   | n=18/97 (19%) vs. 24/83 (29%) |
|   | Pain on abduction (%)                             | RR 0.74 (0.55 to 1.0)   | n=41/97 (42%) vs. 48/84 (57%) |
|   | Pain on adduction (%)                             | RR 0.67 (0.46 to 0.97)  | n=30/97 (31%) vs. 39/84 (46%) |
|   | Pain on internal rotation (%)                     | RR 0.81 (0.61 to 1.08)  | n=44/97 (45%) vs. 47/84 (56%) |
|   | Pain on external rotation (%)                     | RR 0.79 (0.53 to 1.2)   | n=30/97 (31%) vs. 33/84 (39%) |
|   | Positive FAdIR test (%)                           | RR 0.93 (0.79 to 1.09)  | n=70/96 (73%) vs. 66/84 (79%) |
| Positive FAbER test (%)                         | RR 0.71 (0.53 to 0.94)                            | n=42/96 (44%) vs. 52/84 (62%)                                     |                               |
| Mansell 2018<br>(N=79)<br><br>F/U: 24<br>months | Prescription opiate pain medication use:          |   |                               |
|   | Number of day’s supply                            | MD 6.5 (-98.4 to 111.4)   | n=40 vs. 39                   |
|   | Number of unique prescriptions                    | MD -0.8 (-7.0 to 5.4)   | n=40 vs. 39                   |
|   | Number of days to last prescription from baseline | MD -116.7 (-258.1 to 24.7)  | n=40 vs. 39                   |

FAdIR = pain on flexion, adduction, and internal rotation; FAbER = pain on flexion, abduction, and external rotation; HADS = Hospital Anxiety and Depression Scale; HAGOS=Copenhagen hip and groin outcome score; NAHS = non-arthritis hip score; OHS = Oxford hip score; PA = physical activities; QoL = quality of life; THA = total hip arthroplasty; UCLA = University of California at Los Angeles activity score

\*Higher values indicate better outcomes, with the exception of PainDetect, number of unique prescription for which lower values indicate better outcomes.

†For Palmer, with the exception of the hip assessment tests, all outcomes are adjusted for baseline activities of daily living subscale of HOS, sex and age at randomization, time from randomization (continuous), together with quadratic term; data measured up to 10 months post-randomization included in analysis. RRs calculated by AAI.

‡Post-randomization (around 6 months post-intervention).

## Secondary Outcomes

### Quality of life (QoL), mental health

All three trials reported different measures evaluating patient QoL or mental health at various timepoints (Table 20); the only statistically significant difference seen was for the Hospital Anxiety and Depression Scale (HADS) Depression score in one trial which showed greater improvement in depressive symptoms at 8 months after arthroscopy compared with PT (adjusted MD -1.3; 95% CI -2.2 to -0.4).<sup>153</sup>



### Other outcomes

One smaller RCT found no statistical difference between groups in the risk of progression to osteoarthritis (OA) over 24 months of follow-up, though the frequency was somewhat higher following arthroscopy versus PT (13% vs. 8%; RR 1.7; 95% 0.4 to 6.7); results were similar when patients were evaluated as treated.<sup>125</sup> This same trial, conducted in a military population, reported that fewer patients who underwent arthroscopy were still on active duty (44% vs. 63%) and that more were on medical leave due to hip related problems (44% vs. 24%) compared with patients who received PT, though the difference did not reach statistical significance for either measure likely due to the small sample size. When analyzed according to the actual treatment received, the groups were similar (Table 20).

A second RCT evaluated hip range of motion 8 months post-randomization; only flexion differed statistically between the two treatment groups favoring arthroscopy (Table 20).

**Table 20. Secondary outcomes reported by RCTs comparing arthroscopy vs. physiotherapy for FAIS**

| Author, year                               | Outcome (scale)*                              | Arthroscopy vs. Physiotherapy<br>MD or RR (95% CI)† |                               |
|--|---|---|-------------------------------|
| Quality of Life, Mental health             |   |   |                               |
| Griffin 2018‡<br>(N=348)                   | SF-12 PCS (0-100)<br>6 months                 | adj. MD −0.7 (−2.1 to 0.7)                          | n=146 vs. 142                 |
|  | 12 months                                     | adj. MD 1.1 (−0.2 to 2.5)                           | n=145 vs. 132                 |
|  | SF-12 MCS (0-100)<br>6 months                 | adj. MD −0.1 (−1.5 to 1.3)                          | n=146 vs. 142                 |
|  | 12 months                                     | adj. MD 0.4 (−1.2 to 2.0)                           | n=145 vs. 132                 |
| Palmer 2019§<br>(N=222)<br>F/U: 8 months** | HAGOS – QoL subscale (0-100)                  | adj. MD 13.2 (7.5 to 19.0)                          | n=91 vs. 88                   |
|  | HADS anxiety (0-21)                           | adj. MD −0.6 (−1.4 to 0.3)                          | n=91 vs. 88                   |
|  | HADS depression (0-21)                        | adj. MD −1.3 (−2.2 to −0.4)                         | n=91 vs. 88                   |
| Mansell 2018<br>(N=80)<br>F/U: 24 months   | GRC (−7 to 7); % meeting MCID<br>of ≥3 points |   |                               |
|  | As randomized                                 | RR 0.94 (0.55 to 1.6)                               | n=15/37 (41%) vs. 16/37 (43%) |
|  | As treated                                    | RR 1.8 (0.7 to 5.0)                                 | n=28/62 (45%) vs. 3/12 (25%)  |
| Progression to OA                          |   |   |                               |
| Mansell 2018<br>(N=80)<br>F/U: 24 months   | As randomized                                 | RR 1.7 (0.4 to 6.7)                                 | n=5/39 (13%) vs. 3/40 (8%)    |
|  | As treated                                    | RR 1.5 (0.2 to 11.3)                                | n=7/65 (11%) vs. n=1/14 (7%)  |
| Range of Motion (degrees)                  |   |   |                               |
| Palmer 2019§<br>(N=222)<br>F/U: 8 months** | Flexion                                       | adj. MD 4.8 (0.5 to 9.1)                            | n=96 vs. 85                   |
|  | Extension                                     | adj. MD 1.6 (−0.6 to 3.8)                           | n=96 vs. 83                   |
|  | Abduction                                     | adj. MD 1.0 (−2.1 to 4.1)                           | n=96 vs. 84                   |
|  | Adduction                                     | adj. MD 1.1 (−1.2 to 3.5)                           | n=96 vs. 84                   |
|  | Internal rotation                             | adj. MD 1.4 (−1.6 to 4.4)                           | n=96 vs. 84                   |
|  | External rotation                             | adj. MD −1.1 (−3.6 to 1.4)                          | n=96 vs. 84                   |
| Return to Work (%)                         |   |   |                               |
| Mansell 2018                               | Still on active military duty                 |   |                               |

| Author, year             | Outcome (scale)*  | Arthroscopy vs. Physiotherapy<br>MD or RR (95% CI)† |                                |
|--------------------------|---|---|--------------------------------|
| (N=80)<br>F/U: 24 months | <i>As randomized</i>                                    | RR 0.70 (0.45 to 1.1)                               | n=15/34 (44%) vs. 24/38 (63%)  |
|                          | <i>As treated</i>                                       | RR 1.1 (0.60 to 2.0)                                | n=33/60 (55%) vs. 6/12 (50%)   |
|                          | Medical separation, hip related<br><i>As randomized</i> | RR 1.9 (0.94 to 3.7)                                | n=15/34 (44%) vs. 9/38 (24%)†† |
|                          | <i>As treated</i>                                       | RR 1.0 (0.42 to 2.4)                                | n=20/60 (33%) vs. 4/12 (33%)   |

FAdIR=pain on flexion, adduction, and internal rotation; FAdER=pain on flexion, adduction, and external rotation; GRC = Global Rating of Change; HADS = Hospital Anxiety and Depression Scale; HAGOS=Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; NAHS=non-arthritis hip score; OA = osteoarthritis; OHS=Oxford hip score; QoL = quality of life; UCLA=University of California at Los Angeles activity score

\*Higher values indicate better outcomes, with the exception of HADS (anxiety and depression) scores and medical separation (return to work) for which lower values indicate better outcomes.

†RRs calculated by AAI.

‡For Griffin, outcomes were adjusted for baseline score, impingement type, sex, and study site.

§For Palmer, with the exception of ROM, all outcomes were adjusted for baseline scores, sex, age, time from randomization, and study site. Data measured up to 10 months post-randomization included in analysis. For ROM, adjusted for baseline only.

\*\*Post-randomization (around 6 months post-intervention).

††Unable to verify reason for separation in 4 patients in PT group vs. 1 in surgery group; these patients are not accounted for in analysis.

#### 4.2.2.2 Cohort studies

Two additional observational comparative cohorts (n=180 hips)<sup>98,157</sup> were identified comparing arthroscopic hip surgery to non-operative treatment for FAIS short-term. One study was in adults (N=87 hips; mean age 45.1 years; 33% female; symptom duration not reported)<sup>98</sup> and the other was in adolescent athletes (N=93 hips; mean age 15.3 years; 65% female; symptom duration 10.7 months).<sup>157</sup> Of note, in the adult study patients who received surgery were younger statistically than those who received non-operative treatment (mean age 41.8 vs. 47.9). The proportion of hips with cam-, pincer-, and mixed-type impingement was 50%, 14% and 36% in the adult population and 29%, 32%, and 39% in the pediatric population, respectively. Only the pediatric study reported the presence of a labral pathology (78% with labral tear); 15% of patients also had an open physis. Neither study reported on degree of OA at enrollment. Mean follow-up was similar across both studies, 26.8 (adults) and 27.5 (pediatric) months.

Across both studies, patients underwent a non-operative treatment protocol prior to being offered arthroscopic hip surgery for FAIS (for those who showed no improvement). The non-operative protocols differed greatly across the two studies and arthroscopic surgical techniques were not extensively described by either study. The study in adults<sup>98</sup> required that patients undergo three months of conservative management, which involved activity modification (avoiding squatting, leg crossing, pivoting, excessive physical activity, and sitting on the floor) and taking NSAIDs (initially twice a day for 6 weeks and thereafter as required). The non-operative protocol did not include physical therapy (PT). A total of 44 hips underwent arthroscopic hip surgery and 53 hips underwent non-operative management only. The study in adolescent athletes<sup>157</sup> required that patients undergo a formal 6-week PT program and disengage in any sporting activities. After completion of PT, patients who could return to sport were instructed to modify their activity, while those who could not return to sport were offered an image-guided intraarticular steroid injection (SI) (40 mg Kenalog). If patients remained unsatisfied after PT and/or SI, they were offered arthroscopic surgery for FAIS. A total of 65 hips underwent PT/modified

activity only, 11 hips underwent PT/modified activity plus SI, and 17 hips underwent PT/modified activity, SI (6 hips did not receive SI), and arthroscopic surgery for FAIS.

Both cohort studies were rated high risk of bias; outcome assessors were not blinded to treatment (patient-reported outcomes), loss-to-follow-up was unable to be determined and studies did not control for confounding factors. For details related to risk of bias assessment, see Appendix E.

### ***Effectiveness Results***

#### **Function (Primary outcome)**

Across both studies, one in adults and one in adolescents (both followed short term for a mean of 27 months), all functional outcomes were similar between patients who went on to have arthroscopy versus those who received conservative care only [modified Harris Hip Score (2 studies), Non-Arthritic Hip Score (NAHS, 2 studies), and the Western Ontario and McMasters Osteoarthritis Index (1 study)] with the exception of the proportion of patients achieving a MCID ( $\geq 8$  point improvement) on the NAHS which was lower in patients treated with PT/activity modification (67%) compared with either arthroscopy (85%) or steroid injection (80%); however the differences were not statistically significant likely due to the small and differing sample sizes between groups,

Table 21. Additionally, in both studies, there were differences between study groups but no adjustment or control for confounding was reported. In the study of adults, patients who ended up undergoing arthroscopy were significantly younger than those who received conservative care only (42 vs. 48 years;  $p=0.02$ ). In the study evaluating adolescent athletes, the arthroscopy group was followed for a statistically longer period of time than either the steroid injection or PT/activity modification group (32 vs. 25 and 26 months, respectively;  $p=0.02$ ). These factors potentially bias reported results. Of note, the study in adults did not include an “active” comparator group; patients were simply directed to modify their activity and to take NSAIDs as needed. Conversely, the adolescent patients did undergo a formal PT program with steroid injections if needed.

Pain and conversion to THA were not reported by either study.

**Return to Sport (Secondary outcome)**

There were no statistically significant differences between treatment groups in the proportion of patients who returned to sport in one study evaluating adolescent athletes, though patients who received arthroscopy tended to be less likely to return to the same sport (

Table 21). As stated above, patients who received arthroscopy were followed statistically longer than the conservatively treated groups.

**Table 21. Nonrandomized observational studies comparing arthroscopy with conservative treatment**

|   | Author                             | Outcome*                         | Arthroscopy   | Conservative Treatment                             | p-value |
|---|------------------------------------|----------------------------------|---------------|--|---------|
| <b>Kekatpure 2017</b><br>(N=87, 102 hips)<br><br><i>Arthroscopy (n=44 hips) vs. Activity modification/ NSAIDs (n=53 hips):</i><br><b>Mean age:</b> 42 vs. 48 years, p=0.02<br><b>Mean F/U:</b> 25 vs. 28 months   | <b>Primary Outcomes (function)</b> | <b>mHHS (0-100)</b>              |               |  |         |
|   |                                    | Baseline (mean)                  | 64.2          | 68.2   | 0.18    |
|   |                                    | Follow-up (mean)                 | 95.7          | 95.8   | 0.92    |
|   |                                    | Good or Excellent result (%)†    | 100% (44/44)  | 98.1% (52/53)                                      | NS      |
|   |                                    | <b>NAHS (0-100)</b>              |               |  |         |
|   |                                    | Baseline (mean)                  | 60.5          | 66.4   | 0.11    |
|   |                                    | Follow-up (mean)                 | 93.7          | 95.7   | 0.09    |
|   |                                    | Good or Excellent result (%)†    | 91.0% (40/44) | 98.1% (52/53)                                      | NS      |
|   |                                    | <b>WOMAC (0-100)</b>             |               |  |         |
|   |                                    | Baseline (mean)                  | 52.1          | 53.5   | 0.65    |
|   |                                    | Follow-up (mean)                 | 91.8          | 90.1   | 0.16    |
|   |                                    | Good or Excellent result (%)†    | 100% (44/44)  | 90.6% (48/53)                                      | NS      |
| <b>Pennock 2018</b><br>(N=76, 93 hips, athletes)<br><br><i>Arthroscopy (n=17 hips)† vs. steroid injection (SI) only (n=11 hips) vs. formal PT/activity modification only (n=65 hips)</i><br><b>Mean age:</b> 15 vs. 17 vs. 15 years<br><b>Mean F/U:</b> 32 vs. 25 vs. 26 months, p=0.02 | <b>Primary Outcomes (function)</b> | <b>mHHS (0-100)</b>              |               |  |         |
|   |                                    | Baseline (mean ± SD)             | 68.4 ± 9.4    | <u>SI</u> : 68.3 ± 12.2<br><u>PT</u> : 69.9 ± 13.9 | 0.89    |
|   |                                    | Follow-up (mean)                 | 89.0 ± 9.9    | <u>SI</u> : 90.0 ± 10.2<br><u>PT</u> : 90.0 ± 11.8 | 0.58    |
|   |                                    | <b>NAHS (0-100)</b>              |               |  |         |
|   |                                    | Baseline (mean)                  | 72.8 ± 10.8   | <u>SI</u> : 72.8 ± 13.7<br><u>PT</u> : 74.1 ± 16.3 | 0.81    |
|   |                                    | Follow-up (mean)                 | 86.7 ± 13.1   | <u>SI</u> : 86.3 ± 10.4<br><u>PT</u> : 87.1 ± 14.3 | 0.46    |
|   |                                    | MCID (≥ 8 point improvement) (%) | 85% (11/13)   | <u>SI</u> : 80% (8/10)<br><u>PT</u> : 67% (43/64)  | 0.36    |
|   | <b>Secondary Outcomes</b>          | <b>Return to Sport§</b>          |               |  |         |
|   |                                    | Total (%)                        | 47% (7/15)    | <u>SI</u> : 50% (5/10)<br><u>PT</u> : 57% (26/46)  | 0.46    |
|   |                                    | Same sport (%)                   | 27% (4/15)    | <u>SI</u> : 40% (4/10)<br><u>PT</u> : 46% (21/46)  | NR      |
|   |                                    | Different Sport (%)              | 20% (3/15)    | <u>SI</u> : 10% (1/10)<br><u>PT</u> : 11% (5/46)   | NR      |
|   |                                    | Quit Sport (%)                   | 33% (5/15)    | <u>SI</u> : 40% (4/10)<br><u>PT</u> : 26% (12/46)  | NS      |
|   |                                    | Quit sport due to pain           | 20% (3/15)    | <u>SI</u> : 10% (1/10)<br><u>PT</u> : 17% (8/46)   | NR      |

mHHS = modified Harris Hip Score; NAHS=non-arthritic hip score; NS = not statistically significant; WOMAC = Western Ontario and McMasters Osteoarthritis Index.

\*Higher values indicate better function,

†As defined by authors; no specifics provided.

‡6 patients proceeded straight to arthroscopy following failed conservative care and 11 had steroid injections, did not improve, and subsequently had arthroscopy.

§5 patients were omitted because they did not play sport at initial visit (n=71); 12 patients (17%) did not respond to questionnaire and 7 (10%) who did respond gave no reason for why they quit their sport.

### 4.2.3 Operative vs. Operative Treatment

#### Studies included

A total of 15 comparative studies were identified including one RCT comparing labral repair versus labral debridement<sup>106</sup> and 14 observational cohorts<sup>6,17,21,27,49,84,113,135,169,170,179,184,209,215</sup> comparing various surgical approaches to the treatment of FAIS, most commonly arthroscopy versus open hip dislocation and labral repair versus labral debridement. In addition, one case series in an adolescent population and 14 case series in adult populations with at least 5 years of follow-up were identified that reported progression to osteoarthritis (OA) or conversion to total hip arthroplasty (THA).

Strength of evidence was not done on studies comparing operative techniques.

#### Summary of results

- In one small RCT, patients who received labral repair versus labral debridement, reported significantly better function according to HOS-ADL and HOS-Sport subscale scores at a mean follow-up of 32 months (short term). Baseline scores did not differ statistically between groups as reported by the authors; however, when comparing the change scores from baseline to follow-up on both functional measures the two treatment groups appear more similar. No other outcomes were reported by this trial.
- Across 12 observational cohorts comparing different surgical approaches to the treatment of FAIS, results varied across the function measures reported. In general, results were comparable between surgical treatment groups; when statistical differences were seen they tended to favor arthroscopy as opposed to open hip dislocation surgery and labral repair as opposed to labral debridement. Only two comparative cohort studies reported on pain (via various different measures) with inconsistent results. Only one, small cohort reported the proportion of patients who required THA with no significant difference seen between the arthroscopy and open surgery groups (3% vs. 13%, respectively); the difference may be clinically important.
- In Across 13 surgical case series with at least 5 years of follow-up, the frequency of conversion to THA in adults ranged from 2% to 34%; in the two large systematic reviews of case series, pooled THA rates were 6.3% and 6.5%. Only three of these case series reported progression to OA which ranged from 8% to 12%.
- Twelve surgical case series provided effectiveness data for pediatric populations receiving operative treatment for FAIS; statistically significant improvements from baseline were seen for function and pain (based on various measures) over a wide range of follow-up periods (mean 1.5 to 50 months). A high proportion of adolescent athletes (86% to 100%) returned to sport following surgery as reported by five studies. No patient required a conversion to THA following arthroscopy in one small case series (N=28) of adolescent athletes followed for a mean of 40 months.

- Results for comparative studies of surgical intervention should be interpreted cautiously given their potential for high risk of bias. In the absence of studies comparing surgical intervention with active comparators (e.g. exercise, specific rehabilitation and manual therapies that may be designed to change the way the joint is being used), conclusions about the benefits of surgical intervention are limited.

#### 4.2.3.1 Randomized controlled trials

One small trial was identified that met inclusion criteria and compared two different surgical approaches to treating labral tears associated with FAIS.<sup>106</sup>

#### Study characteristics

The RCT (N=36)<sup>106</sup> compared labral repair versus selective labral debridement in female patients (mean age 38.5 years) undergoing arthroscopy for the treatment of primarily mixed-type (83%) or pincer-type (17%) FAI (pure cam-type was excluded), Table 22. Diagnosis was made based on patient history, positive impingement test, and radiographic evidence (i.e., cross-over sign and prominent ischial spine sign, coxa profunda, acetabular protrusion; in most cases, the diagnosis was confirmed via an intra-articular injection of lidocaine. Presence of a labral tear/pathology on magnetic resonance imaging was required. Patients younger than 18 years of age, with prior hip surgery, Tönnis grade 2 or greater OA, or hip dysplasia were excluded. In the labral repair group, the labrum was detached in order to remove the bony overgrowth on the anterior rim of the acetabulum (i.e., the pincer lesion); after resection of the bone the labrum was rolled back and repaired to the rim using multiple suture anchors. In the labral debridement group, the pincer lesion was resected without separating the labrum from the acetabulum; the goal of debridement was to preserve as much stable labrum as possible. In cases of mixed-type FAI, additional resection of the cam lesion was performed. All procedures were done under fluoroscopic guidance. All patients received the same post-operative care which consisted of immediate passive motion, crutches with partial weight bearing for 2 weeks, and initiation of hip-specific physical therapy within 7 to 10 days of surgery.

This RCT was considered to be at moderately high risk of bias for the following reasons: unclear method of random sequence generation, lack of blinded assessment (neither the patient nor the surgeon were blinded), and failure to control for variables unbalanced at baseline (preoperative function scores were better in those who received labral repair vs. labral debridement). For details of risk of bias determination, see Appendix E.

**Table 22. Demographics and inclusion and exclusion criteria in RCTs comparing arthroscopic labral repair with labral debridement for primarily mixed-type FAI.**

|                                | Krych 2013                           |   |
|--------------------------------|--------------------------------------|---|
|                                | Arthroscopic labral repair<br>(n=18) | Arthroscopic labral debridement<br>(n=18) |
| Mean age                       | 38 years                             | 39 years                                  |
| Female (%)                     | 100%                                 | 100%                                      |
| Mean duration of symptoms      | NR                                   | NR  |
| Pincer/mixed-type FAI (%)      | 17%/83%                              | 17%/83%                                   |
| Hip laterality: right/left (%) | NR                                   | NR  |



|   | Krych 2013  |   |
|---|---|---|
|   | Arthroscopic labral repair<br>(n=18)  | Arthroscopic labral debridement<br>(n=18) |
| Median time from randomization to treatment | NR  | NR  |
| INCLUSION CRITERIA                          |   |   |
| Age   | ≥18 years   |   |
| Sex   | Female  |   |
| Type of FAI                                 | Pincer or mixed<br>(see imaging criteria below)   |   |
| Pain  | Yes – “symptomatic”   |   |
| Failed conservative treatment               | NR  |   |
| Failed previous PT                          | NR  |   |
| Positive impingement                        | Yes – specifics not reported  |   |
| Positive imaging sign                       | Yes – positive cross over sign and prominent ischial spine sign; coxa profunda; acetabular protrusion; or pincer divot at femoral head-neck junction on AP radiograph; with or without alpha angle >45° on oblique radiograph |   |
| Intra-articular injection                   | Yes – in most patients  |   |
| Other                                       | • Presence of labral tear/pathology was required on MRI   |   |
| EXCLUSION CRITERIA                          |   |   |
| Preexisting OA                              | Yes – Tonnis grade ≥2   |   |
| Hip dysplasia                               | Yes   |   |
| Previous surgery                            | Yes   |   |
| Previous PT                                 | NR  |   |
| Other                                       | • Evidence of a Wiberg lateral center edge angle <25°   |   |

AP = anterior-posterior; FAI = femoroacetabular impingement; MRI = magnetic resonance imaging; OA = osteoarthritis; PT = physical therapy.

### **Efficacy Results**

All analyses are based on intention-to-treat (ITT) analyses unless otherwise noted.

The only primary outcome reported was short-term function. Patients who received labral repair, as compared with labral debridement, had significantly better scores on the HOS-ADL (mean 91 vs. 81, respectively) and HOS-Sport (mean 89 vs. 76) subscales, at a mean follow-up of 32 months (Table 23).<sup>106</sup> Baseline scores on both measures did not differ statistically between groups as reported by the authors; however, when comparing the change scores from baseline to follow-up on both functional measures the two treatment groups appear more similar.

Regarding secondary outcomes, significantly more patients who received labral repair reported that they would describe their current hip function as “normal” compared with those who had labral debridement: 72% vs. 8% (RR 2.6, 95% CI 1.2 to 5.8),

Table 23.<sup>106</sup>

Results of this trial should be interpreted with caution give the small sample size and apparent substantial imprecision (wide ranges); it is unclear if other trials would find results consistent with those found here.

**Table 23. RCT (Krych 2013) comparing arthroscopic rim trim and labral repair vs. labral debridement.**

| Author                             | Outcome*                          | Arthroscopic Labral Repair (n=18) | Arthroscopic Labral Debridement (n=18) | MD or RR (95% CI)  | p-value |
|------------------------------------|-----------------------------------|-----------------------------------|--|--------------------|---------|
| <b>Primary Outcomes (function)</b> | <b>HOS-ADL (0-100)</b>            |                                   |  |                    |         |
|                                    | Baseline, mean (range)            | 68.2 (26.6–92.6)                  | 60.2 (23.5–91.2)                       | -----              | NS      |
|                                    | F/U: mean 32 months, mean (range) | 91.2 (73.3–100)                   | 80.9 (42.6–100)                        | 10.3 (NR)          | <0.05   |
|                                    | <b>HOS-Sport (0-100)</b>          |                                   |  |                    |         |
|                                    | Baseline, mean (range)            | 47.5 (0–80.6)                     | 40.6 (0–97.2)                          | -----              | NS      |
|                                    | F/U: mean 32 months, mean (range) | 88.7 (28.6–100)                   | 76.3 (28.6–100)                        | 12.4 (NR)          | <0.05   |
| <b>Secondary Outcomes</b>          | <b>Patient Subjective Outcome</b> |                                   |  |                    |         |
|                                    | Baseline, % (n/N)                 |                                   |  |                    |         |
|                                    | Severely abnormal/abnormal        | 72% (13/18)                       | 72% (13/18)                            |                    | NS      |
|                                    | F/U: mean 32 months, % (n/N)      |                                   |  |                    |         |
|                                    | Normal                            | 72% (13/18)                       | 8% (5/18)                              | RR 2.6 (1.2, 5.8)  | 0.01    |
|                                    | Near normal                       | 22% (4/18)                        | 50% (9/18)                             | RR 0.4 (0.2, 1.2)  | NS      |
|                                    | Severely abnormal/abnormal        | 6% (1/18)                         | 22% (4/18)                             | RR 0.3 (0.03, 2.0) | NS      |

mHHS = modified Harris Hip Score; NAHS=non-arthritic hip score; NS = not statistically significant; WOMAC = Western Ontario and McMasters Osteoarthritis Index.

\*Higher values indicate better function.

†Calculated by AAI.

#### 4.2.3.2 Cohort studies

Of the 14 observational cohort studies comparing different surgical approaches to the treatment of FAI, 12 were rated high risk of bias<sup>6,17,21,27,84,135,169,170,179,184,209,215</sup> and two moderately high risk of bias<sup>49,113</sup>; outcome assessors were not blinded to treatment (when possible), attrition was rarely able to be determined and few studies controlled for confounding factors. For details related to risk of bias assessment, see Appendix E. One of the studies comparing arthroscopy versus open hip dislocation surgery<sup>21</sup> and one comparing no labral detachment/no refixation with labral detachment and refixation<sup>209</sup> did not report any primary effectiveness outcomes; results for these studies can be found in Section 3.2.3 on safety.

Given the potential for high risk of bias, results related to effectiveness from comparative surgical cohorts should be interpreted cautiously.

#### **Arthroscopy versus open hip dislocation surgery**

Six observational comparative cohorts (N range, 23 to 201) that met inclusion criteria were identified comparing arthroscopic hip surgery to open surgical hip dislocation for the treatment of FAIS<sup>17,21,49,170,179,215</sup>; one of these studies provided data on complications only and results can be found in Section 3.2.3 on safety.<sup>21</sup> Across the six studies, mean age ranged from 19.4 to 36 years and the proportion of females from 18% to 100%. No study provided information regarding symptom duration. None of the studies reported if athletes were included in their population. FAIS was diagnosed according to radiographic evidence in all six studies as well as positive impingement test (3 studies),<sup>49,170,215</sup> pain or presence of symptoms (2 studies),<sup>17,215</sup> patient history (1 study),<sup>49</sup> and diagnostic injection (1 study)<sup>17</sup>; in the remaining two studies<sup>21,179</sup>, no further clinical diagnostic criteria were mentioned, but all patients appeared to have pain on presentation. Studies enrolled patients with various morphology types: two studies included predominately mixed- and pincer-type<sup>49,215</sup>; two studies included predominately mixed- and cam-type<sup>21,179</sup>; and one study each reported exclusively on patients with mixed-type<sup>17</sup> and cam-type<sup>170</sup> FAIS. Only two studies reported whether patients had labral pathology at presentation (100% with labral tears in both).<sup>17,49</sup> Three studies included only patients with Tönnis grade 0 or 1 osteoarthritis (OA)<sup>17,49,215</sup>; in the remaining three studies patients with a greater degree of OA (i.e., Tönnis grade 2 or higher) comprised only small portions of each population (3%,<sup>21</sup> 16%,<sup>179</sup> and 21%).<sup>170</sup> Mean follow-up (across 5 studies)<sup>17,21,49,170,179</sup> ranged from 11.3 to 44 months in the arthroscopy groups and 16.2 to 76 months in the open surgical dislocation groups. One study reported on all patients at 12 months.<sup>215</sup>

Four studies provided details regarding surgical procedures to the bone and/or cartilage. In one study,<sup>21</sup> all patients received at minimum femoral osteochondroplasty; in another,<sup>215</sup> 95% of all patients received acetabuloplasty (no additional surgical details provided for either study). Across two studies,<sup>17,179</sup> 44% and 49% of arthroscopic procedures, and 71% and 100% of open surgical dislocation procedures involved femoral osteoplasty or osteochondroplasty. Acetabuloplasty was carried out in 29% and 89% of arthroscopic procedures and 29% and 100% of open surgical dislocation procedures. Four studies provided information regarding surgical procedures performed on the labrum.<sup>17,49,179,215</sup> Labral repair/refixation was performed in 12% to 85% of cases in the arthroscopy groups, and 30% to 100% of cases in the open surgical dislocation groups. Labral debridement was performed in 15% to 67% of cases in the arthroscopy groups, and 0% to 40% of cases in the open surgical dislocation groups.

### ***Labral repair versus labral debridement***

Five additional comparative cohorts were identified comparing surgery with labral repair/reattachment to surgery with labral debridement/resection.<sup>6,27,113,135,184</sup> FAIS diagnostic criteria were not comprehensively reported, but all studies did require radiographic confirmation of FAIS. All patients had labral tears. Four studies utilized arthroscopic surgical techniques<sup>27,113,135,184</sup> and one utilized open surgical dislocation.<sup>6</sup>

Across the four studies performing arthroscopy, mean age ranged from 29.8 to 41 years, with the proportion of females ranging from 25% to 48%. One study reported that mean symptom duration prior to surgery was 2.8 years.<sup>135</sup> Bilateral operation occurred in 4.2%<sup>135</sup> and 9%<sup>113</sup> of patients, reported on by two studies. Studies enrolled patients with various morphology types. Three studies included patients with predominantly combined type FAIS (range, 58% to 82%),<sup>27,113,135</sup> while one study included mostly patients with cam-type FAIS (55%).<sup>184</sup> Three studies provided information on Tönnis grade osteoarthritis (OA). Most patients had Grade 1 or 2 OA. Few hips had Tönnis grade 2 (range, 1.4% to 6%) and no

patients had greater than grade 2 OA. None of the studies reported if athletes were included in their population. Mean follow-up ranged from 29.3 to 120 months.

The study utilizing open surgical hip dislocation (n=52) had a mean age of 29 years and 33% of patients were female. Diagnosis of FAIS required a positive impingement test and radiographic evidence of FAIS. Eight (15.4%) patients had both hips operated on. All patients had combination type FAIS and only 1 patient had Tönnis grade 2 OA. Mean follow-up was 148.8 months.

### ***Arthroscopic surgery with labral detachment versus without labral detachment***

Two observational comparative cohorts were identified comparing arthroscopic surgery with labral detachment to arthroscopic surgery without labral detachment<sup>169,209</sup>; one study only reported on revision rate following surgery which is included in section 3.2 on safety.<sup>209</sup> Sample sizes for the two studies were 174 (mean age 32.9 years; 75.5% female) and 950 (mean age 35.7 years; 54% female). Only one study described how FAIS was diagnosed, which required that patients have radiographic evidence of FAIS.<sup>169</sup> Symptom duration was not reported on by either study. In one study patients had either pincer or combined type FAIS,<sup>169</sup> while in the other all patients had pincer-type FAIS.<sup>209</sup> Only one study reported on presence of OA (0% detachment group; 9% non-detachment group).<sup>209</sup>

All patients in both studies underwent acetabuloplasty; 61% of procedures also involved femoral osteoplasty in one study.<sup>169</sup> In one study, all patients had a labral tear.<sup>169</sup> Patients without an intact CLJ formed the detachment group, while patients with an intact CLJ formed the non-detachment group. In both groups, the labrum was refixed using suture anchors. In the other study,<sup>209</sup> 73% of the detachment group had a pre-existing labral tear that was debrided and then subsequently used to gain access to acetabular rim prior to refixing with suture anchors. The other 27% of this group did not have a labral tear and therefore had their labrum incised in order to gain access to the acetabular rim, which was then refixed using suture anchors. None of the patients forming the non-detachment group of this study had presence of a labral tear, thus there was no need to use suture anchors.

### ***Femoral osteochondroplasty with or without acetabular osteoplasty***

One small comparative cohort (N=23; 30 hips)<sup>84</sup> was identified that compared femoral osteochondroplasty alone versus with acetabular osteoplasty (“rim trim”) during open hip dislocation surgery for mixed-type impingement. Labral pathology (degeneration or tear) was noted in 2 hips (22%) in the “no rim trim” group and 13 hips (62%) in the “rim trim” group which were treated with partial labral excision (if needed) and debridement. Mean patient age was 24.3 years, 78% were male, and seven patients (30%) had bilateral staged procedures. All patients were symptomatic (i.e., persistent pain and mechanical symptoms) and had radiographically confirmed structural abnormalities of the hip. In addition, all had failed 6 months of conservative treatment, including activity modification and restriction of athletics. The mean follow-up time was 19.2 months.

## ***Effectiveness Results***

### ***Arthroscopy versus open hip dislocation surgery***

#### **Primary outcomes**

### Function

Results across five studies,<sup>17,49,170,179,215</sup> and across the functional outcome measures they reported, varied (Table 24); when a statistical difference was seen between groups it favored arthroscopy, as opposed to open hip dislocation surgery. Some of the differences may be clinically meaningful. The single, poor-quality prospective cohort study<sup>215</sup> reported greater improvement in function according to the mHHS following arthroscopy (compared with open surgery) at all timepoints through 12 months; however, results according to the WOMAC were less consistent. Of note, two of the retrospective cohort studies had considerable overlap in patient populations.<sup>17,49</sup>

### Pain

Only two studies reported pain outcomes (Table 25). One retrospective cohort found no difference in VAS pain scores over a mean follow-up 25 months between patients treated with arthroscopy versus open surgery.<sup>49</sup> A second prospective cohort reported significantly better scores for those who received arthroscopy on the VAS pain scale measured at rest and during ADLs (but not during sport) and on the WOMAC pain scale at some, but not all, timepoints measured up to 12 months.<sup>215</sup>

### Conversion to total hip arthroplasty (THA)

Only one, small retrospective cohort reported the proportion of patients who required THA over a mean 36 months of follow-up with no significant difference seen between the arthroscopy and open surgery groups: 3% (1/40) versus 13% (2/16); RR 0.20 (95% CI 0.02 to 2.05).<sup>179</sup>

**Table 24. Functional results: Nonrandomized observational studies comparing arthroscopy vs. open hip dislocation for FAIS.**

| Follow-up                     | Author                        | Arthroscopy<br>n | Open<br>n | Arthroscopy<br>mean ± SD | Open<br>mean ± SD    | p-value       |
|-------------------------------|-------------------------------|------------------|-----------|--------------------------|----------------------|---------------|
| <b>Outcome: mHHS (0-100)*</b> |                               |                  |           |                          |                      |               |
| <b>Baseline</b>               | Botser 2014†                  | 18               | 5         | 67.8                     | 66.2                 | NS            |
|                               | Domb 2013†                    | 20               | 10        | 68.2                     | 69.6                 | NS            |
|                               | Roos 2017                     | 41 hips          | 17 hips   | 65 ± 9.8                 | 63 ± 9               | NS            |
|                               | Zingg 2013                    | 23               | 15        | 75.2 ± 10.3              | 80.2 ± 8.3           | NS            |
| <b>1.5 mos.</b>               | Zingg 2013                    | 23               | 15        | 81.4 ± 14.1              | 55.3 ± 16.7          | <0.001        |
| <b>3 mos.</b>                 | Botser 2014†                  | 18               | 5         | change score: 21         | change score: 11     | NS            |
|                               | Domb 2013†                    | 20               | 10        | change score: 17.5       | change score: 14     | NR            |
|                               | Zingg 2013                    | 23               | 15        | 92.2 ± 11.1              | 80.6 ± 16.2          | 0.034         |
| <b>6 mos.</b>                 | Botser 2014                   | 18               | 5         | change score: 19         | change score: 17     | NS            |
| <b>12 mos.</b>                | Botser 2014†                  | 18               | 5         | change score: 22         | change score: 21     | NS            |
|                               | Domb 2013†                    | 20               | 10        | change score: 23         | change score: 17     | NR            |
|                               | Zingg 2013                    | 23               | 15        | 93.4 ± 11.7              | 84.9 ± 14            | 0.027         |
| <b>Final F/U<br/>(mos.)</b>   | Domb 2013                     | 20               | 10        | 92.4 ± 7.1               | 92 ± 12.6            | mean: 0.914   |
|                               | [mean f/u: 25.5 vs. 24.8]     |                  |           | (change 24.3 ± 11.2)     | (change 22.5 ± 12.8) | change: 0.696 |
|                               | <b>Good/Excellent result‡</b> |                  |           | 95% (19/20)              | 90% (9/10)           | %; 0.605      |
|                               | Roos 2017                     | 41 hips          | 17 hips   | 88 ± 11                  | 88 ± 22              | NS for all    |
|                               | [mean f/u: 29 vs. 52]         |                  |           | (change 22.1)            | (change 21.7)        |               |

| Follow-up  | Author                                 | Arthroscopy<br>n | Open<br>n | Arthroscopy<br>mean ± SD                      | Open<br>mean ± SD                             | p-value                      |
|--|--|------------------|-----------|---|---|------------------------------|
| <b>Good/Excellent result‡</b>                                |  |                  |           | <b>76% (31/41)</b>                            | <b>71% (12/17)</b>                            |                              |
| <b>Outcome: NAHS (0-100)*</b>                                |  |                  |           |   |   |                              |
| <b>Baseline</b>  | Botser 2014†                           | 18               | 5         | 66.5 (NR)                                     | 66.9 (NR)                                     | NS                           |
|  | Domb 2013†                             | 20               | 10        | 66.1 (NR)                                     | 67.4 (NR)                                     | NS                           |
|  | Rego                                   | 102              | 96        | 53 (range, 12–93)                             | 48 (range, 10–94)                             | NS                           |
|  | Roos 2017                              | 41 hips          | 17 hips   | 68.8 ± 12.5                                   | 65 ± 11.3                                     | NS                           |
| <b>3 mos.</b>  | Botser 2014†                           | 18               | 5         | change score: 24                              | change score: 2                               | 0.002                        |
|  | Domb 2013†                             | 20               | 10        | 88.1 (NR)<br>(change, 22)                     | 75.3 (NR)<br>(change, 8)                      | mean: 0.01<br>change: NR     |
| <b>6 mos.</b>  | Botser 2014                            | 18               | 5         | change score: 23                              | change score: 16                              | NR                           |
| <b>12 mos.</b>   | Botser 2014†                           | 18               | 5         | change score: 25                              | change score: 18                              | NS                           |
|  | Domb 2013†                             | 20               | 10        | change score: 22                              | change score: 19                              | NR                           |
| <b>Final F/U<br/>(mos.)</b>                                  | Domb 2013<br>[mean f/u: 25.5 vs. 24.8] | 20               | 10        | 94.2 ± 4.5<br>(change 28.1 ± 16.0)            | 85.7 ± 12.4<br>(change 18.3 ± 12.6)           | mean: 0.01<br>change: 0.103  |
|  | Rego 2018<br>[mean f/u: 44 vs. 76]     |                  |           | 82 (range, 30–100)                            | 83 (range, 35–100)                            | NS                           |
|  | Roos 2017<br>[mean f/u: 29 vs. 52]     | 41 hips          | 17 hips   | 92.5 ± 10<br>(change score, 21.5)             | 90 ± 20<br>(change score, 20.4)               | NS                           |
|  |  |                  |           |   |   |                              |
| <b>Outcome: HOS-ADL (0-100)*</b>                             |  |                  |           |   |   |                              |
| <b>Baseline</b>  | Botser 2014†                           | 18               | 5         | 72.6 (NR)                                     | 66.4 (NR)                                     | NS                           |
|  | Domb 2013†                             | 20               | 10        | 72.2 (NR)                                     | 68.6 (NR)                                     | NS                           |
| <b>3 mos.</b>  | Botser 2014†                           | 18               | 5         | change score: 19                              | change score: 11                              | NS                           |
|  | Domb 2013†                             | 20               | 10        | change score: 17                              | change score: 12.5                            | NR                           |
| <b>6 mos.</b>  | Botser 2014                            | 18               | 5         | change score: 16                              | change score: 14                              | NS                           |
| <b>12 mos.</b>   | Botser 2014†                           | 18               | 5         | change score: 21                              | change score: 23                              | NS                           |
|  | Domb 2013†                             | 20               | 10        | change score: 20                              | change score: 19                              | NR                           |
| <b>Final F/U<br/>(mos.)</b>                                  | Domb 2013<br>[mean f/u: 25.5 vs. 24.8] | 20               | 10        | 95.3 ± 5.4<br>(change: 23.1 ± 13.4)           | 91.5 ± 7.7<br>(change: 22.9 ± 13.9)           | mean: 0.129<br>change: 0.971 |
| <b>Outcome: HOS-Sport (0-100)*</b>                           |  |                  |           |   |   |                              |
| <b>Baseline</b>  | Botser 2014†                           | 18               | 5         | 45.7 (NR)                                     | 52.3 (NR)                                     | NS                           |
|  | Domb 2013†                             | 20               | 10        | 44.3 (NR)                                     | 53.8 (NR)                                     | NS                           |
| <b>3 mos.</b>  | Botser 2014†                           | 18               | 5         | change score: 22.5                            | change score: 12                              | NS                           |
|  | Domb 2013†                             | 20               | 10        | change score: 31                              | change score: 14                              | NR                           |
| <b>6 mos.</b>  | Botser 2014                            | 18               | 5         | change score: 32.5                            | change score: 10                              | NR                           |
| <b>12 mos.</b>   | Botser 2014†                           | 18               | 5         | change score: 27                              | change score: 30                              | NS                           |
|  | Domb 2013†                             | 20               | 10        | change score: 40                              | change score: 25                              | NR                           |
| <b>Final F/U<br/>(mos.)</b>                                  | Domb 2013<br>[mean f/u: 25.5 vs. 24.8] | 20               | 10        | 87.1 ± 12.1<br>(change score: 42.8<br>± 25.7) | 77.3 ± 22.7<br>(change score: 23.5 ±<br>19.7) | mean: 0.131<br>change: 0.047 |
| <b>Outcome: WOMAC (Total 0-96; ADL 0-68; Stiffness 0-8)§</b> |  |                  |           |   |   |                              |

| Follow-up | Author     | Arthroscopy<br>n | Open<br>n | Arthroscopy<br>mean ± SD                                   | Open<br>mean ± SD  | p-value              |
|-----------|------------|------------------|-----------|--|--|----------------------|
| Baseline  | Zingg 2013 | 23               | 15        | Total: 2.3 ± 1.9<br>ADL: 2.1 ± 1.7<br>Stiffness: 2.4 ± 2.7 | Total: 2.9 ± 2.1<br>ADL: 2.5 ± 2.0<br>Stiffness: 3.1 ± 2.9 | NS<br>NS<br>NS       |
| 1.5 mos.  |            |                  |           | Total: 2.0 ± 1.6<br>ADL: 2.2 ± 1.6<br>Stiffness: 2.5 ± 2.3 | Total: 2.7 ± 1.9<br>ADL: 3.2 ± 1.8<br>Stiffness: 2.5 ± 2.8 | NS<br>NS<br>NS       |
| 3 mos.    |            |                  |           | Total: 0.9 ± 1.1<br>ADL: 0.8 ± 1.1<br>Stiffness: 1.2 ± 1.4 | Total: 2.3 ± 1.9<br>ADL: 2.0 ± 2.0<br>Stiffness: 2.7 ± 2.4 | 0.024<br>NS<br>0.041 |
| 12 mos.   |            |                  |           | Total: 1.1 ± 1.5<br>ADL: 0.9 ± 1.8<br>Stiffness: 1.6 ± 1.9 | Total: 2.3 ± 2.1<br>ADL: 1.9 ± 2.2<br>Stiffness: 2.6 ± 2.5 | NS<br>NS<br>NS       |

F/U = follow-up; HOS-ADL = Hip Outcome Score Activities of Daily Living subscale; HOS-Sport= Hip Outcome Score Sport subscale; mHHS = modified Harris Hip Score; NAHS=non-arthritis hip score; NS = not statistically significant; WOMAC = Western Ontario and McMasters Osteoarthritis Index.

\*Higher values indicate better function

†Considerable overlap in patient populations.

‡Score of >80 on the mHHS.

§Lower values indicate better function

**Table 25. Pain results: Nonrandomized observational studies comparing arthroscopy with open hip dislocation surgery.**

| Author  | Outcome*                                | Arthroscopy<br>Mean ± SD | Open Surgery<br>Mean ± SD | p-value |
|---|---|--------------------------|---------------------------|---------|
| <b>Domb 2013<br/>Retro cohort<br/>(n=20 vs. 10)</b> | <b>VAS pain, NOS (0-10)</b>             |                          |                           |         |
|   | Baseline                                | NR                       | NR                        | NS      |
|   | Follow-up (mean 25.5 vs. 24.8 mos.)     | 2.0 ± 1.2                | 2.8 ± 3.1                 | 0.328   |
|   | Change scores a follow-up               | 4.7 ± 2.0                | 2.1 ± 4.4                 | 0.13    |
| <b>Zingg 2013<br/>Pro cohort<br/>(n=23 vs. 15)</b>  | <b>VAS pain at rest (scale NR)</b>      |                          |                           |         |
|   | Baseline                                | 15 ± 21.9                | 18.3 ± 13.8               | NS      |
|   | 1.5 mos.                                | 6.3 ± 11.1               | 14.7 ± 20.7               | NS      |
|   | 3 mos.                                  | 2.4 ± 7.4                | 10 ± 13.6                 | 0.021   |
|   | 12 mos.                                 | 5.5 ± 12.2               | 15 ± 22.8                 | NS      |
|   | <b>VAS pain during ADLs (scale NR)</b>  |                          |                           |         |
|   | Baseline                                | 33.5 ± 25.3              | 40 ± 22.3                 | NS      |
|   | 1.5 mos.                                | 14.5 ± 14.5              | 20.1 ± 17.8               | NS      |
|   | 3 mos.                                  | 13.2 ± 17.9              | 24.5 ± 18.6               | 0.034   |
|   | 12 mos.                                 | 10.1 ± 17.4              | 24.3 ± 26                 | 0.042   |
|   | <b>VAS pain during sport (scale NR)</b> |                          |                           |         |
|   | Baseline                                | 52.1 ± 31.2              | 65.9 ± 27                 | NS      |
|   | 3 wks.                                  | 18.7 ± 24                | 13.6 ± 6.3                | NS      |
|   | 12 mos.                                 | 15.3 ± 24.5              | 16.4 ± 16.1               | NS      |
|   | <b>WOMAC pain (0-20)</b>                |                          |                           |         |

| Author | Outcome* | Arthroscopy<br>Mean ± SD | Open Surgery<br>Mean ± SD | p-value |
|--------|----------|--------------------------|---------------------------|---------|
|        | Baseline | 2.5 ± 2.1                | 3.0 ± 2.1                 | NS      |
|        | 1.5 mos. | 1.6 ± 1.4                | 2.1 ± 1.8                 | NS      |
|        | 3 mos.   | 0.7 ± 1.2                | 2.2 ± 2.0                 | 0.012   |
|        | 12 mos.  | 0.9 ± 1.2                | 2.3 ± 1.9                 | 0.011   |

mHHS = modified Harris Hip Score; NAHS=non-arthritic hip score; NOS = not otherwise specified; NS = not statistically significant; WOMAC = Western Ontario and McMasters Osteoarthritis Index.

\*Higher values indicate better function,

†As defined by authors; no specifics provided.

‡6 patients proceeded straight to arthroscopy following failed conservative care and 11 had steroid injections, did not improve, and subsequently had arthroscopy.

§5 patients were omitted because they did not play sport at initial visit (n=71); 12 patients (17%) did not respond to questionnaire and 7 (10%) who did respond gave no reason for why they quit their sport.

### Labral repair versus Labral debridement

#### **Primary outcomes**

##### *Function*

Five studies reported functional outcomes following repair versus debridement of labral tears during arthroscopy (4 studies)<sup>27,113,135,184</sup> or open surgery (1 study)<sup>6</sup> to correct FAI (



Table 26). Across studies using an arthroscopic approach, greater improvement in mHHS at last follow-up was reported by patients who underwent labral repair in two of three studies<sup>113,184</sup>; the study that found no difference between groups had considerably longer follow-up (10 years) than the other two studies (mean 29 and 42 months). No differences were seen between groups for other measures reported: HOS-ADL (2 studies)<sup>27,135</sup> and HOS-Sport (one study).<sup>135</sup> In the study involving an open approach to surgery, significant differences favoring the labral repair (vs. debridement) group were reported for the Merle d'Aubigne'-Postel (MAP) score at a mean follow-up of 12 years.<sup>6</sup>

### ***Pain***

Three studies reported pain outcomes (Table 27). Two cohort studies comparing arthroscopic labral repair vs. labral debridement found no differences between groups in VAS pain scores over mean follow-ups of 42 and 45 months.<sup>27,113</sup> The third trial used an open approach to surgery and reported significantly better MAP pain scores in patients who received labral repair vs. debridement.<sup>6</sup>

### ***Conversion to total hip arthroplasty (THA)***

No statistical differences were seen across four studies in the proportion of patients requiring subsequent THA over mean follow-up periods ranging from 29 to 149 months (Table 28).<sup>6,27,113,184</sup> Samples sizes were small and follow-up was likely too short in the majority of studies.

**Table 26. Functional results: Nonrandomized observational studies comparing labral repair vs. labral debridement\* for FAIS.**

| Follow-up   | Author                             | Labral Repair<br>n | Labral Debridement<br>n | Labral Repair<br>mean ± SD   | Labral Debridement<br>mean ± SD  | MD or RR<br>(95% CI)<br>p-value |
|---|------------------------------------|--------------------|-------------------------|--|--|---------------------------------|
| <b>Outcome: mHHS (0-100)†</b>   |                                    |                    |                         |  |  |                                 |
| <b>Baseline</b>   | Larson 2012                        | 50 hips            | 44 hips                 | 64.5 (NR)  | 64.7 (NR)  | NS                              |
|   | Menge 2017                         | 74                 | 71                      | median 65<br>(IQR, 55–70)  | median 62<br>(IQR, 50–71)  | NS                              |
|   | Schilders 2011                     | 69 hips            | 32 hips                 | 60.2 (range, 24–85)  | 62.8 (range, 29–96)  | NS                              |
| <b>Final F/U<br/>(mos.)</b>   | Larson 2012<br>(mean f/u: 42)      | 50 hips            | 44 hips                 | 94.3<br>(change score: 29.8)   | 84.9<br>(change score: 20.2)   | mean: NR<br>change: <0.001      |
|   | Menge 2017<br>(f/u: max. 120)      | 74                 | 71                      | median 85<br>(IQR, 63–99)  | median 90<br>(IQR, 85–100)   | 0.173                           |
|   | Schilders 2011<br>(mean f/u: 29.3) | 69 hips            | 32 hips                 | 93.6 (range, 55–100);<br>(change score: 33.4,<br>range, 0–76)                            | 88.8 (range, 35–100);<br>(change score: 26.1,<br>range, 0–61)                            | adj. MD 7.0<br>(0.3–13.7)       |
| <b>Outcome: HOS-ADL (0-100)†</b>  |                                    |                    |                         |  |  |                                 |
| <b>Baseline</b>   | Cetinkaya 2016                     | 33                 | 34                      | 55.1 ± 6.0   | 52.5 ± 7.1   | NS                              |
|   | Menge 2017                         | 74                 | 71                      | median 71<br>(IQR, 63–83)  | median 71<br>(IQR, 57–81)  | NS                              |
| <b>Final F/U<br/>(mos.)</b>   | Cetinkaya 2016<br>(mean f/u: 45)   | 33                 | 34                      | 87.2 ± 11.3  | 84.2 ± 11.3  | NS                              |
|   | Menge 2017<br>(f/u: max. 120)      | 74                 | 71                      | median 96<br>(IQR, 88–100)   | median 96<br>(IQR, 89–100)   | 0.858                           |
| <b>Outcome: HOS-Sport (0-100)†</b>                                      |                                    |                    |                         |  |  |                                 |
| <b>Baseline</b>   | Menge 2017                         | 74                 | 71                      | median 47<br>(IQR, 33–61)  | median 42<br>(IQR, 25–58)  | NS                              |
| <b>F/U max.<br/>120 mos.</b>  |                                    |                    |                         | median 87<br>(IQR, 75–100)   | median 89<br>(IQR, 67–100)   | 0.969                           |
| <b>Outcome: MAP (overall, 0-18; mobility and walking ability, 0-6)†</b> |                                    |                    |                         |  |  |                                 |
| <b>Baseline</b>   | Anwander<br>2017                   | 28 hips            | 17 hips                 | <u>overall</u> : 12.6 ± 1.8<br><u>mobility</u> : 5.6 ± 0.6<br><u>walking</u> : 5.5 ± 1.1 | <u>overall</u> : 12.4 ± 1.9<br><u>mobility</u> : 5.4 ± 0.8<br><u>walking</u> : 5.6 ± 0.7 | NS<br>NS<br>NS                  |
| <b>Mean<br/>F/U: 149<br/>mos.‡</b>                                      |                                    |                    |                         | <u>overall</u> : 16.7 ± 1.5<br><u>mobility</u> : 5.8 ± 0.4<br><u>walking</u> : 5.9 ± 0.3 | <u>overall</u> : 15.3 ± 2.4<br><u>mobility</u> : 5.7 ± 0.7<br><u>walking</u> : 5.8 ± 0.4 | 0.028<br>0.473<br>0.228         |
| <b>Proportion of hips with MAP score &lt;15</b>                         |                                    |                    |                         | 14% (5/35)   | 48% (12/25)  | RR 0.3 (0.1–0.7)§               |
| <b>10-year probability (95% CI) of MAP score &gt;15</b>                 |                                    |                    |                         | 83% (70%–97%)  | 48% (28%–69%)  | 0.009                           |

adj. = statistically adjusted; CI = confidence interval; FAIS = femoroacetabular impingement syndrome; F/U = follow-up; HOS-ADL = Hip Outcome Score Activities of Daily Living subscale; HOS-Sport = Hip Outcome Score Sport subscale; IQR = interquartile range; MAP =

Merle d'Aubigne-Postel score; MD = mean difference; mHHS = modified Harris Hip Score; NR = not report; NS = not statistically significant; RR = risk ratio; SD = standard deviation.

\*With the exception of Anwander 2017 which performed open hip dislocation surgery, all studies used an arthroscopic approach.

†Higher values indicate better function

‡Patients had a minimum of 10 years follow-up

§Calculated by AAI

**Table 27. Pain results: Nonrandomized observational studies comparing labral repair vs. labral debridement\* for FAIS.**

| Follow-up                        | Author                           | Labral Repair<br>n | Labral Debridement<br>n | Labral Repair<br>mean ± SD      | Labral Debridement<br>mean ± SD | p-value                   |
|----------------------------------|----------------------------------|--------------------|-------------------------|---------------------------------|---------------------------------|---------------------------|
| <b>Outcome: VAS pain (0-10)†</b> |                                  |                    |                         |                                 |                                 |                           |
| <b>Baseline</b>                  | Cetinkaya 2016                   | 33                 | 34                      | 8 (NR)                          | 8.2 (NR)                        | NS                        |
|                                  | Larson 2012                      | 50 hips            | 44 hips                 | 5.7 (NR)                        | 6.5 (NR)                        | NR                        |
| <b>Final F/U<br/>(mos.)</b>      | Cetinkaya 2016<br>(mean f/u: 45) | 33                 | 34                      | 2.3 (NR)                        | 2.1 (NR)                        | NS                        |
|                                  | Larson 2012<br>(mean f/u: 42)    | 50 hips            | 44 hips                 | 0.7 (NR)<br>(change score: 5.0) | 1.7 (NR)<br>(change score: 4.8) | mean: NR<br>change: 0.492 |
| <b>Outcome: MAP pain (0-6)†</b>  |                                  |                    |                         |                                 |                                 |                           |
| <b>Baseline</b>                  | Anwander 2017                    | 28 hips            | 17 hips                 | 1.5 ± 0.9                       | 1.4 ± 0.8                       | NS                        |
| <b>Mean F/U:<br/>149 mos.‡</b>   |                                  |                    |                         | 5.0 ± 1.0                       | 3.9 ± 1.7                       | 0.014                     |

FAIS = femoroacetabular impingement syndrome; F/U = follow-up; MAP = Merle d'Aubigne-Postel score; NR = not report; NS = not statistically significant; SD = standard deviation; VAS = visual analog scale.

\*With the exception of Anwander 2017 which performed open hip dislocation surgery, all studies used an arthroscopic approach.

†For VAS pain, lower values indicate less pain; for MAP pain, higher values indicate improved pain.

‡Patients had a minimum of 10 years follow-up.

**Table 28. Conversion to THA in cohort studies comparing labral repair versus labral debridement during surgery for FAIS.**

| Author*               | Mean<br>follow-up | Intervention<br>% (n/N) | Comparator<br>% (n/N) | RR (95% CI)<br>p-value |
|-----------------------|-------------------|-------------------------|-----------------------|------------------------|
| <b>Anwander 2017</b>  | 149 mos.          | 6% (2/35 hips)          | 12% (3/25 hips)       | RR 0.5 (0.1 to 2.6)    |
| <b>Cetinkaya 2016</b> | 44.9 mos.         | 6% (2/33)               | 3% (1/33)             | RR 2.1 (0.2, 21.7)     |
| <b>Larson 2012</b>    | 42.4 mos.         | 1.9% (1/52)             | 0% (0/44)             | NS                     |
| <b>Schilders 2011</b> | 29.3 mos.         | 0% (0/69 hips)          | 0% (0/32 hips)        | -----                  |

FAIS = femoroacetabular impingement syndrome; mHHS = modified Harris Hip Score; NAHS=non-arthritic hip score; NOS = not otherwise specified; NS = not statistically significant; THA = total hip arthroplasty; WOMAC = Western Ontario and McMasters Osteoarthritis Index.

\*With the exception of Anwander 2017 that uses open hip dislocation, all other trials other use arthroscopic approach.

## Acetabuloplasty and labral refixation without or with labral detachment

### Primary outcomes

#### Function, Pain, and Conversion to THA

One retrospective cohort evaluated the treatment of pincer- and mixed-type FAI with arthroscopic acetabuloplasty and labral refixation without (when possible) versus with labral detachment and reported similar function and pain outcomes between the two groups at 24 months (Table 29).<sup>169</sup> No difference was seen in the incidence of conversion to THA, respectively, 1.2% (1/85 hips) vs. 0% (0/105 hips).

**Table 29. Function and Pain results: Nonrandomized observational study comparing acetabuloplasty and labral refixation without and with labral detachment for FAI.**

| Author<br>No. hips (n)<br>Study design<br>Follow-up                      | Outcome‡                 | Acetabuloplasty + labral<br>refixation <i>without</i> labral<br>detachment<br>Mean ± SD | Acetabuloplasty +<br>labral refixation <i>with</i><br>labral detachment<br>Mean ± SD | p-value |
|--|--------------------------|---|--|---------|
| Redmond 2015<br><br>N=85 vs. 105<br><br>Retro cohort<br><br>F/U: 24 mos. | <b>mHHS (0-100)</b>      |   |  |         |
|  | Baseline                 | 64.2 (NR)   | 61.2 (NR)  | 0.17    |
|  | 24 mos.                  | 86.6 ± 5.4  | 84.4 ± 15.9  | 0.45    |
|  | Change scores at F/U     | 22.4 (NR)   | 23.2 (NR)  | 0.76    |
|  | <b>NAHS (0-100)</b>      |   |  |         |
|  | Baseline                 | 60.6 (NR)   | 59.1 (NR)  | 0.57    |
|  | 24 mos.                  | 83.8 ± 17.7   | 84 ± 14.7  | 0.91    |
|  | Change scores at F/U     | 23.3 (NR)   | 25 (NR)  | 0.54    |
|  | <b>HOS-ADL (0-100)</b>   |   |  |         |
|  | Baseline                 | 65.3 (NR)   | 62.7 (NR)  | 0.39    |
|  | 24 mos.                  | 87.3 ± 17.2   | 86.2 ± 16.1  | 0.65    |
|  | Change scores at F/U     | 22 (NR)   | 23.5 (NR)  | 0.62    |
|  | <b>HOS-Sport (0-100)</b> |   |  |         |
|  | Baseline                 | 45.0 (NR)   | 40.1 (NR)  | 0.18    |
|  | 24 mos.                  | 75.1 ± 28   | 74.1 ± 25.4  | 0.78    |
|  | Change scores at F/U     | 30.1 (NR)   | 33.9 (NR)  | 0.37    |
|  | <b>VAS pain (0-10)</b>   |   |  |         |
|  | Baseline                 | 5.7 (NR)  | 6.3 (NR)   | 0.04    |
|  | 24 mos.                  | 2.6 ± 2.5   | 2.8 ± 2.3  | 0.43    |
|  | Change scores at F/U     | 3.1 (NR)  | 3.5 (NR)   | 0.38    |

mHHS = modified Harris Hip Score; NAHS=non-arthritic hip score; NOS = not otherwise specified; NS = not statistically significant; WOMAC = Western Ontario and McMasters Osteoarthritis Index.

\*Higher values indicate better function and pain.

‡Lower values indicate better function and pain.

## Open femoral osteochondroplasty with and without acetabular osteoplasty

### Primary outcomes

#### Function and Pain

One small retrospective cohort compared the effectiveness of performing an acetabular osteoplasty (“rim trim”) in addition to a femoral osteochondroplasty for the treatment of mixed-type FAIS.<sup>84</sup> For

most WOMAC outcomes, compared to those who did not, patients who received a “rim trim” had slightly worse results over a mean follow-up of 19.5 months, although a statistical comparison between groups was not made and differences are likely not statistically significant (Table 30).

**Table 30. Function and Pain results: Nonrandomized observational study comparing open femoral osteochondroplasty with and without acetabular osteoplasty (“rim trim”) for FAIS.**

| Author<br>No. hips (n)<br>Study design<br>Follow-up  | Outcome*                     | Open femoral<br>osteochondroplasty +<br>acetabular osteoplasty<br>("rim trim")<br>Mean ± SD | Open femoral<br>osteochondroplasty<br>only<br>("no rim trim")<br>Mean ± SD | p-value |
|--|------------------------------|---|--|---------|
| <b>Hingshamer<br/>2015</b><br><br>n=21 vs. 9<br><br>Retro cohort<br><br>Mean F/U:<br>19.5 mos. | <b>WOMAC function (0-68)</b> |   |  |         |
|  | Baseline                     | 15.4 ± 20.1   | 12.9 ± 12.2  | 0.73    |
|  | Mean 19.5 mos.               | 11.0 ± 10.8   | 7.3 ± 12.2   | NR      |
|  | Change scores at F/U         | -4.4 ± 18.4<br>(95% CI -12.7, 4.0)  | -5.6 ± 2.8<br>(95% CI, -7.7, -3.4)   | NR      |
|  | <b>WOMAC stiffness (0-8)</b> |   |  |         |
|  | Baseline                     | 2.4 ± 2.0   | 1.8 ± 1.9  | 0.41    |
|  | Mean 19.5 mos.               | 2.5 ± 1.6   | 0.8 ± 1.4  | NR      |
|  | Change scores at F/U         | 0.5 ± 1.9<br>(95% CI -0.8, 0.9)   | -1.0 ± 1.8<br>(95% CI -2.4, 0.4)   | NR      |
|  | <b>WOMAC pain (0-20)</b>     |   |  |         |
|  | Baseline                     | 6.9 ± 4.2   | 6.6 ± 3.0  | 0.85    |
|  | Mean 19.5 mos.               | 3.9 ± 4.0   | 2.3 ± 3.6  | NR      |
|  | Change scores at F/U         | -3.0 ± 5.1<br>(95% CI -5.3, -0.7)   | -4.2 ± 2.8<br>(95% CI -6.4, -2.1)  | NR      |

NOS = not otherwise specified; NS = not statistically significant; WOMAC = Western Ontario and McMaster Osteoarthritis Index.

\*Higher values indicate better function and pain.

#### 4.2.3.3 Case series

Due to the relatively short follow-up periods in the RCTs and cohort studies, case series with at least 5 years of follow-up that met all other inclusion criteria were included to evaluate progression to osteoarthritis (OA) and conversion to total hip arthroplasty (THA). In addition, given that no RCT and only one cohort at high risk of bias comparing arthroscopy versus non-operative care was in a pediatric population, all identified case series evaluating adolescents and children are included here for completeness. Strength of evidence was not done for any of these outcomes/studies.

In pediatrics, 12 case series (13 publications)<sup>23,24,39,41,53,69,115,122,133,149,162,193,204</sup> in pediatric populations were included for effectiveness outcomes. Sample size ranged from 18 to 108 months, mean age from 15 to 17.6 years (across 11 series), and proportion female from 15% to 84% (across 11 series). Mean follow-up was from 14 to 50.6 months. Across the 8 series (9 publications)<sup>23,24,39,41,53,133,149,162,204</sup> reporting on impingement type, cam ranged from 10% to 100%, pincer from 4% to 15%, and mixed type from 22% to 84%. 10 series (11 publications)<sup>23,24,39,41,53,115,122,133,162,204</sup> evaluated arthroscopy and 2 series (2 publications)<sup>149,193</sup> evaluated open surgery.

In adult populations, 13 case series (14 publications)<sup>29,37,48,73,74,93,118,135,143,158,159,194,197,198</sup> with greater than 5-years of follow-up were included that evaluated progression to osteoarthritis and/or conversion to total hip arthroplasty. Sample sizes ranged from 42 to 295 patients, mean age from 30.0 to 55.2 years, proportion of female from 30% to 89%, and mean follow-up from 60.7 to 132. One study<sup>135</sup> required that patients have a minimum 120 month follow-up, but did not report a mean follow-up. Across the 5 series (6 publications)<sup>37,73,74,135,197,198</sup> reporting on impingement type, cam ranged from 4% to 48%, pincer from 1% to 25%, and mixed type from 27% to 85%. 10 series<sup>29,37,48,73,93,118,135,158,159,194</sup> evaluated arthroscopy and 3 series (4 publications)<sup>74,143,197,198</sup> evaluated open surgery.

### Conversion to THA in adult populations

Across thirteen case series (14 publications)<sup>29,37,48,73,74,93,118,135,143,158,159,194,197,198</sup> with mean follow-up periods ranging from 61 to 132 months conversion to THA was reported in 2% to 34% of patient/hips (Table 31). The study with the greatest number of THAs had one of the longest follow-ups (120 months).<sup>135</sup> Though mean follow-up periods varied widely and did not meet the 5 year cut-off imposed for individual case-series, across the two systematic reviews (SRs) of case series in adult undergoing arthroscopy for FAIS, the frequency of conversion to THA was 6.3% (456/7241)<sup>178</sup> and 6.5% (128/1981)<sup>139</sup>; there was some overlap in included studies between the SRs.

### Progression to OA

Only three case series (4 publications) reported on whether patients progressed to OA following operative management of FAIS; frequencies ranged from 8% to 12% over a mean of 84 to 132 months (<sup>73,74,197,198</sup>). Progression to OA was not reported by any of the SRs included for safety.

**Table 31. Conversion to total hip arthroscopy and progression to osteoarthritis in case series with 5 years or longer follow-up.**

|                              | Mean follow-up<br>(months) | Morphology Type, %<br>(Cam/Pincer/Mixed) | Frequency<br>% (n/N) |
|------------------------------|----------------------------|--|----------------------|
| <b>CONVERSION TO THA</b>     |                            |  |                      |
| <i>Chen 2019</i>             | 69.3                       | NR/NR/NR                                 | 2% (1/50)            |
| <i>Lee 2019</i>              | 92.4                       | NR/NR/NR                                 | 2.4% (1/41)          |
| <i>Naal 2012*</i>            | 60.7                       | NR/NR/NR                                 | 3% (7/240 hips)      |
| <i>Haefeli 2017*</i>         | 84                         | 48%/25%/27%                              | 4% (2/50)            |
| <i>Perets 2019</i>           | 68.7                       | NR/NR/NR                                 | 7.6% (25/327 hips)   |
| <i>Steppacher 2014/2015*</i> | 132                        | 4%/11%/85%                               | 11% (11/97)          |
| <i>Hanke 2017</i>            | 132                        | 7.10%/10.70%/82.10%                      | 14% (9/65 hips)      |
| <i>Comba 2016</i>            | 91                         | 16.60%/4.70%/78.50%                      | 16.7% (7/42)         |
| <i>Domb 2017</i>             | 70.1                       | NR/NR/NR                                 | 17.1% (50/292 hips)  |
| <i>Kaldau 2018</i>           | 82.9                       | NR/NR/NR                                 | 18% (15/84)          |
| <i>Skendzel 2014</i>         | 73                         | NR/NR/NR                                 | 25% (117/466)        |
| <i>Perets 2018</i>           | 70.1                       | NR/NR/NR                                 | 27.7% (26/94)        |
| <i>Menge 2017</i>            | 120                        | 14.90%/2.60%/82.50%                      | 34% (50/154)         |
| <b>PROGRESSION TO OA</b>     |                            |  |                      |
| <i>Steppacher 2014/2015</i>  | 132                        | 4%/11%/85%                               | 8% (8/97)            |
| <i>Hanke 2017</i>            | 132                        | 7.10%/10.70%/82.10%                      | 8% (5/65 hips)       |
| <i>Haefeli 2017</i>          | 84                         | 48%/25%/27%                              | 12% (6/50)           |

\*Evaluated open surgical dislocation (all other studies evaluated arthroscopy)

OA=osteoarthritis; THA=total hip arthroplasty

### Effectiveness in pediatric populations

Twelve case series were identified that evaluated effectiveness following surgical intervention for FAIS in adolescents or children.<sup>23,39,41,53,69,115,122,133,149,162,193,204</sup> A statistically significant improvement from baseline to follow-up was reported for both function and pain: mHHS (11 studies), HOS-Sport subscale (5 studies), HOS-ADL subscale and NAHS (3 studies each), i-HOTT (2 studies), and HOOS (1 study) across mean follow-up periods of 1.5 to 50 months; and VAS pain (3 studies) across a mean 31 to 50 months (Table 32). Only function according to the UCLA score and quality of life (SF-12) did not improve post-operatively in one study each. The proportion of adolescent athletes that returned to sport over mean follow-up periods of 12 to 40 months post-surgery ranged from 86% to 100% across five studies (Table 33). However, whether this improvement is a result of the surgery, or the postoperative rehabilitation, or the change in activity subsequent to the surgery or placebo is not known. Only one small case series (N=28; 37 hips) in adolescent athletes (mean age 16 years; 75% male) reported conversion to THA, with no cases seen over a mean follow-up period of 40 months.<sup>115</sup>

**Table 32. Function, pain and quality of life in pediatric populations undergoing operative treatment for FAIS.**

| Outcome          | N   | Mean Age | Mean F/U | Athletes | Baseline           | Follow-up  | p-value | % meeting MCID |
|------------------|-----|----------|----------|----------|--------------------|------------|---------|----------------|
| <b>mHHS</b>      |     |          |          |          |                    |            |         |                |
| Byrd 2016a/b     | 108 | 15.9     | 29.8     | 96%      | 68.3               | 93.6       | NR      | NR             |
| Cvetanovich 2018 | 37  | 17       | 31.2     | 81%      | 43.9               | 72.2       | <0.001  | 84%            |
| Degen 2017       | 32  | 16       | 34.1     | NR       | 63.8               | 86         | <0.001  | NR             |
| Fabricant 2012   | 21  | 17.6     | 18       | 100%     | 67                 | 88         | <0.001  | NR             |
| Larson 2019      | 28  | 15.9     | 39.8     | 100%     | 66.8               | 94.5       | <0.001  | 81.1%          |
| Philippon 2012   | 60  | 15       | 42       | 100%     | 57                 | 91         | <0.001  | NR             |
| Tran 2013        | 34  | 15.7     | 14       | 94%      | 77.39              | 94.15      | <0.001  | NR             |
| Sink 2013*       | 44  | 16       | 27       | NR       | 57.7               | 85.8       | NR      | NR             |
| Litrenta 2018    | 43  | 16.1     | 50.4     | NR       | 65.1               | 90.3       | <0.001  | NR             |
| Novais 2016*     | 24  | 15.5     | 22       | 100%     | Median: 52.8       | Median: 92 | <0.0001 | NR             |
| Guindani 2017    | 18  | 14       | 36       | NR       | Mean change: -13.2 |            | 0.02    | NR             |
| <b>HOS-Sport</b> |     |          |          |          |                    |            |         |                |
| Cvetanovich 2018 | 37  | 17       | 31.2     | 81%      | 43.9               | 72.2       | <0.001  | 97%            |
| Degen 2017       | 32  | 16       | 34.1     | NR       | 52.2               | 85.7       | <0.001  | NR             |
| Fabricant 2012   | 21  | 17.6     | 18       | 100%     | 49                 | 82         | 0.001   | NR             |
| Philippon 2012   | 60  | 15       | 42       | 100%     | 38                 | 82         | <0.001  | NR             |
| Litrenta 2018    | 43  | 16.1     | 50.4     | NR       | 48.5               | 85.3       | <0.001  | NR             |
| <b>HOS-ADL</b>   |     |          |          |          |                    |            |         |                |
| Cvetanovich 2018 | 37  | 17       | 31.2     | 81%      | 66.9               | 85.9       | <0.001  | 81%            |
| Degen 2017       | 32  | 16       | 34.1     | NR       | 74.5               | 93.1       | <0.001  | NR             |

| Outcome          | N  | Mean Age | Mean F/U | Athletes | Baseline         | Follow-up  | p-value | % meetin g MCID |
|------------------|----|----------|----------|----------|------------------|------------|---------|-----------------|
| Fabricant 2012   | 21 | 17.6     | 18       | 100%     | 77               | 92         | <0.001  | NR              |
| NAHS             |    |          |          |          |                  |            |         |                 |
| Tran 2013        | 34 | 15.7     | 14       | 94%      | 76.34            | 93.18      | <0.0005 | NR              |
| Litrenta 2018    | 43 | 16.1     | 50.4     | NR       | 65.1             | 90.3       | <0.001  | NR              |
| Guindani 2017    | 18 | 14       | 36       | NR       | Mean change: -11 |            | 0.01    | NR              |
| iHOT-33/iHOT-12  |    |          |          |          |                  |            |         |                 |
| Degen 2017       | 32 | 16       | 34.1     | NR       | 43.1             | 73.6       | <0.001  | NR              |
| McConkey 2019    | 24 | 16.1     | 1.5      | 100%     | 49               | 67         | <0.001  | NR              |
| HOOS             |    |          |          |          |                  |            |         |                 |
| Novais 2016*     | 24 | 15.5     | 22       | 100%     | Median: 39       | Median: 91 | <0.0001 | NR              |
| UCLA             |    |          |          |          |                  |            |         |                 |
| Novais 2016*     | 24 | 15.5     | 22       | 100%     | Median: 10       | Median: 10 | 0.2303  | NR              |
| VAS pain         |    |          |          |          |                  |            |         |                 |
| Cvetanovich 2018 | 37 | 17       | 31.2     | 81%      | 7.6              | 2          | <0.001  | NR              |
| Larson 2019      | 28 | 15.9     | 39.8     | 100%     | 5.9              | 1.2        | <0.001  | NR              |
| Litrenta 2018    | 43 | 16.1     | 50.4     | NR       | 5.3              | 1.2        | <0.001  | NR              |
| SF-12 PCS        |    |          |          |          |                  |            |         |                 |
| Sink 2013*       | 44 | 16       | 27       | NR       | 42.4             | 50.5       | NR      | NR              |
| SF-12 MCS        |    |          |          |          |                  |            |         |                 |
| Sink 2013*       | 44 | 16       | 27       | NR       | 51.9             | 53.9       | NR      | NR              |

ADL=activities of daily living; HOOS=Hip Disability Osteoarthritis and Outcomes Score; HOS=Hip outcome score; iHOT=international Hip Outcomes Tool; MCS=mental component score; mHHS=modified Hip Harris Score; NAHS=Non-arthritis Hip Score; PCS=physical component score; VAS=visual analogue scale

\*Evaluated open surgical dislocation (all other studies evaluated arthroscopy)

**Table 33. Return to sport in pediatric populations undergoing operative treatment for FAIS.**

| Author, year     | Mean age | Athletes | Mean F/U | Return to sport, % (n/N) |
|------------------|----------|----------|----------|--------------------------|
| Byrd 2016a       | 16       | 100%     | 38       | 86% (100/116)            |
| Cvetanovich 2018 | 17       | 81%      | 31.2     | 100% (29/29)             |
| Larson 2019      | 15.9     | 100%     | 39.8     | 93% (NR/NR)              |
| Tran 2013        | 15.7     | 94%      | 14       | 90.6% (29/32)            |
| Novais 2016*     | 15.5     | NR       | 22       | 90% (19/21)              |

\*Evaluated open surgical dislocation (all other studies evaluated arthroscopy)

F/U = follow-up.



### 4.3 Key Question 2: Safety

#### Summary of results

- Two randomized controlled trials (RCTs) comparing arthroscopy versus physical therapy (PT) reported treatment-related adverse events (AEs) from both groups; there were no deaths and both serious and non-serious AEs were more common following arthroscopy. Given that arthroscopy is invasive while PT is not, one would not expect serious adverse events or death with PT. (SOE: low)
- Across RCTs, comparative surgery cohorts, case series and systematic reviews of case series in adults it appears that the frequency of most serious surgical complications may be low (<3%) . Surgical complications with higher risks included nerve injury (0% to 25%; 0% to 9% excluding outliers) and revision surgery (0% to 8%). In adolescent patients, limited information from case series also suggests that the complication rate is low (<3%); no cases of physeal arrest/growth disturbance, femoral fracture, nonunion of the greater trochanter, avascular necrosis, acute iatrogenic slipped capital femoral epiphysis, or iatrogenic instability were seen in any study of adolescent patients. (SOE: low)

#### 4.3.1 Number of studies retained

All comparative studies included for efficacy/effectiveness were evaluated for safety outcomes. Case series with at least 40 patients (except in the event of rare outcomes) that were designed to look at safety outcomes were also included; for pediatric populations, no limits were placed on inclusion of case-series. In addition, systematic reviews that focused on safety were sought. In total, 58 studies (3 RCTs,<sup>66,125,153</sup> 12 cohort studies,<sup>17,21,27,49,84,113,135,169,170,179,209,215</sup> 4 SRs of cases series,<sup>16,40,139,178</sup> and 40 additional case series [across 42 publications]<sup>14,23,24,28,30,38,41,46,50,53,60,69,73,77,80,85,91,102,111,115,122,129,133,136,143,148,149,154,155,158,159,176,180,182,186,187,193,204,214</sup> provided data related to safety. The RCT evaluating labral repair versus labral debridement<sup>106</sup> and the two observational comparative cohorts comparing operative versus non-operative care<sup>98,157</sup> did not provide data on complications.

#### 4.3.2 Randomized controlled trials

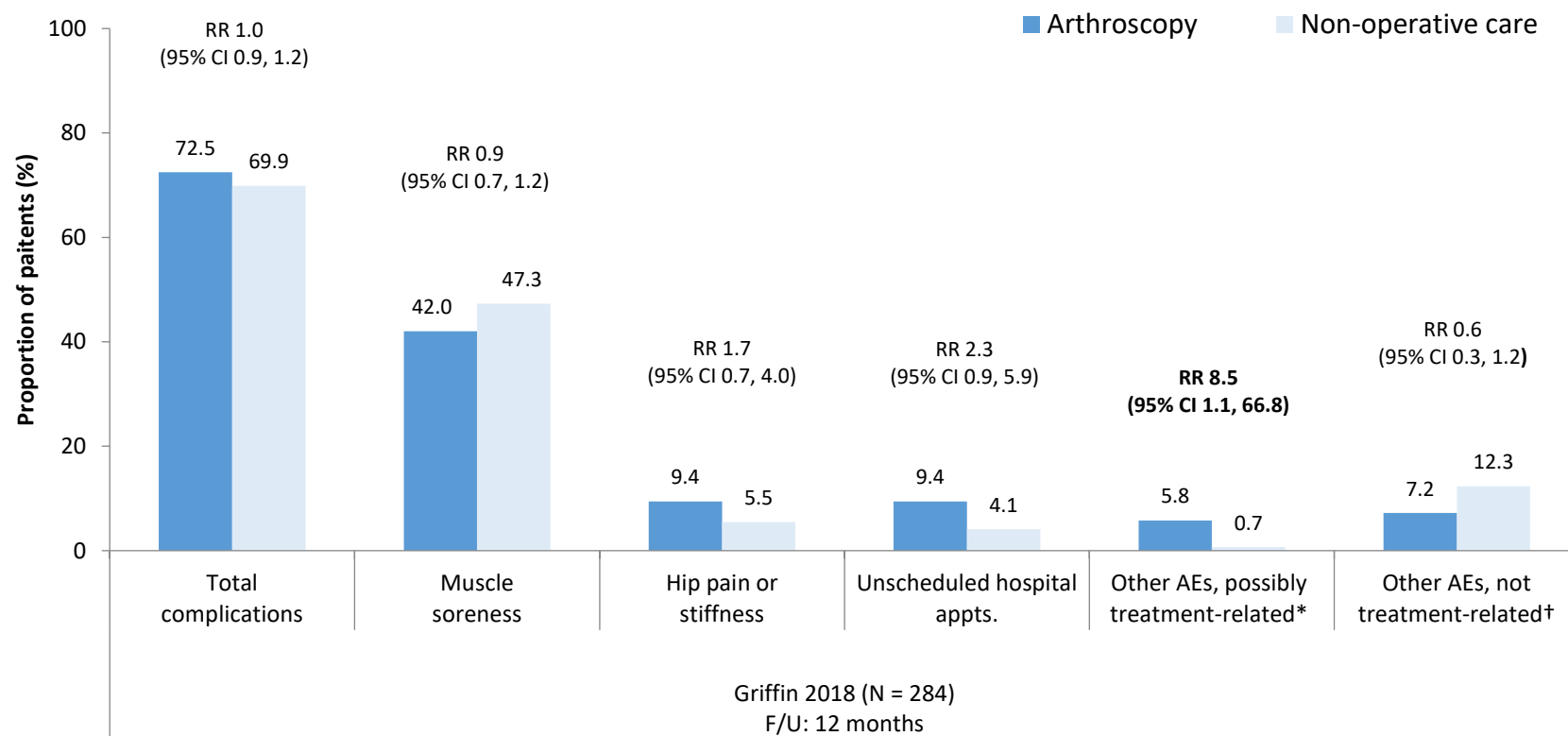
Adverse events were reported variably across the three RCTs comparing arthroscopy with non-operative care (i.e., physiotherapy). Follow-up ranged from 8 to 24 months.

#### *Arthroscopy versus Non-operative treatment*

The frequency of any serious adverse event was low and somewhat greater following arthroscopy versus non-operative care across two trials (2.5% vs. 0.4% over 8 and 12 months),<sup>66,153</sup> though the pooled effect estimate did not reach statistical significance and the confidence interval was very wide (RR 6.1, 95% CI 0.7, 50.5). Individually, neither trial reported a statistically significant difference between groups in the risk of any serious adverse event (4.3% vs. 0.7%, RR 6.4, 95% CI 0.8 to 52.1 in 1 RCT with 12-month follow-up<sup>66</sup> and none in either group in the other RCT with 8 month follow-up<sup>153</sup>); however, one RCT<sup>66</sup> found that the risk of a treatment-related serious adverse event was greater in patients treated with arthroscopy (n=5) versus non-operative care (n=0) at 12 months: 3.6% vs. 0%, p=0.02.<sup>66</sup> (The serious treatment-related adverse events included an overnight admission post-arthroscopy, scrotal haematoma requiring readmission, superficial wound infections that required oral

antibiotics [2 patients], hip joint infection that required further surgery and ultimately a THA). Hip fracture was rare and was reported in only one patient who had received arthroscopy across two trials with 12 and 24 months of follow-up (pooled proportions: 0.5% vs. 0%).<sup>66,125</sup> Contralateral hip surgery occurred more often over a 24 month follow-up period in patients who received arthroscopy versus non-operative treatment (9.2% vs. 0%) in one small RCT conducted in a military population, however the difference did not reach statistical significance likely due to the small sample size.<sup>125</sup> No treatment related deaths were reported by one RCT over 12 months<sup>66</sup>; a second trial reported that one patient allocated to arthroscopy died during the study period due to an unrelated condition.<sup>125</sup>

A number of other complications were reported by one trial with 12-month follow-up (Figure 7)<sup>66</sup>; only “other adverse events possibly treatment-related” differed statistically between groups and was reported in eight arthroscopy patients (9 events) and one non-operative patient (5.8% vs. 0.7%; RR 8.5, 95% CI 1.1 to 66.8); the number of events was few and the confidence interval was extremely wide.

**Figure 7. Other complications from the RCT by Griffin et al. 2018 comparing arthroscopy versus non-operative care for FAIS.**

AEs = adverse events; appt. = appointments; CI = confidence interval; F/U = follow-up; RCT = randomized controlled trial; RR = risk ratio.

\*Arthroscopy group (n=8; 9 events): 2 numbness proximal thigh; 1 each of the following: scrotal infection, scrotal bruising, labial swelling, ankle pain, erratic International Normalized Ratio, nausea secondary to analgesia, numbness to tip of tongue for 2 weeks after operation. Non-operative group: 1 muscle spasms.

†Arthroscopy group (n=10): 3 knee pain, 2 lower back pain, 1 shingles, 1 urinary tract infection, 1 essential thrombocythaemia, 1 hernia surgery, 1 contralateral foot pain; Non-operative group (n=18): 7 lower back pain, 2 knee pain, 2 road traffic collisions, 2 abdominal pain under investigation, 1 viral illness, 1 endometriosis, 1 chronic pain referred to rheumatologist, 1 skin discoloration, 1 multiple sclerosis.

### Complications Specific to Operative Treatment

Regarding complications specific to arthroscopy (Table 34), the frequency of treatment-related nerve injury was 2.1% (5/237) across two RCTs and included lateral femoral cutaneous nerve injury or numbness in four patients and numbness to tip of tongue in one patient<sup>66,153</sup>; the risk of any nerve injury was 16.9% across the trials which includes numbness of the groin, leg or foot as reported by one trial (unclear whether or not these events were considered treatment-related).<sup>66</sup> Infection was reported by all three trials and occurred in a total of eleven patients (3.6%). When considering specific types of infection, the frequency was as follows: hip joint infection (0.5% across 2 RCTs, N=203),<sup>66,125</sup> any superficial wound infection (4.2% across 2 RCTs, N=237),<sup>66,153</sup> and superficial wound infection requiring antibiotics (2.1% across 2 RCTs, N=237).<sup>66,153</sup> One case (1.5%) of heterotopic ossification and five cases (7.7%) of revision surgery were reported in one trial conducted in a military population.<sup>125</sup> There were no incidences of deep vein thrombosis (2 RCTs)<sup>66,125</sup> or avascular necrosis (1 RCT)<sup>125</sup> reported. Sample sizes may have precluded detection of rare events.

**Table 34. Operative-specific adverse events from RCTs.**

|   |           |   | Arthroscopy |       |
|---|-----------|---|-------------|-------|
| Author  | Follow-up | Complication                                      | n/N         | %     |
| NERVE INJURY  |           |   |             |       |
| Griffin 2018  | 12 months | Numbness, proximal thigh*                         | 2/138       | 1.4%  |
|   |           | Numbness, tip of tongue*                          | 1/138       | 0.7%  |
|   |           | Numbness, groin, leg or foot                      | 35/138      | 25.4% |
| Palmer 2019   | 8 months  | Nerve injury, lateral femoral cutaneous nerve†    | 2/99        | 2.0%  |
| Pooled, any   |           |   | 40/237      | 16.9% |
| Pooled, [potentially] treatment-related                   |           |   | 5/237       | 2.1%  |
| INFECTION   |           |   |             |       |
| Griffin 2018  | 12 months | Superficial wound infection‡                      | 9/138       | 6.5%  |
|   |           | Scrotal infection*                                | 1/138       | 0.7%  |
|   |           | Hip joint infection                               | 1/138       | 0.7%  |
| Mansell 2018  | 24 months | Hip joint infection                               | 0/65        | 0%    |
| Palmer 2019   | 8 months  | Superficial wound infection, required antibiotics | 1/99        | 1.0%  |
| Pooled, any   |           |   | 11/302      | 3.6%  |
| Pooled, hip joint infection                               |           |   | 1/203       | 0.5%  |
| Pooled, any superficial wound infection                   |           |   | 10/237      | 4.2%  |
| Pooled, superficial wound infection requiring antibiotics |           |   | 5/237       | 2.1%  |
| THROMBOEMBOLIC EVENTS                                     |           |   |             |       |
| Griffin 2018  | 12 months | Deep vein thrombosis                              | 0/138       | 0%    |
| Mansell 2018  | 24 months | Deep vein thrombosis                              | 0/65        | 0%    |
| AVASCULAR NECROSIS, HETEROTOPIC OSSIFICATION              |           |   |             |       |
| Mansell 2018  | 24 months | Avascular necrosis                                | 0/65        | 0%    |
|   |           | Heterotopic ossification                          | 1/65        | 1.5%  |

| Author           | Follow-up | Complication     | Arthroscopy |      |
|------------------|-----------|------------------|-------------|------|
|                  |           |                  | n/N         | %    |
| REVISION SURGERY |           |                  |             |      |
| Mansell 2018     | 24 months | Revision surgery | 5/65        | 7.7% |

Denominators = number of patients unless otherwise specified.

\*Potentially related to treatment per authors.

†Treatment-related; transient.

‡Four patients required antibiotics.

### 4.3.3 Comparative cohort studies

A total of 12 observational comparative cohort studies reported complications following various surgical approaches to FAI over a wide range of follow-up periods (12 to 120 months).<sup>17,21,27,49,84,113,135,169,170,179,209,215</sup> Complications were not reported by either of the two cohort studies that compared operative versus non-operative treatment.<sup>98,157</sup>

Regardless of surgical approach, there were no cases of avascular necrosis (4 studies),<sup>17,84,113,179</sup> or femoral neck fracture (3 studies)<sup>84,113,179</sup> reported. The frequency of heterotopic ossification (HO) was low in both the intervention and control groups across three studies (0%-1% vs. 0%)<sup>17,113,170</sup>; one study reported a relatively high frequency of HO in its population (arthroscopy 10% [4/40] vs. open surgery 31% [5/16]), however the sample size was small and unbalanced between groups.<sup>179</sup> Nerve injuries were reported in 0% to 4% of patients in the intervention groups compared with 0% to 25% (0% after removal of one outlier study<sup>179</sup>) in the control groups across four studies.<sup>17,170,179,215</sup> An additional study reported nerve palsy (femoral, pudendal, and obturator) in 9% of the total population (not reported by group).<sup>27</sup> The frequency of revision surgery ranged from 0% to 8% and from 0% to 12% in the intervention and control groups, respectively, across ten studies.<sup>17,21,27,49,113,135,169,170,209,215</sup> Results according to specific surgical comparisons are below. Sample sizes within and across studies may have been insufficient to detect rare events.

#### **Arthroscopic versus open surgery**

Six cohort studies comparing arthroscopic with open surgery reported on complications over follow-up periods ranging from 12 months to a mean of 59 months (Table 35).<sup>17,21,49,170,179,215</sup> In one small retrospective study (N=56), grade 1 heterotopic ossification (HO) and lateral femoral cutaneous nerve injury (transient) were less frequent following arthroscopic vs. open surgery (HO: 8% vs. 31%; RR 0.2, 95% CI 0.1 to 0.9; nerve injury: 0% vs. 25%, p=0.001)<sup>179</sup>; no statistical difference between groups was seen across other studies reporting HO (2 studies) and nerve injury (3 studies). Additional surgery to remove hardware was required in no patient who underwent arthroscopy compared with 20% to 80% of patients who received open surgery as reported by three studies<sup>17,49,215</sup>; the difference between groups was statistically significant in two of the studies (p<0.001).<sup>49,215</sup> There were no incidences of avascular necrosis, femoral neck fracture, or deep infection reported. No statistically significant differences were seen between groups across studies for any other adverse event reported. Sample sizes within and across studies may have been insufficient to detect rare events.

**Table 35. Adverse events from nonrandomized observational cohort studies comparing arthroscopy vs. open hip dislocation surgery.**

|   | Mean follow-up (months) | Arthroscopy % (n/N)   | Open % (n/N)   | RR (95% CI)*<br>p-value*                     |
|---|-------------------------|---|--|--|
| <b>AVASCULAR NECROSIS</b>                                 |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 0% (0/18)   | 0% (0/5)   | -----  |
| <i>Roos 2017</i>  | 36                      | 0% (0/40)   | 0% (0/16)  | -----  |
| <b>BONE COMPLICATIONS</b>                                 |                         |   |  |  |
| <b>Femoral neck fracture</b>                              |                         |   |  |  |
| <i>Roos 2017</i>  | 36                      | 0% (0/40)   | 0% (1/16)  | -----  |
| <b>Nonunion of the greater trochanter</b>                 |                         |   |  |  |
| <i>Buchler 2013</i>                                       | 15.5                    | 0% (0/66)   | 2% (3/135) <sup>†</sup>                                      | NS   |
| <i>Rego 2018</i>  | 59                      | 0% (0/102)  | 1% (1/96) (grade 3) <sup>†</sup>                             | NS   |
| <b>Delayed consolidation of greater trochanter</b>        |                         |   |  |  |
| <i>Rego 2018</i>  | 59                      | 0% (0/102)  | 2% (2/96) (grade 2) <sup>‡</sup>                             | NS   |
| <b>HETEROTOPIC OSSIFICATION</b>                           |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 0% (0/18)   | 0% (0/5)   | -----  |
| <i>Roos 2017 (any grade HO)</i>                           | 36                      | any: 10% (4/40)<br>grade 1: 8% (3/40)<br>grade 3: 3% (1/40) | any: 31% (5/16)<br>grade 1: 31% (5/16)<br>grade 3: 0% (0/16) | RR 0.3 (0.1, 1.0)<br>RR 0.2 (0.1, 0.9)<br>NS |
| <i>Rego 2018</i>  | 59                      | 1% (1/102) (grade 1)  | 0% (0/96)  | NS   |
| <b>NERVE COMPLICATIONS</b>                                |                         |   |  |  |
| <b>Lateral femoral cutaneous nerve injury (transient)</b> |                         |   |  |  |
| <i>Roos 2017</i>  | 36                      | 0% (0/40)   | 25% (4/16)   | p=0.001                                      |
| <i>Zingg 2013</i>   | max. 12                 | 4% (1/23)   | 0% (0/15)  | NS   |
| <b>Pudendal nerve injury (transient)</b>                  |                         |   |  |  |
| <i>Roos 2017</i>  | 36                      | 3% (1/40)   | 0% (0/16)  | NS   |
| <i>Rego 2018</i>  | 59                      | 2% (2/102)  | 0% (0/96)  | NS   |
| <b>Neuropraxia (NOS)</b>                                  |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 0% (0/18)   | 0% (0/5)   | -----  |
| <b>THROMBOEMBOLIC EVENTS</b>                              |                         |   |  |  |
| <b>DVT</b>  |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 0% (0/18)   | 0% (0/5)   | -----  |
| <i>Roos 2017</i>  | 36                      | 3% (1/40)   | 0% (1/16)  | NS   |
| <i>Rego 2018</i>  | 59                      | 0% (0/102)  | 2% (2/96)  | NS   |
| <b>WOUND COMPLICATIONS</b>                                |                         |   |  |  |
| <b>Deep/major infection</b>                               |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 0% (0/18)   | 0% (0/5)   | -----  |
| <i>Roos 2017</i>  | 36                      | 0% (0/40)   | 0% (0/16)  | -----  |
| <b>Superficial wound infection</b>                        |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 6% (1/18)   | 0% (0/5)   | NS   |
| <i>Rego 2018</i>  | 59                      | 0% (0/102)  | 1% (1/96)  | NS   |
| <i>Roos 2017</i>  | 36                      | 0% (1/40)   | 0% (1/16)  | -----  |
| <b>OTHER VASCULAR COMPLICATIONS</b>                       |                         |   |  |  |
| <b>Compartment syndrome</b>                               |                         |   |  |  |
| <i>Rego 2018</i>  | 59                      | 1% (1/102) (grade 3) <sup>§</sup>                           | 0% (0/96)  | NS   |
| <b>Hematoma</b>   |                         |   |  |  |
| <i>Rego 2018</i>  | 59                      | 1% (1/102) (grade 2) <sup>**</sup>                          | 0% (0/96)  | NS   |
| <b>REVISIONS AND ADDITIONAL SURGERIES</b>                 |                         |   |  |  |
| <b>Revision</b>   |                         |   |  |  |
| <i>Botser 2014</i>  | 14.7                    | 6% (1/18) <sup>††</sup>                                     | 0% (0/5)   | NR   |

|                                    | Mean follow-up (months) | Arthroscopy % (n/N) | Open % (n/N) | RR (95% CI)*<br>p-value* |
|------------------------------------|-------------------------|---------------------|--------------|--------------------------|
| <i>Buchler 2013</i>                | 15.5                    | 6% (4/66)           | 12% (16/135) | RR 0.5 (0.2, 1.5)        |
| <i>Domb 2013</i>                   | 25                      | 0% (0/20)           | 10% (1/10)   | NS                       |
| <i>Rego 2018†‡</i>                 | 59                      | 1% (1/102)          | 2% (2/96)    | NS                       |
| <i>Zingg 2013</i>                  | max. 12                 | 0% (0/23)           | 7% (1/15)    | NS                       |
| <b>Hardware removal</b>            |                         |                     |              |                          |
| <i>Botser 2014</i>                 | 14.7                    | 0% (0/18)           | 20% (1/5)§§  | NS                       |
| <i>Domb 2013***</i>                | 25                      | 0% (0/20)           | 80% (8/10)   | p<0.001                  |
| <i>Zingg 2013</i>                  | max. 12                 | 0% (0/23)           | 47% (7/15)   | p<0.001                  |
| <b>Additional Surgeries</b>        |                         |                     |              |                          |
| <i>Domb 2013</i>                   | 25                      | 5% (1/20)+++        | 0% (0/10)    | NS                       |
| <i>Rego 2018</i>                   | 59                      | 1% (1/102)‡‡‡       | 0% (0/96)    | NS                       |
| <b>TOTAL COMPLICATIONS</b>         |                         |                     |              |                          |
| <i>Rego 2018 (any)</i>             | 59                      | 7% (7/102)          | 7% (7/96)    | NR                       |
| <i>Buchler 2013 (grade 3/4)§§§</i> | 15.5                    | 6% (4/66)           | 14% (19/135) | RR 0.4 (0.2, 1.2)        |

Denominators = number of patients unless otherwise specified.

NR: Not Reported; ns: not significant.

\*Calculated by AAI

†Required refixation (included in revision count).

‡No treatment required.

§required surgery (included in reoperation count)

\*\*required medical treatment.

††Due to reinjury.

‡‡Due to Adhesive capsulitis grade III (1 patient in both groups) and pseudarthrosis grade III (1 patient in open group)

§§Due to persistent pain.

\*\*\*Authors did not count these screw removals as complications because they were planned.

+++iliopsoas release due to new onset symptomatic internal snapping)

‡‡‡compartment syndrome grade III

§§§ Sink grade II or IV: grade III (treatable and resolved with surgery or inpatient management) or grade IV complications (resulting in a long-term deficit)

### **Labral repair vs. labral debridement**

No statistically significant differences were seen across three studies that reported complications following arthroscopic labral repair versus labral debridement (Table 36). The frequency of revision surgery ranged from 2% to 6% in the repair groups and 3% to 9% in the debridement group across all studies.<sup>27,113,135</sup> There were no incidences of avascular necrosis, femoral neck fracture or heterotopic ossification in the one study that reported these outcomes.<sup>113</sup>

### **Other comparison of surgical approaches**

Two retrospective cohort studies reported similar frequencies of revision surgery following different arthroscopic approaches for treating the labrum in conjunction with acetabuloplasty (Table 36); one evaluated patients with labral tears who had undergone labral refixation without or with labral detachment (8% revision rate for both groups)<sup>169</sup> and the other evaluated patients treated without or with labral detachment and subsequent repair based on the presence of a labral tear (8% vs. 10%, respectively).<sup>209</sup> In the latter study (N=950), capsular adhesion was the only indication for revision surgery that differed significantly between the two groups with a lower frequency in patients who avoided labral detachment and repair versus those who needed it (1% vs. 5%; RR 0.3, 95% CI 0.1 to 0.7). Also in this same study, three patients (0.3%) underwent revision for osteoarthritis; authors did not report patients' OA status at baseline. The length of follow-up was unclear in both studies. A third small

study (N=30 hips) reported no instances of femoral neck fracture, osteonecrosis or other complications (not specified) in patients who did and did not receive subsequent acetabular osteoplasty (i.e., “rim trim”) in conjunction with femoral osteochondroplasty.<sup>84</sup>

**Table 36. Adverse events from nonrandomized observational cohort studies comparing various surgical approaches to the treatment of FAIS.**

| Author  | Mean F/U         | Outcome                          | Intervention<br>% (n/N) | Control<br>% (n/N) | RR (95% CI)<br>p-value |
|---|------------------|----------------------------------|-------------------------|--------------------|------------------------|
| COMPARISON: Labral repair vs. Labral Debridement*       |                  |                                  |                         |                    |                        |
| Cetinkaya<br>2016                                       | 44.9 mos.        | Transient nerve palsy            | overall: 9% (6/67)†     |                    | ----                   |
|   |                  | Revision surgery                 | 3% (1/33)               | 3% (1/34)          | NS                     |
| Larson 2012   | 42.4 mos.        | Femoral neck fracture            | 0% (0/52)               | 0% (0/44)          | ----                   |
|   |                  | AVN                              | 0% (0/52)               | 0% (0/44)          | ----                   |
|   |                  | HO                               | 0% (0/52)               | 0% (0/44)          | ----                   |
|   |                  | Iatrogenic hip<br>instability    | 0% (0/52)               | 0% (0/44)          | ----                   |
|   |                  | Revision surgery                 | 2% (1/52)               | 9% (4/44)          | RR 0.2 (0.02, 1.8)     |
| Menge 2017  | Max. 120<br>mos. | Revision surgery                 | 6% (5/79)               | 3% (2/75)          | RR 2.4 (0.5, 11.9)     |
| COMPARISON: No labral detachment vs. Labral detachment‡ |                  |                                  |                         |                    |                        |
| Redmond<br>2015   | NR               | Revision surgery§                | 8% (7/85 hips)          | 8% (8/105 hips)    | ----                   |
| COMPARISON: No labral repair vs. Labral repair**        |                  |                                  |                         |                    |                        |
| Webb 2019   | NR               | Revision surgery                 | 8% (36/431)             | 10% (54/519)       | RR 0.8 (0.5, 1.2)      |
|   |                  | Adhesion                         | 1% (6/431)              | 5% (25/519)        | RR 0.3 (0.1, 0.7)      |
|   |                  | Non-specific<br>synovitis        | 4% (19/431)             | 3% (17/519)        | RR 1.3 (0.7, 2.6)      |
|   |                  | Synovitis                        | 0% (0/431)              | 0.2% (1/519)       | NS                     |
|   |                  | Partial ligamentum<br>teres tear | 2% (10/431)             | 2% (12/519)        | NS                     |
|   |                  | Cam lesions                      | 3% (11/431)             | 0.6% (3/519)       | RR 4.4 (1.2, 15.7)     |
|   |                  | Chondral<br>calcification        | 0% (0/431)              | 0.2% (1/519)       | NS                     |
|   |                  | Labral tear                      | 0% (0/431)              | 0.2% (1/519)       | NS                     |
|   |                  | Chondral flap                    | 0% (0/431)              | 0.2% (1/519)       | NS                     |
|   |                  | Adductor tendon<br>release       | 0% (0/431)              | 0.2% (1/519)       | NS                     |
|   |                  | Trochanteric<br>bursectomy       | 0.2% (1/431)            | 0.2% (1/519)       | RR 1.2 (0.1, 19.2)     |
|   |                  | Osteoarthritis                   | 0.7% (3/431)            | 0% (0/519)         | NS                     |
|   |                  | No abnormality<br>detected       | 0.5% (2/431)            | 0% (0/519)         | NS                     |
|   |                  | Time to revision                 | 20 months               | 16 months          | p=0.026                |
| COMPARISON: No rim trim vs. Rim trim††                  |                  |                                  |                         |                    |                        |
| Hingshamme<br>r 2015                                    | 19.5 mos.        | Femoral neck fracture            | 0% (0/9 hips)           | 0% (0/21 hips)     | ----                   |
|   |                  | Osteonecrosis                    | 0% (0/9 hips)           | 0% (0/21 hips)     | ----                   |
|   |                  | Other                            | 0% (0/9 hips)           | 0% (0/21 hips)     | ----                   |

AVN = avascular necrosis; CI = confidence interval; F/U = follow-up; HO = heterotopic ossification; max = maximum; mos. = months; NR = not reported; NS = not statistically significant; RR = risk ratio.



\*Patients had primarily mixed-type FAI followed by pincer-type then cam-type. All procedures were via an arthroscopy approach; surgical details varied.

†Two patients each had femoral nerve palsy (1 required surgical release), pudendal nerve palsy, and obturator nerve palsy.

‡All patients had mixed- or pincer-type FAI. Both groups underwent acetabuloplasty and labral refixation; if the chondrolabral junction was in satisfactory condition and the acetabular rim resection could be performed without labral detachment, the labrum was left attached (no labral detachment group); if not, the labrum was detached (labral detachment group).

§Performed for the following indications (not reported by group): labral reinjury, heterotopic ossification, adhesive capsulitis, and chondral injury.

\*\*All patients had pincer-type FAI. Both groups underwent acetabuloplasty. In those without labral tears (no labral repair group) the rim of the acetabulum was approached from the paralabral recess superiorly by partially releasing some of the superior capsule (i.e., in order to avoid damage to the intact chondrolabral junction). In those with labral tears (labral repair group), the labrum was detached and the preexisting tear was used to gain access to the rim and then was subsequently repaired.

††All patients had mixed-type FAI. Both groups underwent femoral osteochondroplasty via open hip dislocation with (rim trim group) or without (no rim trim group) acetabular osteoplasty; labral detachment/refixation and partial labral excision/debridement was done as needed (100% vs. 22% of hips in the groups, respectively).

#### 4.3.4 Case series

Four systematic reviews (SRs) of case series that reported complications following surgical treatment of FAIS were identified; three SRs included studies of adult populations (range across SRs: 28 to 68 studies; mean age, 30 to 36 years)<sup>16,139,178</sup> and one included studies of adolescent populations (8 studies; mean age range 15.7 to 17.6 years).<sup>40</sup> All surgeries were performed via an arthroscopic approach in the three SRs in adult populations; in the SR in adolescents,<sup>40</sup> 81% of hips underwent arthroscopy and 19% had open hip dislocation. One of the SRs in adult populations look specifically at the risk of thromboembolic events<sup>16</sup>; all other SRs reported general complications associated with surgical intervention. There is some overlap between the SRs regarding included case series.

In addition, a total of 40 case series (42 publications) not included in the SRs were identified that met inclusion criteria and evaluated safety outcomes following operative treatment for FAI; 28 (29 publications)<sup>14,26,28,30,38,46,50,60,73,77,80,85,91,102,111,129,136,143,148,154,155,158,159,176,180,182,186,187,214</sup> were in adult populations [sample size ranged from 14 to 14,970, mean age from 19.5 to 44.6 years (across 25 studies), proportion female from 13% to 89% (across 25 studies), and mean follow-up from 18.7 months to 84 months (across 19 studies)] and 12 (13 publications)<sup>23,24,39,41,53,69,115,122,133,149,162,193,204</sup> were in adolescent populations [sample size ranged from 18 to 108, mean age from 15 to 17.6 (across 11 studies), proportion female from 15% to 84% (across 11 studies), and mean follow-up from 14 to 50.6 months]. Impingement type was not extensively reported across the studies; the least common type of FAI across series was pincer. Across the 14 series in adults<sup>28,30,38,50,73,80,91,102,129,148,154,180,182,214</sup> reporting impingement type, cam ranged from 3.5% to 100%, pincer from 0% to 40.3%, and mixed type from 0% to 74.4%. Across the 8 series (9 publications)<sup>23,24,39,41,53,133,149,162,204</sup> in pediatrics reporting impingement type, cam ranged from 10% to 100%, pincer from 4% to 15%, and mixed type from 22% to 84%. For adults, 24 series (25 publications)<sup>14,26,38,46,50,60,73,77,80,85,91,111,129,136,148,154,155,158,159,176,180,182,186,187,214</sup> evaluated arthroscopy and four series (4 publications)<sup>28,30,102,143</sup> evaluated open or mini-open surgery. For pediatrics, 10 series (11 publications)<sup>23,24,39,41,53,69,115,122,133,162,204</sup> evaluated arthroscopy and two series (2 publications)<sup>149,193</sup> evaluated open surgery.

The most commonly reported adverse events and serious adverse events are described below; for all complications reported by case series, please see Appendix G. Studies of arthroscopy and mini-open/open hip dislocations are reported on together unless there was a distinct difference in frequency of the complications between the different surgical approaches; in those instances the approaches are reported on separately.

In addition, Table 37 at the end of this section summarizes adverse events across all study types, including SRs, RCTs, comparative observational cohorts, and case series with at least 300 patients (for adults only).

## **Heterotopic Ossification (HO)**

### ***Adult populations***

Two SRs reported the frequency of HO following arthroscopy which ranged from 0.5% (33/7241)<sup>178</sup> to 0.8% (16/1981)<sup>139</sup> of hips over mean follow-up periods of 34 and 30 months, respectively. Across 14 additional case series, the frequency of heterotopic ossification following arthroscopic surgery ranged from 0.5% to 5.3% of patients (9 studies; N=54 to 1870)<sup>14,50,60,77,91,148,154,159,176</sup> and from 0.8% to 11.5% of hips (2 studies; N=1615 and 52 hips, respectively)<sup>73,111</sup>; following open or mini-open surgical approaches the frequencies were higher: 25% and 33.9% of patients (2 studies; N=16 and 106, respectively)<sup>28,30</sup> and 35% of hips (1 study; N=233 hips).<sup>143</sup>

### ***Pediatric populations***

In one SR in adolescent patients,<sup>40</sup> one case of asymptomatic HO (0.2%; 1/435 hips) was reported in a patient that had undergone open hip dislocation surgery (1.2%; 1/81 hips with open surgery); mean follow-up periods across included studies ranged from 3 to 75 months. Two additional case series reported one case of HO each (2.3%) in their populations over mean follow-up periods of 24 and 50 months after open hip dislocation surgery<sup>193</sup> and arthroscopic surgery,<sup>122</sup> respectively.

## **Avascular Necrosis (AVN)**

### ***Adult populations***

No cases of AVN following arthroscopy were reported in one of the SRs in adults over a mean follow-up period of 34 months.<sup>178</sup> Six additional case series reported frequencies of AVN ranging from 0% to 12.5% of adult patients (Ns ranged from 14 to 1870) across mean follow periods of 25 to 61 months.<sup>28,50,143,176,182,186</sup>

### ***Pediatric populations***

In one SR in adolescent patients (435 hips),<sup>40</sup> no cases of AVN were reported over mean follow-up periods ranging from 3 to 75 months. Similarly, no cases of AVN were reported by four additional case series with follow-up ranging from 14 to 40 months.<sup>23,39,115,204</sup>

## **Fracture**

### ***Adult populations***

Across two SRs in adult populations, femoral neck fracture was very rare with only two reported cases; frequencies were 0.01% (1/7241)<sup>178</sup> and 0.05% (1/1981)<sup>139</sup> across 34 and 30 months of follow-up, respectively. Ten additional case series in adults reported frequencies of femoral fracture ranging from 0% to 6.3% of patients (8 studies; N range 16 to 1870)<sup>28,38,46,50,102,159,176,214</sup> over mean follow-up periods ranging from 1.5 to 68.7 months and 0.07% to 0.1% of hips at a mean of 18.7 months (2 studies; N, 14,945 and 1615, respectively).<sup>111,136</sup> Excluding the one very small case series (N=16)<sup>28</sup> evaluating

surgical hip dislocation for patients with cam FAI, the range of femoral neck fracture was 0% to 2% of patients across seven larger trials. Additionally, one of the larger case series reported 15 cases (0.8%) of pelvic fracture over 48 months or longer of follow-up.<sup>176</sup>

### ***Pediatric populations***

No cases of iatrogenic femoral neck fracture were reported in one SR in adolescent patients (435 hips) over mean follow-up periods ranging from 3 to 75 months<sup>40</sup> or in one additional small case series of 44 children treated with open hip dislocation surgery and followed for 24 months.<sup>193</sup>

## **Nerve injury**

### ***Adult populations***

Across two SRs in adult populations,<sup>139,178</sup> the frequency of various nerve injuries over mean follow-up periods of 34 and 30 months, respectively, was as follows: lateral femoral cutaneous neurapraxia, 0.2% for both (16/7241 and 4/1981); femoral neurapraxia, 0.01% (1/7241) and 0.1% (2/1981); pudendal neurapraxia, 0.3% (25/7241) and 0.1% (2/1981); and sciatic neurapraxia, 0.03% (2/7241) and 0.2% (3/1981). One SR also reported 29 cases (0.4%) of unspecified neurapraxia over a mean of 34 months.<sup>178</sup> Ten additional case series<sup>26,38,46,50,111,129,148,154,159,180</sup> reported variable rates of nerve injury (0.6% to 63% of patients; 0.1% to 1.6 of hips) across follow-up periods ranging from immediately post-operative to 69 months, of which the most commonly reported injuries were to the: femoral cutaneous nerve in 1% to 13% of patients (2 studies, N=197 and 45, respectively)<sup>26,154</sup> and 1.6% of hips (1 study, N=1615)<sup>111</sup>; pudendal nerve 0.6% to 18.8% of patients (5 studies; N range, 40 to 414)<sup>38,46,148,154,180</sup> and 1.2% of hips (1 study, N=1615)<sup>111</sup>; and other non-specific nerve injuries in 5.4% to 13.3% of patients (3 studies; N range, 45 to 295)<sup>26,50,159</sup> and 0.2% of hips (1 study, N=1615)<sup>111</sup>. The large case series in hips was evaluating intraoperative and early postoperative complications after arthroscopic surgery.

### ***Pediatric populations***

Five case series reported the frequency of nerve injury in pediatric populations which ranged from 1.9% to 8.3%<sup>23,24,39,41,133</sup>; rates of specific injuries were as follows: pudendal nerve injury in two studies (1.9% to 2.7%)<sup>24,39</sup> and one study each reporting femoral cutaneous nerve injury (8.3%),<sup>133</sup> perineum nerve injury (1.9%),<sup>23</sup> and other non-specific injuries (3%).<sup>41</sup> Of note, the study reporting the highest rate of nerve injury was in adolescent athletes undergoing simultaneous bilateral arthroscopy for FAIS.<sup>133</sup>

## **Infections**

### ***Adult populations***

The frequency of superficial infections ranged from 0.2% (4/1981)<sup>139</sup> to 0.3% (19/7241)<sup>178</sup> across two SRs in adult populations with mean follow-up periods of 30 and 34 months, respectively; one of these SRs also reported one case (0.01%) of deep infection over a mean of 34 months. Seven additional case series<sup>38,102,111,148,154,159,176</sup> reported on infection rates over mean follow-up periods of 6 to 68.7 months, specifically superficial wound infection in 0% to 2% of patients (4 studies; N range, 48 to 414)<sup>38,102,154,159</sup> and 1.1% of hips (1 study; N=1615 hips)<sup>111</sup>; deep portal infection in 0% of patients in one small study (N=48)<sup>102</sup> and 0.1% of hips in one large study (N=1615 hips)<sup>111</sup>; and infection not otherwise specified occurred in 0.2% to 0.3% of patients across two larger series (N=360, 1870).<sup>148,176</sup>

### ***Pediatric populations***

In one SR in adolescent patients (435 hips),<sup>40</sup> no cases of post-operative infection were reported over mean follow-up periods ranging from 3 to 75 months. Across three additional care series in pediatric patients,<sup>39,193,204</sup> only one case (2.7%) of superficial infection was reported in one small study with a mean of 28 months follow-up.<sup>39</sup>

### **Thromboembolic events**

#### ***Adult populations***

One SR that specifically evaluated the risk of thromboembolic events in low risk adult patients undergoing arthroscopy reported a rate of 1.18% (95% CI, 0.8% to 1.74%) for deep vein thrombosis (DVT) and 0.59% (95% CI 0.38% to 0.92%) for pulmonary embolism (PE) over a mean follow-up of 21 months<sup>16</sup> while a second SR reported a rate of 0.1% (8/7241) for DVT or PE.<sup>178</sup> Only two additional case-series reported the frequency of DVT which was low (0.2% to 2% of patients).<sup>38,102</sup>

Thromboembolic events were not reported by either the SR or the case series evaluating pediatric populations.

### **Revision surgery and additional operations**

#### ***Adult populations***

Across two SRs in adult populations,<sup>139,178</sup> revision surgery was reported in 1.9% (38/1981)<sup>139</sup> over a mean of 30 months and 3.2% (233/7241)<sup>178</sup> over a mean of 34 months follow-up. Thirteen additional case series reported on rates of revision and additional surgeries.{Chiron, 2012 #50;Cvetanovich, 2018 #23;Dietrich, 2014 #25;Gao, 2019 #46;Hatakeyama, 2018 #29;Jackson, 2014 #31;Kempthorne, 2011 #49;Naal, 2012 #48;Park, 2014 #36;Perets, 2018 #38;Perets, 2019 #39;Rhon, 2019 #41;Olach, 2019 #80} For revision, across 11 studies (N range, 15 to 295) the frequency of revision surgery varied greatly ranging from 1.2% to 33.3% of patients and 10.3% of hips in one study (N=233 hips). Additional operations included surgery for HO (1.9%),<sup>91</sup> hematoma (3.7%),<sup>30</sup> and for screw removal (31.3%)<sup>102</sup> in one study each; the latter study was in 48 patients who underwent open hip dislocation.

#### ***Pediatric populations***

In one SR in adolescent patients,<sup>40</sup> revision surgery was required in 3.0% of hips (13/435 hips) over mean follow-up periods across included studies ranged from 3 to 75 months; all revisions occurred after arthroscopic surgery (3.7%; 13/354 hips that received arthroscopy). Nine additional case series reported a revision rate ranging from 0% to 13.6% of patients over mean follow-up periods of 14 to 50 months<sup>23,24,39,41,115,122,133,193,204</sup>; excluding the small study in children treated with open hip dislocation,<sup>193</sup> the revision rates were 0% to 5.9%. Four case series also reported the frequency of additional operations which ranged from 2.3% to 20.5%<sup>69,122,149,193</sup>; the highest frequency was reported in one case series of open hip dislocation surgery which was for screw removal only.<sup>193</sup>

### **Complications specific to pediatric populations**

No cases of physeal arrest or growth disturbance or acute iatrogenic slipped capital femoral epiphysis were reported over mean follow-up periods ranging from 3 to 75 months in the SR (435 hips)<sup>40</sup> or over 14 to 40 months across four additional case series (N range, 18 to 108).<sup>23,39,115,204</sup>

**Table 37. Summary of surgical adverse events across SRs of case series and ranges across surgical arms of RCTs, comparative observational cohorts and case series (of ≥300 patients for adult populations).**

|  | Adults                   |                          |                             |  |   |  | Pediatric  |  |
|--|--------------------------|--------------------------|-----------------------------|--|---|--|--|--|
|  | Systematic Reviews       |                          |                             | Additional studies included 2019 Update                |   |  | Systematic Reviews   | Additional studies included 2019 Update      |
| Author year                                  | Riff 2019 <sup>178</sup> | Bolia 2018 <sup>16</sup> | Minkara 2019 <sup>139</sup> | RCTs   | Cohorts   | Case series (N≥300)                              | de Sa 2014 <sup>40</sup>                                       | Case series                                  |
| N (studies)                                  | 68                       | 38                       | 28                          | 3  | 12  | 8  | 8  | 11   |
| n studies included in our report             | 3                        | 9                        | 0                           | -----  | -----   | -----  | 5  | -----  |
| Mean age, years*                             | 34.8                     | 36                       | 29.9                        | 31 to 36   | 19 to 41  | 32.2 to 40.4                                     | Range: 15.7 to 17.6  | 15.5 to 16.2                                 |
| Mean follow-up, months*                      | 34.2                     | 20.6                     | 29.5                        | 8 to 24  | 12 to 120   | 1.5 to ≥48                                       | Range: 3 to 75   | 14 to 50                                     |
| N*   | Arthroscopy: 7241 hips   | Arthroscopy: 4577 hips   | Arthroscopy: 1981 hips      | 80 to 348  | 23 to 950   | 317 patients to 14,945 hips                      | Arthroscopy: 354<br>Open: 81 hips                              | 18 to 108                                    |
| <b>Total Complication Rate</b>               | 1.9% (139/7241)          | -----                    | 1.7% (95%CI 0.9% to 2.5%)   | -----  | 6% to 14%, 2 cohorts (N=198, 201) <sup>21,170</sup>           | -----  | -----  | -----  |
| <b>Serious AEs, treatment-related</b>        | -----                    | -----                    | -----                       | 2.1% (5/237), <sup>†</sup><br>2 RCTs <sup>66,153</sup> | -----   | -----  | -----  | -----  |
| <b>Other AEs, possibly treatment-related</b> | -----                    | -----                    | -----                       | 5.8% (8/138), <sup>‡</sup><br>1 RCT <sup>66</sup>      | -----   | -----  | -----  | -----  |
| <b>Treatment-related death</b>               | -----                    | -----                    | -----                       | 0% (0/138),<br>1 RCT <sup>66</sup>                     | -----   | -----  | -----  | -----  |
| <b>Heterotopic Ossification</b>              | 0.5% (33/7241)           | -----                    | 0.8% (16/1981)              | 1.5% (1/65),<br>1 RCT <sup>125</sup>                   | 0% to 31%, 4 cohorts (N=23 to 198) <sup>17,113,170,179,</sup> | 0.6% to 4.7%, 4 case series (N=360 to 1870; 1615 | Arthroscopy: 0% (0/354)<br>Open: 1.2% (1/81)<br>(asymptomatic) | 2.3% (1/44),<br>1 case series <sup>193</sup> |

|                                       | Adults                   |                          |                             |  |   |  | Pediatric                        |  |
|---------------------------------------|--------------------------|--------------------------|-----------------------------|--|---|--|----------------------------------|--|
|                                       | Systematic Reviews       |                          |                             | Additional studies included 2019 Update      |   |  | Systematic Reviews               | Additional studies included 2019 Update                        |
| Author year                           | Riff 2019 <sup>178</sup> | Bolia 2018 <sup>16</sup> | Minkara 2019 <sup>139</sup> | RCTs   | Cohorts   | Case series (N≥300)  | de Sa 2014 <sup>40</sup>         | Case series  |
|                                       |                          |                          |                             |  | excluding outlier, <sup>179</sup><br>0% to 1%                     | hips) <sup>14,111,148,176</sup>  |                                  |  |
| <b>Avascular Necrosis</b>             | 0% (0/7241)              | -----                    | -----                       | 0% (0/65),<br>1 RCT <sup>125</sup>           | 0% (0/198),<br>4 cohorts<br>(N=23 to 96) <sup>17,84,113,179</sup> | 0.4% (8/1870),<br>1 case series <sup>176</sup>   | Arthroscopy/<br>Open: 0% (0/435) | 0% (0/197),<br>4 case series <sup>23,39,115,204</sup>          |
| <b>Femoral Fracture</b>               | 0.01%<br>(1/7241)        | -----                    | 0.05%<br>(1/1981)           | 0.5%<br>(1/203),<br>2 RCTs <sup>66,125</sup> | 0% (0/175),<br>3 cohorts<br>(N=23 to 96) <sup>84,113,179</sup>    | 0% to 1%, 6 case series<br>(N=317 to 1870; 1615 to 14,495 hips) <sup>38,46,111,136,176,214</sup>   | Arthroscopy/<br>Open: 0% (0/435) | 0% (0/44), 1 case series <sup>193</sup>                        |
| <b>Nerve Complications</b>            |                          |                          |                             |  |   |  |                                  |  |
| Lateral femoral cutaneous neurapraxia | 0.2%<br>(16/7241)        | -----                    | 0.2%<br>(4/1981)            | 2.0%<br>(1/99),<br>1 RCT <sup>153</sup>      | 0% to 25%,<br>2 cohorts<br>(N=38, 56) <sup>179,215</sup>          | 1.6% (26/1615 hips), 1 case series <sup>111</sup>  | -----                            | 8.3% (2/24),<br>1 case series <sup>133</sup>                   |
| Femoral neurapraxia                   | 0.01%<br>(1/7241)        | -----                    | 0.1%<br>(2/1981)            | -----  | -----   | -----  | -----                            | -----  |
| Pudendal neurapraxia                  | 0.3%<br>(25/7241)        | -----                    | 0.1%<br>(2/1981)            | -----  | 0% to 3%,<br>2 cohorts<br>(N=56, 198) <sup>170,179</sup>          | 0.6% to 18.8%,<br>4 case series<br>(N=317 to 414; 1615 hips) <sup>38,46,111,148</sup> ,<br>excluding outlier, <sup>148</sup><br>0.6% to 2.2% | -----                            | 1.9% to 2.7%,<br>2 case series<br>(N=37, 104) <sup>24,39</sup> |

|   | Adults                   |                          |                             |   |  |   | Pediatric                                    |  |
|---|--------------------------|--------------------------|-----------------------------|---|--|---|--|--|
|   | Systematic Reviews       |                          |                             | Additional studies included 2019 Update                             |  |   | Systematic Reviews                           | Additional studies included 2019 Update                      |
| Author year                                 | Riff 2019 <sup>178</sup> | Bolia 2018 <sup>16</sup> | Minkara 2019 <sup>139</sup> | RCTs  | Cohorts  | Case series (N≥300)   | de Sa 2014 <sup>40</sup>                     | Case series  |
| Perineal neurapraxia                        | -----                    | -----                    | -----                       | -----   | -----  | 0.1% (1/1615 hips), 1 case series <sup>111</sup>                  | Arthroscopy: 0.6% (2/354)<br>Open: 0% (0/81) | 1.9% (2/108), 1 case series <sup>23</sup>                    |
| Sciatic neurapraxia                         | 0.03% (2/7241)           | -----                    | 0.2% (3/1981)               | -----   | -----  | -----   | -----  | -----  |
| Unspecified/other Neurapraxia               | 0.4% (29/7241)           | -----                    | -----                       | -----   | 0% to 9%<br>2 cohorts (N=23, 67) <sup>17,27</sup>  | 0.2% to 4.4%, 2 case series (N=360; 1615 hips) <sup>111,148</sup> | -----  | -----  |
| Potentially treatment-related nerve injury§ | -----                    | -----                    | -----                       | 2.1% (5/237), 2 RCTs <sup>66,153</sup>                              | -----  | -----   | -----  | -----  |
| Any nerve injury                            | -----                    | -----                    | -----                       | -----   | 0% to 25%, 5 cohorts (N=23 to 198) <sup>17,27,170,179,215</sup> ; excluding outlier, <sup>179</sup> 0% to 9% | -----   | -----  | -----  |
| <b>Infection</b>                            |                          |                          |                             |   |  |   |  |  |
| Superficial infection                       | 0.3% (19/7241)           | -----                    | 0.2% (4/1981)               | 4.2% (10/237); 2.1% (5/237) requiring abx; 2 RCTs <sup>66,153</sup> | 0% to 6%, 3 cohort (N=23 to 198) <sup>17,170,179</sup>   | 1%, 2 case series (N=414; 1615 hips) <sup>38,111</sup>            | -----  | 0% to 2.7%, 3 case series (N=34 to 44) <sup>39,193,204</sup> |

|                                    | Adults                   |                              |                             |  |   |  | Pediatric                        |   |
|------------------------------------|--------------------------|------------------------------|-----------------------------|--|---|--|----------------------------------|---|
|                                    | Systematic Reviews       |                              |                             | Additional studies included 2019 Update        |   |  | Systematic Reviews               | Additional studies included 2019 Update |
| Author year                        | Riff 2019 <sup>178</sup> | Bolia 2018 <sup>16</sup>     | Minkara 2019 <sup>139</sup> | RCTs   | Cohorts   | Case series (N≥300)  | de Sa 2014 <sup>40</sup>         | Case series                             |
| Deep infection                     | 0.01% (1/7241)           | -----                        | -----                       | -----  | 0% (0/79), 2 cohorts <sup>17,179</sup>                  | 0.1% (1/1615 hips), 1 case series <sup>111</sup>                 | -----                            | -----                                   |
| Infection (NOS)                    | -----                    | -----                        | -----                       | -----  | -----   | 0.2% to 0.3%, 2 case series (N=360, 1860) <sup>148,176</sup>     | Arthroscopy/<br>Open: 0% (0/435) | -----                                   |
| Any infection**                    | -----                    | -----                        | -----                       | 3.6% (11/302);<br>3 RCTs <sup>66,125,153</sup> | -----   | -----  | -----                            | -----                                   |
| <b>Thromboembolic Events</b>       |                          |                              |                             |  |   |  |                                  |   |
| PE                                 | -----                    | 0.59% (95%CI 0.38% to 0.92%) | -----                       | -----  | -----   | 0.1% (1/1615 hips), 1 case series <sup>111</sup>                 | -----                            | -----                                   |
| DVT                                | -----                    | 1.18% (95%CI 0.8% to 1.74%)  | -----                       | 0% (0/203),<br>2 RCTs <sup>66,125</sup>        | 0% to 3%, 3 cohorts (N=23 to 198) <sup>17,170,179</sup> | 0.1% to 0.2%, 2 case series (N=414, 1615 hips) <sup>38,111</sup> | -----                            | -----                                   |
| DVT or PE                          | 0.1% (8/7241)            | -----                        | -----                       | -----  | -----   | -----  | -----                            | -----                                   |
| <b>Other Bone Complications</b>    |                          |                              |                             |  |   |  |                                  |   |
| Adhesions                          | -----                    | -----                        | 0.5% (10/1981)              | -----  | -----   | -----  | -----                            | -----                                   |
| Iatrogenic Instability             | 0% (0/7241)              | -----                        | -----                       | -----  | -----   | -----  | Arthroscopy/<br>Open: 0% (0/435) | 0% (1/108), 1 case series <sup>23</sup> |
| Nonunion of the greater trochanter | -----                    | -----                        | -----                       | -----  | 0% to 2%, 2 cohorts (N=198, 201) <sup>21,170</sup>      | -----  | -----                            | 0% (0/44), 1 case series <sup>193</sup> |



|  | Adults                   |                          |                             |   |  |  | Pediatric                                     |   |
|--|--------------------------|--------------------------|-----------------------------|---|--|--|---|---|
|  | Systematic Reviews       |                          |                             | Additional studies included 2019 Update |  |  | Systematic Reviews                            | Additional studies included 2019 Update   |
| Author year  | Riff 2019 <sup>178</sup> | Bolia 2018 <sup>16</sup> | Minkara 2019 <sup>139</sup> | RCTs                                    | Cohorts  | Case series (N≥300)  | de Sa 2014 <sup>40</sup>                      | Case series   |
| <b>Other Complications</b>   |                          |                          |                             |   |  |  |   |   |
| Superficial phlebitis  | 0.01% (1/7241)           | ----                     | ----                        | ----                                    | ----   | ----   | ---   |   |
| Labium majus skin necrosis   | ----                     | ----                     | 0.05% (1/1981)              | ----                                    | ----   | ----   | ---   |   |
| Physeal arrest or growth disturbance   | ----                     | ----                     | ----                        | ----                                    | ----   | ----   | Arthroscopy/<br>Open: 0% (0/435)              | 0% (0/197), 4 case series <sup>23,39,115,204</sup>  |
| Acute iatrogenic SCFE  | ----                     | ----                     | ----                        | ----                                    | ----   | ----   | Arthroscopy/<br>Open: 0% (0/435)              | 0% (0/34), 1 case series <sup>204</sup>   |
| Broken hardware, ACS, urinary/sexual dysfunction, chondral scuffing, labral penetration, inadequate correction | ----                     | ----                     | ----                        | ----                                    | ----   | ----   | Arthroscopy/<br>Open: 0% (0/435)              | ----  |
| <b>Additional Surgery</b>  |                          |                          |                             |   |  |  |   |   |
| Revision surgery   | 3.2% (233/7241)          | ----                     | 1.9% (38/1981)              | 7.7% (5/65), 1 RCT <sup>125</sup>       | 0% to 12%, 10 cohorts (N=23 to 950) <sup>17,21,27,49,113,135,169,170,209,215</sup> | 1.2% to 6.5%, 3 case series (N=314 to 1870) <sup>38,46,176</sup> | Arthroscopy: 4.0% (13/354)<br>Open: 0% (0/81) | Arthroscopy: 0% to 5.9%, 8 case series (N=18 to 108) <sup>23,24,39,41,115,122,133,204</sup><br>Open: 13.6% (6/44), 1 case series <sup>193</sup> |
| Hardware removal   | ----                     | ----                     | ----                        | ----                                    | 0% arthroscopy; 20% to 80% open; 3   | ----   | ----  | ----  |

|                           | Adults                   |                          |                             |   |  |                     | Pediatric                |   |
|---------------------------|--------------------------|--------------------------|-----------------------------|---|--|---------------------|--------------------------|---|
|                           | Systematic Reviews       |                          |                             | Additional studies included 2019 Update |  |                     | Systematic Reviews       | Additional studies included 2019 Update   |
| Author year               | Riff 2019 <sup>178</sup> | Bolia 2018 <sup>16</sup> | Minkara 2019 <sup>139</sup> | RCTs                                    | Cohorts  | Case series (N≥300) | de Sa 2014 <sup>40</sup> | Case series   |
|                           |                          |                          |                             |   | cohorts (N=23 to 38) <sup>17,49,215</sup>                |                     |                          |   |
| Additional surgery        | -----                    | -----                    | -----                       | -----                                   | 0% to 5%,††<br>2 cohorts (N=30 to 198) <sup>49,170</sup> | -----               | -----                    | Arthroscopy: 2.3% to 11.1%, 2 case series (N=43, 18 hips) <sup>69,122</sup><br>Open, 4.2% to 20.5%, 2 case series (N=24, 44) <sup>149,193</sup> |
| Contralateral hip surgery | -----                    | -----                    | -----                       | 9.2% (6/65),<br>1 RCT <sup>125</sup>    | -----  | -----               | -----                    | -----   |

ACS = abdominal compartment syndrome; AE = adverse event; DVT = deep vein thrombosis; RCT = randomized controlled trial; PE = pulmonary embolism; SCFE = slipped capital femoral epiphysis; SR = systematic review.

\*For the RCTs, comparative cohorts, and case series the numbers reflect the range across studies.

†1 event in the PT group in the RCT by Griffin; 0.7% (1/146), not related to treatment, biliary sepsis

‡1 event in PT group 0.7% (1/146) muscle spasms

§Includes numbness proximal thigh (2/138), 1.4%; numbness tip of tongue (1/138), [Griffin] 0.7% and lateral femoral cutaneous nerve (22/99) [Palmer]

\*\*Includes superficial wound infection, hip infection and scrotal infection.

††One case of iliopsoas release due to new onset symptomatic internal snapping and one case of compartment syndrome grade III; both following arthroscopy.

## 4.4 Key Question 3: Differential Efficacy and Safety in Subpopulations

### Summary of results

- Age was found to modify the treatment effect in one of the two trials with results suggesting that difference in function may be greater and in favor of arthroscopy compared with physiotherapy for younger patients with the effect decreasing with increasing age; however the strength of evidence was insufficient.

#### 4.4.1 Number of studies retained

For this key question, RCTs that stratified on baseline patient characteristics and evaluated effect modification were sought. Subgroups of interest included (but were not limited to): age, sex, race, ethnicity, type of FAI, socioeconomic status, payer, and worker's compensation. All RCTs included to evaluate the efficacy or safety of operative treatment versus comparators of interest were assessed.

#### 4.4.2 Operative vs. Non-operative Treatment

Two RCTs,<sup>66,153</sup> both comparing arthroscopy with conservative treatment (i.e, physiotherapy), formally evaluated effect modification (Table 38). Across both trials, no evidence of an interaction was seen for type of FAI (e.g., cam, pincer, mixed), and in one trial, sex, Kellgren-Lawrence grade (0 vs.1), study site, and baseline HOS-ADL scores. Age was found to modify the treatment effect in only one of the two trials and results suggested that difference in the HOS-ADL may be greater and in favor of arthroscopy compared with physiotherapy for younger patients with the effect decreasing with increasing age. This trial evaluated age as a continuous outcomes which may have given it more power to detect an effect, compared to the other trial which dichotomized age by <40 and ≥40 years and found no effect. Outcomes evaluated were also different across the two trials as was length of follow-up.

**Table 38. Results of subgroup analyses evaluating effect modification for RCTs comparing arthroscopy versus physiotherapy.**

| Author, year  | Subgroup<br>(n's for arthroscopy vs. PT) | Arthroscopy vs. PT<br>Adj. ES (95% CI)‡ | p-value for<br>interaction |
|---|--|---|----------------------------|
| <b>Griffin 2018</b><br>(N=358)<br><br><i>Outcome measure:</i><br>iHOT-33<br><br>F/U: 12 months* | <b>FAI type</b>                          | <b>Cam</b> (n=120 vs. 124)              | 8.3 (2.5, 14.2)            |
|   |  | <b>Pincer</b> (n=12 vs. 12)             | 4.0 (-14.6, 22.7)          |
|   |  | <b>Mixed</b> (n=26 vs. 27)              | 1.1 (-11.5, 13.7)          |
|   | <b>Age (years)</b>                       | <b>&lt;40</b> (n=103 vs. 117)           | 5.0 (-1.2, 11.3)           |
|   |  | <b>≥40</b> (n=55 vs. 46)                | 10.9 (1.7, 20.1)           |
| <b>Palmer 2019</b><br>(N=222)<br><br><i>Outcome measure:</i><br>HOS-ADL<br><br>F/U: 8 months*   | <b>FAI type</b>                          | <b>Cam</b> (n=92 vs. 83)                | 10.1 (4.3, 15.9)           |
|   |  | <b>Mixed</b> (n=7 vs. 5)                | -5.7 (-28.1, 16.8)         |
|   | <b>Sex</b>                               | <b>Female</b> (n=68 vs. 58)             | 9.7 (3.0, 16.5)            |
|   |  | <b>Male</b> (n=32 vs. 30)               | 8.4 (-1.18, 18.0)          |
|   | <b>KL grade</b>                          | <b>Grade 0</b> (n=80 vs. 67)            | 11.1 (4.9, 17.2)           |
|   |  | <b>Grade 1</b> (n=14 vs. 17)            | 9.7 (-3.8, 23.1)           |
|   | <b>Study center</b>                      | <b>Center 1</b> (n=67 vs. 58)           | 12.0 (5.3, 18.8)           |

| Author, year | Subgroup<br>(n's for arthroscopy vs. PT) | Arthroscopy vs. PT<br>Adj. ES (95% CI)‡                         | p-value for<br>interaction         |
|--------------|--|---|------------------------------------|
|              | <b>Center 2</b> (n=15 vs. 14)            | 13.0 (-1.0, 27.0)   |                                    |
|              | <b>Center 3</b> (n=1 vs. 4)              | 26.3 (-15.9, 68.4)  |                                    |
|              | <b>Center 4</b> (n=8 vs. 5)              | -3.4 (-24.9, 18.1)  |                                    |
|              | <b>Center 5</b> (n=4 vs. 3)              | -4.9 (-33.7, 23.9)  |                                    |
|              | <b>Center 6</b> (n=5 vs. 3)              | -20.1 (-47.6, 7.4)  |                                    |
|              | <b>Subgroup, continuous variable</b>     | <b>Arthroscopy vs. PT<br/>Adj. Interaction effect (95% CI)§</b> | <b>p-value for<br/>interaction</b> |
|              | <b>Age</b>                               | -0.31 (-0.44, -0.18)  | 0.001                              |
|              | <b>Baseline HOS-ADL</b>                  | -0.19 (-0.41, 0.03)   | 0.084                              |

Adj = adjusted; CI = confidence interval; ES = effect estimate; FAI = femoroacetabular impingement; F/U = follow-up; HOS-ADL = Hip Outcome Score – Activities of Daily Living; iHOT-33 = International Hip Outcome Tool, 33-items; KL = Kellgren-Lawrence; PT = physiotherapy;

\*Post-randomization

‡Adjusted for treatment group, impingement type, sex and baseline scores, recruiting center and interaction term between subgroup of interest and treatment group.

§ the interaction effect between the two variables (treatment and age) represents a change for each one unit increase in age in the arthroscopy group; adjusted for baseline HOS ADL, sex, age at randomization, and site.

## 4.5 Key Question 4: Cost Effectiveness

### Bullet points:

- Conclusions regarding the cost-effectiveness of hip arthroscopy compared with non-operative care (including conservative care) were inconsistent across three cost-utility studies that met the inclusion criteria. Differences in methods, modeling, data sources and perspectives contribute to the inconsistent findings. Only one study was based on a head to head trial of operative versus non-operative care.
  - One moderate quality cost-utility analysis from the U.K. National Health Service perspective, based on the recent RCT comparing arthroscopy with personalized physical therapy (PT) by Griffin, et al, found that personalized PT was both more effective and less costly than arthroscopy at one year. The short-term follow-up didn't allow for evaluation of long-term outcomes, however, and the applicability to the U.S. healthcare system is unclear. The study was funded by the Health Technology Assessment Program of National Institute of Health Research.
  - Two poor quality cost-utility analyses from the U.S. found that arthroscopy was more cost-effective than non-operative care (based on expert opinion) from a societal perspective and more cost-effective than observation from a hospital cost perspective. Clinical data, health status information and assumptions for condition progression were from case series, expert opinion and for one study a retrospective survey of arthroscopy patients. Both used an unvalidated method for determining utility. One study was industry funded; the funding source for the other was not clear.

## Summary

Three full economic studies met the inclusion criteria; all were cost-utility analyses (CUA).<sup>66,131,190</sup> The included studies ranged from poor to moderate quality (QHEs from 65 to 79 out of 100 points). Hip arthroscopy was considered as the intervention in all three analyses, while the non-operative care comparator varied in definition in each of the studies (including “observational”, “non-operative” and “best conservative care”). Costing years ranged from 2010 to 2016 time horizons from 1 year to lifetime models. Two of the studies took on a societal perspective that included indirect costs while one evaluated only direct costs. The average patient ages ranged from 33 to 36. All tested the robustness of their results through various sensitivity analyses. Conclusions regarding the cost-effectiveness of hip arthroscopy were inconsistent across the studies. Only one study was based on a head to head trial of operative versus non-operative care.

One study of moderate quality (QHEs 79/100 points) was conducted in the UK and funded by the HTA program of the National Institute of Health Research.<sup>66</sup> As part of a larger randomized control trial comparing arthroplasty with personalized physical therapy, the level of evidence was considered to be of high quality, however, the short follow up time of only 1 year and the applicability to the U.S. health care systems raised some concerns. The insufficient follow up period prevented authors from fully capturing long term risks such as the development of osteoarthritis, future surgeries, recurrent pain or recurrent labral tears. There also remained some ambiguity surrounding the methodology of approximating indirect costs. The study found hip arthroscopy to be dominated by personalized physical therapy (meaning that personalized PT care was both more effective and less costly).

In contrast, there were two poor quality studies conducted in the U.S., both of which concluded that surgical intervention for FAI may be cost-effective. The most recent study (QHEs 67/100 points) was performed by surgeons doing high volumes of arthroscopy with various ties to commercial interests.<sup>131</sup> It cites some of the same methods and clinical data sources as the other U.S. study. The study implemented a Markov decision tree model that forecasted a 10-year time horizon for a hypothetical cohort to evaluate cost effectiveness. The study found non-operative care to be dominated by hip arthroscopy (meaning that surgery was both more effective and less costly) in patients who had failed nonoperative treatment lasting on average 6 weeks. The other poor quality study (QHEs 65/100 points) relied on costing data from a single site in California and clinical effectiveness data from a review of published literature.<sup>190</sup> It constructed a lifetime Markov model. The study found that the cost of adding one quality-adjusted-life-year by using hip arthroscopy to treat FAIS was ICER = \$21,700/QALY when compared to the observation only group. Methodological concerns across these two studies included apparent use of data and assumptions for condition progression from case series (some of which may not be specific to FAI) or from expert opinion, unclear rationale for modeling various health states, and use of unvalidated methods for converting effectiveness estimates to the quality of life values.

## Detailed Results

Table 39 summarizes characteristics and findings from the included studies.

### *Griffin 2018*

#### **Study characteristics and framework**

A moderate quality cost-utility analysis conducted in the United Kingdom assessed the cost-effectiveness of hip arthroscopy compared to best conservative care for treating femoroacetabular

impingement syndrome.<sup>66</sup> The analysis was as part of a randomized control trial evaluating surgical versus non-surgical personalized hip therapy that is included in this HTA; it was rated as moderately low risk of bias. As such, it relied on patient level data, itemized hospital costs and care usage. It assumed a British societal perspective and incorporated costs relating to resource use, deliveries of interventions, and lost productivity. All costs were reported in 2016 British pounds sterling and converted to US dollars using official US Department of Treasury exchange rates for that year.<sup>205</sup> The average age was 35.3 with patients over the age of 16 years-old, 39% were female. Therapy lasted 12 to 24 weeks and time of final follow-up for both groups was 12 months. Failure of previous non-operative treatment was not an inclusion criterion.

Being part of an RCT, high quality effectiveness data were derived directly from patients using health-related quality of life instruments including EQ-5D-3L, EQ-5D-5L and SF-12. Patients presenting with hip pain and radiographic evidence of cam or pincer morphology were randomly allocated to surgery or to physical therapy, 171 and 177 respectively. The majority of surgical procedures involved treatment of labral tear. Patients with osteoarthritis were excluded (Tönnis grade >1 or less than 2mm or superior joint space on an antero-posterior radiograph). Furthermore, any patients with a previous hip injury or shape-changing surgery were also excluded. Crossover between groups was allowed and occurred at a rate of 7.3% moving from therapy to surgery in the first 12 months, however, pertinent details relating to how these patients were accounted for was not explicitly discussed and the long-term implications of the effects were not fully explored.

### Base Case Results

The mean cost for surgery was reported to be \$4,083 ranging from \$3,068 to \$53,793 (upon review, the upper limit is suspiciously high and is perhaps inaccurately reported. Meanwhile, hip therapy was delivered primarily by physiotherapists at an assumed hourly rate of \$73.83/hour which include the facilities, administrative and other overhead costs. The total cost to society of surgery was estimated to be \$5,023 while best conservative care group saw costs of \$2,055 in the first year. Quality adjusted life years (QALY's) were not reported individually by treatment group however, the difference between groups favored conservative care by a small amount of 0.02 QALY's. Therefore, surgery was both costlier and less effective and found to be dominated by physical therapy.

### Sensitivity Analyses

Many of the underlying assumptions and conceivable uncertainties were tested in both pre-specified and post hoc sensitivity analyses. The results from the base case analysis remained, for the most part, robust. The unadjusted model (not accounting for differences in age, sex, treatment allocations, study site, impingement type, and baseline quality of life and costs) changed to slightly favor surgery in QALY's generated but conservative care remained cost effective with a willingness to pay (WTP) of \$67,114. Assuming that same WTP, there was a 0.08 probability that surgery became cost-effective. In all post hoc sensitivity analyses PT dominated surgery while varying key costs such as the cost of surgery from \$1,919 to \$8,573. Subgroup analysis investigated the impact of age, gender, length of time after randomization patients had surgery and impingement type. Isolating the analysis by these characteristics did not change the base case findings, however in some cases, small sample sizes of the subgroups caused greater variability which led the results to be less conclusive.

### Conclusions and Limitations

The 12-month time horizon did not show that surgery was a cost-effective alternative to conservative care for treating femoroacetabular impingement syndrome.

While well conducted in many regards, the limited follow up time did not allow for a full exploration of all relevant costs and health outcomes. Longer term risks including development of osteoarthritis, future surgeries, recurrent pain or recurrent labral tears all would likely impact on costs and effectiveness. Also important to consider, is the 7.3% crossover rate to surgery. Over time this may significantly increase costs of the physical therapy group and makes surgery increasingly cost-effective.

The authors claim to assume a societal perspective and that their model includes indirect costs such as lost wages. It was unclear how these costs were estimated. The findings in the other economic studies meeting the inclusion criteria show such costs to be among the leading factors of determining cost effectiveness and given their importance (even given the shorter time horizon) more details would be helpful in drawing comparisons.

Furthermore, when compared to the other two cost utility analyses that met the inclusion criteria, both of which were based on the U.S. healthcare system, there were many relevant differences. Cost structures for interventions were different as were sources of clinical data. Clinical data for this study were based on a head to head comparison of operative care vs personalized PT while data for the U.S. studies were derived from sources that did not directly compare treatment options (e.g. case series). The type of nonoperative care (which was not well specified in the U.S. studies), access to therapy and healthcare systems also differed across studies.

The QHES score for this study was 79/100 points.

### ***Mather 2018***

#### **Study characteristics and framework**

A poor quality cost utility analysis examined differences in hip arthroscopy versus a broad non-operative comparator for the treatment of FAIS.<sup>131</sup> The study used a Markov decision model to project 10-year cost effectiveness of the two groups. Surveys from patients who received arthroscopy from two high-volume (>300 hips/year) surgeons between April 2013 and May 2014 were gathered to estimate effectiveness parameters. Non-operative patient treatment was loosely defined and described as what a panel of surgeons would recommend as alternatives for patients who did not have access to surgery; specifics were not provided. In addition to expert opinion, most model utility parameters and transition probabilities came from another cost utility analysis and related case series (reviewed below).<sup>190</sup> A societal perspective was assumed with the indirect costs being inferred from a separately constructed complex model that used a regression analysis to link an increase functionality resulting from surgery to an increase in productivity and therefore, in earnings in patients who had failed non-operative care and went on to have surgery. The increase in earnings was then incorporated into the primary decision model. However, the complexity of this model and the overall reliance on expert opinion poses potential challenges in reproducing the author's findings.

A five-stage Markov Model was implemented. After the initial treatment patients remained in a posttreatment state for the first year. Following that a non-operative treatment patient is assumed to have either recovered fully or seen no benefit. If not benefiting from treatment a patient can either stay in that "fair" state or move to a "poor" state where they will require a total hip arthroplasty (THA). Patients undergoing surgery, will either experience a full recover, no benefit, or have a procedural complication. All outcomes that are not favorable can lead to an eventual THA, in which case, the authors assume a good outcome follows without giving further justification. Transition probabilities are based on expert opinion and case series.

Model information for patient-reported pre- and post-surgical functional status was based on surveys of arthroscopy patients who had failed six months of non-operative treatment obtained from two surgeon's institutions. Based on reported survey methods, selection bias for the sample is highly likely (patient sampling methods were not described; surveys with incomplete responses were excluded, less than 50% response rate). Patients (N = 91, 70% female) had "noncontroversial indications for hip arthroscopy". Data on patients receiving non-operative care was not described; it appears that pre-surgical functional status recalled by patients served as a surrogate for patients receiving non-operative care and may be subject to recall bias; it is unclear how representative such data are, particularly for patients who may have FAI but not have "noncontroversial indications" for arthroscopy which seemed to include Tonnis grade 0 or 1 and no more than mild hip dysplasia (<20% angle) in this patient cohort, information regarding specific surgical procedures or prevalence of labral tears was provided. Based on CPT codes used to determine direct costs from a commercial administrative data base for 365 patients, it appears that modeled patients all had labral tears and acetabuloplasty and/or femoral osteochondroplasty. The mean age modeled was 33 (ranging from 18 to 50 years-old).

For the model, the following utility parameters were assumed: FAIS 0.75, primary THA 0.9, post-arthroscopy 0.94 and post-surgical complications 0.5. Health state utilities were sourced primarily from another cost utility analysis (also reviewed here)<sup>190</sup> that relied on unvalidated methodologies using modified Harris Hip Scores and a process of linear extrapolation to generate utility values. Transition probabilities were derived primarily from expert opinion and were as follows: non-operative success rate 0.23, reoccurrence if non-operative treatment initially effective 0.67, major arthroscopy complications 0.10. Symptom severity was assumed to progress at a rate of 0.05 annually.

### Base Case Results

The initial cost of hip arthroscopy was reported to be \$14,363 with postoperative rehabilitation costing an additional \$3,296. Non-operative costs were found to be \$1,669 annually. The productivity gap derived from the secondary regression model suggested that the surgery created \$8,968 in additional earnings each year.

As a result, over the course of a decade, the authors found hip arthroscopy and non-operative treatment to respectively cost an average of \$23,120 and \$91,602. Their corresponding effectiveness was 8.51 and 6.48 QALY's respectively. Surgery was therefore found to be both less expensive and more effective and thus dominant.

### Sensitivity Analyses

One, two and three-way sensitivity analyses were performed as well as probabilistic simulations. All variables were found to be robust with a willingness to pay (WTP) of \$100,000. The time horizon, cost of surgery and post-surgery productivity most sensitive variables, however costs of the procedure would need to reach \$76,826 in order for the two groups to cost the same after 10 years. Looking at only direct costs yields an ICER of \$2,751, which would still make surgery a cost-effective intervention by commonly accepted WTP's. The non-operative rate of success would need to exceed 90% and simultaneously reduce the rate of reoccurrence for costs to be equal. Probabilistic Monte Carlo simulations suggest arthroscopy was cost effective in 99% of trials.

### Conclusions and Limitations

Authors conclude that arthroscopy reduced the economic cost of FAI while contributing to improved quality of life from a societal perspective. Authors acknowledge the importance of 6 to 12 weeks of nonoperative treatment before surgery.



Potential conflicts of interest were noted and include numerous ties to industry coupled with the heavy reliance on expert opinion. While their analyses suggest that the findings are robust, a number of methodological limitations including the use of data from a selected patient population and case series, some of which may not be representative of patients with FAIS need to be considered. It should also be noted that the utility values used were sourced using an unvalidated method. Many key assumptions also went unjustified particularly with regards to how non-operative patients were defined and regarding the lasting benefits of arthroscopy. Authors acknowledge that outcome data for nonoperative treatment of FAIS are limited and that results may not be generalizable. The primary cost drivers are the time horizon and productivity difference both of which depend heavily results from their secondary analysis calculating the indirect cost on earnings which in turn relied on numerous assumptions, many of which came from expert opinion. It should also be noted that only procedural costs were considered in the other U.S. study that met the inclusion criteria. In the Mather study, based on direct non-operative treatment costs ranged from costing \$68,483 more than arthroscopy to being cost saving by \$5,625. Although they present information on direct costs, they argue that the societal perspective that incorporates indirect costs from lost productivity provides a more complete picture of the impact of arthroscopic surgery for FAI.

The QHES score for this study was 67/100 points.

### ***Shearer 2012***

#### **Study characteristics and framework**

One poor quality CUA modeled the cost-effectiveness of hip arthroscopy and observation, though it was unclear whether those under observation received specific non-operative treatments.<sup>190</sup> Authors hypothesize that arthroscopy may prevent or delay the progression of osteoarthritis in patients with FAI. This study implemented a lifetime Markov model that derived its parameters from the weighted average of 5 reviewed studies with “symptomatic FAIS” from 2008 to 2010.<sup>11,12,81,112,161</sup> The comprehensiveness of the literature search, data abstraction and methodology for determining patient population/characteristics were not well described. Clinical inputs were based primarily on case series of surgical patients with FAI and the progression of osteoarthritis was based on a small prognostic study of radiographic features. No crossover to surgery arm was allowed.

The average age of the hypothetical cohort was 36. This study used findings from a small prognostic study of radiographic parameters, including those pertaining to FAI, in patients with a history of symptomatic idiopathic arthritis to assume that all patients progressed uniformly to poor hip function at a rate of 3.3% per year (33% over 10 years).<sup>12</sup> Three years was the longest follow up for arthroscopy treatment found in their review of the literature. Nevertheless, they forecasted a lifetime model. It was further assumed that both groups moved towards THA in the event of progression to end stage arthritis.

A narrower cost perspective compared to the other studies meeting the inclusion criteria was used. A hospital’s perspective assessing direct, procedural costs was taken for the analysis as authors report there was insufficient means to calculate societal costs and the authors assumed the findings would be similar across groups. The costs were sourced from a review of 10 procedures at a single site using a cost-to-charge ratio to evaluate payments received.

Eight discrete health states were considered in the model. All patients in the observation group began with fair hip function, defined as a state of hip pain and function in untreated symptomatic FAI. If

patients progress to poor hip function it is assumed that they suffer from hip pain and hip function comparable to end stage arthritis and required total hip arthroplasty. If a patient underwent arthroscopy they could either experience only symptomatic relief or they could delay the progression of arthritis. However, the authors cite that because the longest follow up available for arthroscopic treatment was limited to 3 years the model conservatively assumed that patients could only experience benefits for that amount of time. Minor and major complications were also considered but specific events for each category were not described.

To measure effectiveness, modified Harris Hip Scores<sup>76</sup> that included both pain and function domains were abstracted from published literature. Linear extrapolation was then used to generate utility values. This method for determining health utilities has not been validated. For the model the following utility parameters were used: FAIS 0.75, primary THA 0.9, Post-arthroscopy 0.94, poor hip function 0.5, fair hip function 0.75, good hip function 0.94. A complication rate of 1.5% during arthroscopies was assumed. Afterwards, the probability of major complication for arthroscopy was 0.1 and 0.117 for THA.

The cost of a hip arthroscopy procedure was estimated to be \$11,850. The cost of a primary THA was \$24,200 with a revision costing \$34,700.

### Base Case Results

The study did not report the cost or QALY's for each treatment group but presented their differences. The estimated incremental cost effectiveness ratio (ICER) for the primary analysis was found to be \$21,700. For patients with preoperative arthritis the ICER climbed to 79,500/QALY as a result of less post-operative utility and poorer hip functionality.

### Sensitivity Analyses

The authors examined a variety of their assumptions and approached their sensitivity analysis by assuming a willingness to pay of \$50,000 for each additional quality adjusted life year (QALY) then calculating how the parameters would need to change in order to yield an ICER = WTP. Varying the durations of benefit from 3 years to 13 months resulted in the ICER = \$50,000/QALY. Similarly, increasing cost of arthroscopy to \$27,300 would have the same impact. The ICER was robust for wide range of cost and outcome of THA.

Furthermore, a probabilistic Monte Carlo simulation suggested the ICER was less than \$50,000 in 85% of trials and less than \$100,000 in 97%.

### Conclusions and Limitations

Authors conclude that, arthroscopy in patients without arthritis is cost effective for a commonly accepted WTP of \$50,000.

Uncertainty remains regarding the quality of life, duration of benefits and effect on subsequent THA following arthroscopy. A key limitation of this study relates to the quality of literature available for clinical input (i.e. surgical case series). The authors acknowledge that the impact of arthroscopy on progression of arthritis is unclear, that the scenario of progression is hypothetical and that conclusions are limited based on the poor quality of available evidence. In addition, they state that their model suggests that in patients with FAI and osteoarthritis, arthroscopy would have a relatively small incremental benefit which would negatively impact the cost-effectiveness.

In terms of cost estimates, only direct costs were considered and sourced on a single hospital with small

sample of patients; accuracy as well as broader applicability therefore may be questionable..

The study used unvalidated methods for converting effectiveness estimates to the quality of life values. This limitation was made more significant by the fact that the sensitivity analysis revealed postoperative utility to be a highly influential parameter in the model.

The QHES score for this study was 65/100 points.

**Table 39. Summary of included full economic studies.**

|                     | Griffin 2018 <sup>66</sup>  | Mather 2018 <sup>131</sup>   | Shearer 2012 <sup>190</sup>   |
|---------------------|---|--|---|
| <b>Population</b>   | <p>Mean Age: 35.3 (&gt;16)<br/>Gender: 39% female</p> <p>RCT based:<br/>171 surgery; 177 PT<br/>Presenting hip pain w/<br/>radiographic evidence of cam<br/>or pincer morphology no<br/>osteoarthritis</p> <p>Allowed crossover (7.3% to<br/>surgery). Authors don't<br/>describe how or if this is<br/>incorporated into the model</p> | <p>Mean Age: 33 (18 to 50)<br/>Gender: 70% female<br/>Mean F/U: 15 months</p> <p>"noncontroversial indications<br/>for surgery" Tonnis grade 0<br/>or 1 and no more than mild<br/>hip dysplasia (&lt;20% angle)<br/>All patients underwent 6wks<br/>non-operative treatment<br/>prior to start</p> <p>No crossover</p> | <p>Mean Age: 36</p> <p>Weighted average of 5<br/>reviewed surgical case series<br/>with "symptomatic FAIS"<br/>from 2008 to 2010</p> <p>Patients progress to poor hip<br/>function at a rate of 3.3% per<br/>year (33% over 10 years)</p> <p>Assumed benefit of<br/>arthroscopy only lasted 3<br/>years</p> <p>No crossover</p> |
| <b>Intervention</b> | Hip arthroscopy   | Hip arthroscopy  | Hip arthroscopy   |
| <b>Comparator</b>   | Personalized Hip Therapy<br>(12-24 weeks)<br>best conservative care   | Non-operative: oral NSAIDs,<br>activity modification, physical<br>therapy and corticosteroid<br>injection  | Observation followed by THA<br>if progresses to end stage<br>arthritis  |
| <b>Country</b>      | UK  | USA  | USA   |
| <b>Funding</b>      | HTAP of National Institute of<br>Health Research  | Funded by Mitek Sports<br>Medicine, Stryker<br>Orthopedics and Smith &<br>Nephew, Inc. and authors<br>disclosed numerous ties to<br>commercial interest  | Funding unclear<br><br>Reports no conflicting<br>interest   |
| <b>Study design</b> | CUA   | CUA  | CUA   |
| <b>Perspective</b>  | Societal:<br>UK National Health Service   | Societal   | Hospital<br><br>Direct procedural cost only   |
| <b>Time horizon</b> | 1 year  | 10 year model; data from<br>case series and patient<br>surveys collected over 1 year   | Lifetime model using small<br>number (N= 10) of "recent<br>cases" for cost estimates  |

|   | Griffin 2018 <sup>66</sup>  | Mather 2018 <sup>131</sup>  | Shearer 2012 <sup>190</sup>   |
|---|---|---|---|
| <b>Analytic model</b>                   | Micro-costing/sampling direct costs   | Markov decision tree 5 state model  | Markov decision tree 8 state model  |
| <b>Effectiveness outcome</b>            | QALY  | QALY  | QALY  |
| <b>Effectiveness outcome components</b> | RCT outcomes:<br>EQ5D-3I<br>EQ5d-5L<br>SF-12  | Utility: (Unvalidated methods)<br>FAIS 0.75<br>Post-surgical complications 0.5<br>primary THA 0.9<br>Post-arthroscopy 0.94<br><br>Disutility:<br>Arthroscopy -0.05<br>Arthroplasty -0.10<br>Revision arthroplasty -0.12 | Modified Harris Hip Score that included both pain and function scores. Used linear extrapolation to generate utility values. (Unvalidated)<br>Utility:<br>FAIS 0.75<br>Primary THA 0.9<br>Poor hip function 0.5<br>Fair hip function 0.75<br>Good hip function 0.94.<br>Disutility:<br>Arthroscopy -0.05<br>Arthroplasty -0.10<br>Revision arthroplasty -0.12<br>Arthroscopy complication rate 1.5% |
| <b>Source for effectiveness data</b>    | RCT   | Relied heavily on expert opinion; published case series Published literature  | Published case series   |
| <b>Costing year</b>                     | 2016  | 2015  | 2010  |
| <b>Currency</b>                         | Reported in Pounds converted to USD using \$1 =£0.745*  | USD   | USD   |
| <b>Discounting</b>                      | None (short time horizon)   | 3%  | 3%  |
| <b>Components of cost data</b>          | Resource use and Delivery of intervention<br>Health services for F/U<br>Lost productivity and societal impact         | Arthroscopy (\$14,363), revision, Post-op Non-Op (\$1,669 annual)<br>Lost productivity (modeled)  | Arthroscopy (\$11,850), THA \$24,200  |
| <b>Cost sources</b>                     | RCT<br>Micro-costing for surgery<br>Personal Social Services<br>Research Unit for PT<br>Follow up care costs from NHS | PearlDiver Inc. (Insurance claim records)<br>Expert panel consulted; survey of patients from surgery practices<br>Survey results from National Health Interview Survey  | A review of 10 procedures<br>Cost-to-charge ratio to evaluate payments received.  |
| <b>Sensitivity analysis</b>             | 1-way sensitivity analysis (pre-specified and post hoc)   | One, two and three-way, probabilistic   | One, two-way, probabilistic   |
| <b>QHEs</b>                             | 79  | 67  | 65  |
| <b>Results:</b>                         |   |   |   |
| <b>Cost / QALY of intervention</b>      | \$5,023/NR QALY   | \$23,120/8.52 = \$2,7134/QALY   | NR  |

|                                  | Griffin 2018 <sup>66</sup>  | Mather 2018 <sup>131</sup>   | Shearer 2012 <sup>190</sup>  |
|----------------------------------|---|--|--|
| <b>Cost / QALY of comparator</b> | \$2,055/NR QALY   | \$18,828/6.48 = \$2,906/QALY   | NR   |
| <b>ICER</b>                      | PT Dominates Arthroscopy<br>Surgery is an additional:<br>\$3,184/-0.02 QALY   | Arthroscopy Dominates<br>Nonoperative care   | \$21,700/QALY  |
| <b>One-way SA</b>                | Unadjusted model slightly favored surgery in QALY's generated<br>With WTP = \$67,114 there was a 0.08 probability that surgery was cost-effective<br>Adjusting for sex, study site, impingement type, healthcare service surgery was significantly more expensive.    | All variables robust with WTP of \$100,000. Time horizon, cost of surgery and post-surgery productivity most sensitive variables. Costs are equal when procedure reaches \$76,826<br>Looking at only direct costs yields an ICER of \$2,751<br>Must change nonoperative rate of success to >90% AND reduce rate of recurrence of symptoms to <5% to make it dominant                     | Varying the durations of benefit to 13 months the ICER = \$50,000/QALY<br>Increasing cost of arthroscopy to \$27,300 the ICER = \$50,000/QALY<br>With arthritis: ICER = 79,500/QALY<br>ICER robust for wide range of cost and outcome of THA   |
| <b>Other SA</b>                  | In all post hoc sensitivity analyses PT dominated surgery while reasonably varying costs and assumptions behind utility measures  | Probabilistic Monte Carlo simulations suggest arthroscopy CE in 99% of trials  | Probabilistic Monte Carlo simulations suggest ICER <\$50,000 in 85% of trials <\$100,000 in 97%  |
| <b>Author's Conclusion</b>       | Cross over to surgery increases costs of PT group and makes surgery increasingly cost-effective   | Arthroscopy greatly reduces the economic cost of FAI while contributing to improved quality of life. Acknowledges the importance of 6 to 12 weeks of nonoperative treatment before surgery.  | Uncertainty remains regarding the QoL, duration of benefits and effect on subsequent THA. However, with given data, arthroscopy in patients without arthritis is cost effective.   |
| <b>Limitations</b>               | UK based, applicability to US unclear<br><br>Lack of clarity regarding handling of cross over<br><br>Short term prevented from fully investigating long term risk - development of osteoarthritis, need for future surgeries, recurrent pain or recurrent labral tear | Sourcing of data for clinical benefits, transition probabilities and abstraction poorly documented – relied heavily on expert opinion<br><br>Direct patient data came from survey of 2 surgeons' practices -high likelihood of selection bias<br><br>No data for non-op pts other than what was recalled by patients regarding their pre-op status<br><br>Potential conflict of interest | Case series as primary source of clinical data;<br>Uncertainty with input parameters such as the rate of progression of arthritis<br><br>Unvalidated utility methods<br><br>Only considered direct costs; perspective is not clearly stated<br><br>Relied on a single hospital costs with small sample of patients |

|  | Griffin 2018 <sup>66</sup> | Mather 2018 <sup>131</sup>  | Shearer 2012 <sup>190</sup> |
|--|----------------------------|-----------------------------|-----------------------------|
|  |                            | Unvalidated utility methods |                             |

\*Conversion rate based on Treasury Reporting Rates Of Exchange As Of June 30, 2016<sup>205</sup>

## 5 Strength of Evidence (SOE)

For efficacy, strength of evidence (SOE) tables are provided only for the highest quality (i.e., RCTs) studies comparing operative versus non-operative treatment. Two trials were considered to be at moderately low risk of bias and one trial was at moderately high risk of bias. Individual study ratings are found in Main Appendix E. Comparative studies (i.e., RCT, observational cohort studies) evaluating different surgical approaches were considered case series for safety purposes and the vast majority of included cohort studies were considered high risk of bias. For effectiveness, all case series were considered to be at high risk of bias; in the absence of studies comparing patients from the same underlying population (using contemporaneous cohorts of patients assigned to respective treatments), the evidence was considered to be insufficient to draw conclusions regarding effectiveness of operative treatment for FAIS. All study designs and treatment comparisons were included to evaluate safety. For safety, the focus was on complications related to surgical interventions given the invasive nature of surgery and the fact that one would not expect serious treatment-related adverse events with non-operative care (e.g., physical therapy, activity modification, non-steroidal anti-inflammatory drugs, injections, etc.).

Determination and interpretation of SOE are described in the Methods section. Bodies of evidence consisting of RCTs are initially considered as High strength of evidence. In general, the GRADE and AHRQ methodologies initially consider nonrandomized studies as Low strength of evidence as such studies typically are at higher risk of bias due to lack of randomization and inability of investigators to control for critical confounding factors. Observational studies with few methodologic limitations which control for risk of bias via study conduct or analysis may be initially considered as moderate versus low, particularly for harms and outcomes when such studies may be at lower risk of bias due to confounding

### 5.1 Strength of Evidence Summary for Key Question 1: Efficacy Results for Operative (Arthroscopy) versus Non-operative (Physiotherapy) Treatment

| Outcome*   | Time     | Studies, Year, N  | Serious Risk of Bias  | Serious Inconsistency | Serious Indirectness | Serious Imprecision   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE)        |
|--|----------|---|-----------------------|-----------------------|----------------------|-----------------------|--|----------------------|
| Proportion achieving clinically important improvement in HOS-ADL (0-100) | 8 mos.   | 1 RCT (N=188)<br><br>Palmer 2019                                  | No                    | Unknown               | No                   | No                    | <ul style="list-style-type: none"> <li>MCID (<math>\geq 9</math> points): 51% (51/100) vs. 32% (28/88); RR 1.6 (1.1 to 2.3)</li> <li>PASS (score <math>&gt; 87</math> points): 48% (48/100) vs. 19% (17/88); RR 2.5 (1.5 to 4.0)</li> </ul> <u>Conclusion:</u> More arthroscopy patients compared with PT patients achieved clinically important improvements in function. | ⊕⊕○○<br>LOW          |
| iHOT-33 (0-100, higher score = better function)                          | 6-8 mos. | 3 RCTs (N=569)<br><br>Griffin 2018<br>Mansell 2018<br>Palmer 2019 | No                    | Yes <sup>2</sup> (-1) | No                   | Yes <sup>4</sup> (-1) | Pooled MD 1.94 (0.13, 3.03), $I^2 = 0\%$<br><u>Conclusion:</u> Small improvement with arthroscopy vs. PT which is likely not clinically important.   | ⊕⊕○○<br>LOW          |
|  | 12 mos.  | 2 RCTs (N=395)<br><br>Griffin 2018<br>Mansell 2018                | No                    | No                    | No                   | Yes <sup>4</sup> (-1) | Pooled MD 6.55 (-0.19, 12.6), $I^2 = 0\%$<br><u>Conclusion:</u> No clear difference between groups across trials; one trial reached statistical significance favoring arthroscopy but the clinical relevance of the difference is unclear.   | ⊕⊕○○<br>LOW          |
|  | 24 mos.  | 1 RCT (N=74)<br><br>Mansell 2018                                  | Yes <sup>1</sup> (-1) | Unknown               | No                   | Yes <sup>4</sup> (-1) | MD 6.30 (-6.11, 18.71)<br><u>Conclusion:</u> No difference between groups; crossover from PT to arthroscopy was high (70%) and sample size was small.  | ⊕○○○<br>INSUFFICIENT |
| HOS-ADL (0-100, higher score = better function)                          | 6-8 mos. | 2 RCTs (N=296)<br><br>Mansell 2018<br>Palmer 2019                 | No                    | Yes                   | No                   | Yes <sup>4</sup> (-1) | Pooled MD 6.26 (-6.52, 16.96), $I^2 = 77\%$<br><u>Conclusion:</u> No difference between groups. The larger, better quality trial found a statistically significant improvement following arthroscopy vs. PT; difference may be clinically important.   | ⊕⊕○○<br>LOW          |

| Outcome*   | Time        | Studies, Year, N  | Serious Risk of Bias  | Serious Inconsistency | Serious Indirectness | Serious Imprecision   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality (SoE)        |
|--|-------------|---|-----------------------|-----------------------|----------------------|-----------------------|---|----------------------|
|  | 12, 24 mos. | 1 RCT (N=74)<br><br>Mansell 2018                        | Yes <sup>1</sup> (-1) | Unknown               | No                   | Yes <sup>4</sup> (-1) | 12 mos.: MD 4.90 (-3.65, 13.45)<br>24 mos.: MD 3.80 (-6.00, 13.60)<br><u>Conclusion:</u> No difference between groups at either timepoint; crossover from PT to arthroscopy was high (70%) and sample size was small.   | ⊕○○○<br>INSUFFICIENT |
| <b>HOS-Sport (0-100, higher score = better function)</b> | 6-8 mos.    | 2 RCTs (N=296)<br><br>Mansell 2018<br>Palmer 2019       | Yes <sup>1</sup> (-1) | No                    | No                   | Yes <sup>4</sup> (-1) | Pooled MD 10.98 (5.67, 16.30), I <sup>2</sup> = 0%<br><u>Conclusion:</u> Improvement with arthroscopy vs. PT; difference may be clinically important.   | ⊕⊕○○<br>LOW          |
|  | 12, 24 mos. | 1 RCT (N=74)<br><br>Mansell 2018                        | Yes <sup>1</sup> (-1) | Unknown               | No                   | Yes <sup>4</sup> (-1) | 12 mos.: MD 0.60 (-12.04, 13.24)<br>24 mos.: MD 1.80 (-11.16, 14.76)<br><u>Conclusion:</u> No difference between groups at either timepoint; crossover from PT to arthroscopy was high (70%) and sample size was small.   | ⊕○○○<br>INSUFFICIENT |
| <b>HAGOS pain subscale (0-100)</b>                       | 8 mos.      | 1 RCT (N=180)<br><br>Palmer 2019                        | No                    | Unknown               | No                   | Yes <sup>4</sup> (-1) | adj. MD 12.7 (8.1 to 17.2)<br><u>Conclusion:</u> Improvement in pain favoring arthroscopy; difference may be clinically important.  | ⊕⊕○○<br>LOW          |
| <b>Pain on hip assessment (%)</b>                        | 8 mos.      | 1 RCT (N=varies, see Results column)<br><br>Palmer 2019 | No                    | Unknown               | No                   | Yes <sup>4</sup> (-1) | <ul style="list-style-type: none"> <li>Flexion: 47% (46/97) vs. 66% (56/85); RR 0.72 (0.56 to 0.93)</li> <li>Adduction: 31% (30/97) vs. 46% (39/84); RR 0.67 (0.46 to 0.97)</li> <li>FABER test: 44% (42/96) vs. 62% (52/84); RR 0.71 (0.53 to 0.94) [N=180]</li> </ul> <u>Conclusion:</u> Fewer patients who received arthroscopy versus PT reported pain on hip flexion, hip adduction and the FABER test; no differences between groups on other assessments: hip extension, abduction, internal and external rotation, and the FAdIR test. Clinical relevance of difference is unclear. | ⊕⊕○○<br>LOW          |



| Outcome*                                   | Time        | Studies, Year, N                                   | Serious Risk of Bias  | Serious Inconsistency | Serious Indirectness | Serious Imprecision   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality (SoE)        |
|--|-------------|--|-----------------------|-----------------------|----------------------|-----------------------|---|----------------------|
| <b>Prescription opiate pain medication</b> | 24 mos.     | 1 RCT (N=79)<br><br>Mansell 2018                   | Yes <sup>1</sup> (-1) | Unknown               | No                   | Yes <sup>4</sup> (-2) | <ul style="list-style-type: none"> <li>Number of days' supply: MD 6.5 (-98.4 to 111.4)</li> <li>Number of unique prescriptions: MD -0.8 (-7.0 to 5.4)</li> <li>Days to last prescription: MD -116.7 (-258.1 to 24.7)</li> </ul> <u>Conclusion:</u> Sample size was small and CIs were wide precluding firm conclusions. | ⊕○○○<br>INSUFFICIENT |
| <b>Conversion to THA (%)</b>               | 12, 24 mos. | 2 RCTs (N=363)<br><br>Griffin 2018<br>Mansell 2018 | No                    | No                    | No                   | Yes <sup>4</sup> (-2) | 1.0% (2/203) vs. 0% (0/160)<br><u>Conclusion:</u> No difference between groups; Sample size and follow-up likely impacted the ability to adequately capture this event  | ⊕○○○<br>INSUFFICIENT |

Adj. = adjusted; FAbER = Pain on flexion, abduction, and external rotation; FAdIR = Pain on flexion, adduction, and internal rotation; HAGOS = Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; MD = mean difference; NAHS=non-arthritis hip score; OHS = Oxford hip score; PASS = patient acceptable symptom state; RR = risk ratio; THA = conversion to total hip arthroplasty; UCLA = University of California at Los Angeles activity score.

\*Higher values indicate better outcomes, with the exception of pain on hip assessment and number of days' supply of prescription opiate pain medication, for which lower values indicate better outcomes.

#### Reasons for downgrade:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details). Studies which did control for confounding via study design and/or statistical analyses (e.g. Adequate randomization and concealment, matching, multivariate regression, propensity matching) may not be downgraded for risk of bias depending other potential sources of bias (e.g. substantial loss to follow-up).
2. Inconsistency: differing estimates of effects across trials; if point estimates/effect size across trials are in the same direction, do not vary substantially or heterogeneity can be explained, results may not be downgraded for inconsistency. The consistency of single studies is unknown; evidence from single studies was not downgraded. Consistency may also be unknown if there is substantial differences between study populations across studies.
3. Indirect, intermediate or surrogate outcomes may be downgraded.
4. Imprecise effect estimate for an outcome: small sample size and/or confidence interval includes both negligible effect and appreciable benefit or harm with the intervention may be downgraded; If sample size is likely too small to detect rare outcomes, evidence may be downgraded twice. If the estimate is statistically significant, it is imprecise if the CI ranges from "mild" to "substantial". If the estimate is not statistically significant, it is imprecise if the CI crosses the threshold for "mild/small" effects. Wide (or unknown) confidence interval and/or small sample size may result in downgrade.

## 5.2 Strength of Evidence Summary for Key Question 2: Safety Results with a Focus on Operative Treatment.

| Outcome*   | Studies, Year, N<br>Timing*   | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE) |
|--|---|-------------------------|--------------------------|-------------------------|------------------------|--|---------------|
| <b>Operative (Arthroscopy) vs. Non-operative (Physiotherapy) treatment</b> |   |                         |                          |                         |                        |  |               |
| <b>Serious- and treatment-related adverse events</b>                       | 2 RCTs (N=479)<br><br>Griffin 2018, 24 months<br>Palmer 2019, 8 months  | No                      | Unknown                  | No                      | Yes                    | <b>Treatment-related death:</b> <ul style="list-style-type: none"> <li>No events in either treatment group [1 RCT, Griffin, N=284]</li> </ul> <b>Serious, treatment-related AEs:</b> <ul style="list-style-type: none"> <li>Griffin: 3.6% (5/138)<sup>†</sup> vs. 0% (0/146)</li> <li>Palmer: 0% (0/99) vs. 0% (0/96)</li> </ul> <b>Other, potentially treatment-related AEs:</b> <ul style="list-style-type: none"> <li>5.8% (8/138) (9 events) vs. 0.7% (1/146); RR 8.5 (95% CI 1.1, 66.8) [1 RCT, Griffin]</li> </ul> <b>Conclusion:</b> Given that arthroscopy is invasive while PT is not, one would not expect serious adverse events or death with PT, precluding definitive conclusions. | ⊕⊕○○<br>LOW   |
| <b>Adverse events associated with operative treatment</b>                  |   |                         |                          |                         |                        |  |               |
| <b>Heterotopic ossification (HO)</b>                                       | <u>Adults</u><br>2 SRs of case series (N=9,222 hips)<br>Riff 2019, Minkara 2019<br><br>1 RCT (N=65)<br>Mansell 2018<br><br>4 cohorts (N=23 to 198)<br>Botser 2014, Larson 2012, Rego 2018, Roos 2017<br><br>4 case series (N=360 to 1870, 1615 hips)<br>Rhon 2019a, Larson 2016, Nossa 2014, Bedi 2012<br><br><u>Pediatrics</u> | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <u>Adults</u> <ul style="list-style-type: none"> <li>SRs: 0.5% (33/7241) and 0.8% (16/1981)</li> <li>RCT: 1.5% (1/65)</li> <li>Cohorts: range, 0% to 31%; excluding outlier [Roos 2017], 0% to 1%</li> <li>Case series: range, 0.6% to 4.7%</li> </ul> <u>Pediatrics</u> <ul style="list-style-type: none"> <li>SR: 0.2% (1/435); arthroscopy 0% (0/354) vs. open hip dislocation 1.2% (1/81)</li> <li>Case series: one case (2.3%) in each study (one arthroscopy and one open hip dislocation)</li> </ul>  | ⊕⊕○○<br>LOW   |

| Outcome*                        | Studies, Year, N<br>Timing*   | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality (SoE) |
|---------------------------------|---|-------------------------|--------------------------|-------------------------|------------------------|---|---------------|
|                                 | 1 SR of case series (N=435)<br>de Sa 2014<br><br>2 case series (N=43, 44)<br>Litrenta 2018, Sink 2013   |                         |                          |                         |                        | <u>Conclusion:</u> The frequency of HO ranged from 0% to 4.7% across all studies (excluding outlier in adults); in pediatric populations, the range was 0.2% to 2.3% across 1 SR and 2 small case series.   |               |
| <b>Avascular necrosis (AVN)</b> | <u>Adults</u><br>1 SR of case series (N=7,241 hips)<br>Riff 2019<br><br>1 RCT (N=65)<br>Mansell 2018<br><br>4 cohorts (N=23 to 96)<br>Botser 2014, Hingsammer 2015, Larson 2012, Roos 2017<br><br>1 case series (N=1870)<br>Rhon 2019a<br><br><u>Pediatrics</u><br>1 SR of case series (N=435)<br>de Sa 2014<br><br>4 case series (N=197)<br>Byrd 2016b, Cvetanovich 2018, Larson 2019, Tran 2013 | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <u>Adults</u><br>• SR: 0% (0/7241)<br>• RCT: 0% (0/65)<br>• Cohorts: 0% (0/198)<br>• Case series: 0.4% (8/1870)<br><br><u>Pediatrics</u><br>• SR: 0% (0/435)<br>• Case series: 0% (0/197)<br><br><u>Conclusion:</u> AVN was very rare as reported by these studies with only 8 events (0.4%) reported by one large case series in adults. | ⊕⊕○○<br>LOW   |
| <b>Femoral fracture</b>         | <u>Adults</u><br>2 SRs of case series (N=9,222 hips)<br>Riff 2019, Minkara 2019<br><br>2 RCTs (N=203)<br>Griffin 2018, Mansell 2018<br><br>3 cohorts (N=23 to 96)   | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <u>Adults</u><br>• SRs: 0.01% (1/7241) and 0.05% (1/1981)<br>• RCTs: 0.5% (1/203)<br>• Cohorts: 0% (0/175)<br>• Case series: range, 0% to 1%<br><br><u>Pediatrics</u><br>• SR: 0% (0/435)   | ⊕⊕○○<br>LOW   |

| Outcome*                                  | Studies, Year, N<br>Timing*  | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality (SoE) |
|---|--|-------------------------|--------------------------|-------------------------|------------------------|---|---------------|
|   | <p>Hingsammer 2015, Larson 2012, Roos 2017</p> <p>6 case series (N=317 to 1870; 1615 to 14,495 hips)<br/>Cvetanovich 2018, Dietrich 2014, Larson 2016, Merz 2015, Rhon 2019a, Zingg 2014</p> <p><u>Pediatrics</u><br/>1 SR of case series (N=435)<br/>de Sa 2014</p> <p>1 case series (N=44)<br/>Sink 2013</p> |                         |                          |                         |                        | <ul style="list-style-type: none"> <li>Case series: 0% (0/44)</li> </ul> <p><u>Conclusion:</u> Femoral fracture was rare ranging from 0% to 1% across all studies; there were no instances reported in pediatric patients.</p>  |               |
| <b>Nonunion of the greater trochanter</b> | <p><u>Adults</u><br/>2 cohorts (N=198, 201)<br/>Buchler 2013, Rego 2018</p> <p><u>Pediatrics</u><br/>1 case series (N=44)<br/>Sink 2013</p>  | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <ul style="list-style-type: none"> <li>Adults: 0% and 2%; 0% across arthroscopy arms (N=66, 102) vs. 1% and 2% (N=96, 135) in open hip dislocation arms</li> <li>Pediatrics: 0% (open hip dislocation)</li> </ul> <p><u>Conclusion:</u> Across 3 studies, frequency of nonunion ranged from 0% to 2% with all cases occurring following open hip dislocation in adults.</p>   | ⊕⊕○○<br>LOW   |
| <b>Nerve injury‡</b>                      | <p><u>Adults</u><br/>2 SRs of case series (N=9,222 hips)<br/>Riff 2019, Minkara 2019</p> <p>2 RCTs (N=237)<br/>Griffin 2018, Palmer 2019</p> <p>5 cohorts (N=23 to 198)<br/>Botser 2014, Cetinkaya 2016, Rego 2018, Roos 2017, Zingg 2013</p>  | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><u>Adults</u></p> <ul style="list-style-type: none"> <li>SRs: range, 0.01% to 0.4%</li> <li>RCTs: 2.1% (5/237)</li> <li>Cohorts: range, 0% to 25%; excluding outlier, 0% to 9%</li> <li>Case series: range, 0.1% to 18.8%; excluding outlier, 0.1% to 4.4%</li> </ul> <p><u>Pediatrics</u></p> <ul style="list-style-type: none"> <li>SR: 0.5% (2/435); arthroscopy 0.6% (2/354) vs. open hip dislocation 0% (0/81)</li> </ul> | ⊕⊕○○<br>LOW   |

| Outcome*                     | Studies, Year, N<br>Timing*  | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE) |
|------------------------------|--|-------------------------|--------------------------|-------------------------|------------------------|--|---------------|
|                              | <p>4 case series (N=317 to 414; 1615 hips) Cvetanovich 2018, Deitrich 2014, Larson 2016, Nossa 2014</p> <p><u>Pediatrics</u></p> <p>1 SR of case series (N=435) de Sa 2014</p> <p>5 case series (N=24 to 108) Byrd 2016a, Byrd 2016b, Cvetanovich 2018, Degen 2017, McConkey 2019</p>  |                         |                          |                         |                        | <ul style="list-style-type: none"> <li>Case series: range, 1.9% to 8.3%</li> </ul> <p><u>Conclusion:</u> Across all studies, nerve injury was reported in 0% to 25% of the populations. In adults, the highest rates were seen in the open hip dislocation arm of one small cohort (25%; 4/16) and in one case series (19%; 68/360) that included surgeons who were still learning; in pediatrics, the highest rate (8%; 2/24) was in one small case series evaluating adolescent athletes undergoing simultaneous bilateral hip arthroscopy for FAIS. Excluding these outliers, the range was 0% to 9%.</p> |               |
| <b>Superficial infection</b> | <p><u>Adults</u></p> <p>2 SRs of case series (N=9,222 hips) Riff 2019, Minkara 2019</p> <p>2 RCTs (N=237) Griffin 2018, Palmer 2019</p> <p>3 cohorts (N=23 to 198) Botser 2014, Rego 2018, Roos 2017</p> <p>2 case series (N=414; 1615 hips) Cvetanovich 2018, Larson 2016</p> <p><u>Pediatrics</u></p> <p>3 case series (N=34 to 44) Cvetanovich 2018, Sink 2013, Tran 2013</p> | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><u>Adults</u></p> <ul style="list-style-type: none"> <li>SRs: 0.3% (19/7241) and 0.2% (4/1981)</li> <li>RCTs: 4.2% (10/237); requiring antibiotics, 2.1% (5/237)</li> <li>Cohorts: 0% to 6%</li> <li>Case series: 1% in both</li> </ul> <p><u>Pediatrics</u></p> <ul style="list-style-type: none"> <li>Case series: range, 0% to 2.7%</li> </ul> <p><u>Conclusion:</u> Across all studies, the frequency of superficial wound infection ranged from 0% to 6%.</p>  | ⊕⊕○○<br>LOW   |
| <b>Deep infection</b>        | <u>Adults</u>  | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><u>Adults</u></p> <ul style="list-style-type: none"> <li>SR: 0.01% (1/7241)</li> </ul>  | ⊕⊕○○<br>LOW   |

| Outcome*                      | Studies, Year, N<br>Timing*   | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion  | Quality (SoE) |
|-------------------------------|---|-------------------------|--------------------------|-------------------------|------------------------|---|---------------|
|                               | <p>1 SR of case series (N=7241 hips)<br/>Riff 2019</p> <p>2 cohorts (N=79)<br/>Botser 2014, Roos 2017</p> <p>1 case series (N=1615 hips)<br/>Larson 2016</p>  |                         |                          |                         |                        | <ul style="list-style-type: none"> <li>Cohorts: 0% (0/79)</li> <li>Case series: 0.1% (1/1615 hips)</li> </ul> <p><u>Conclusion:</u> Deep wound infection was rare as reported by 4 studies ranging from 0% to 0.1%. No study in pediatric patients reported this complication.</p>  |               |
| <b>Thrombo-embolic events</b> | <p><u>Adults</u></p> <p>2 SRs (N=11,818 hips)<br/>Riff 2019, Bolia 2018</p> <p>2 RCTs (N=203)<br/>Griffin 2018, Mansell 2018</p> <p>3 cohorts (N=23 to 198)<br/>Botser 2014, Roos 2017, Rego 2018</p> <p>2 case series (N=414; 1615 hips)<br/>Cvetanovich 2018, Larson 2016</p> | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><u>Adults</u></p> <p><i>Pulmonary embolism (PE)</i></p> <ul style="list-style-type: none"> <li>1 SR [Bolia]: 0.59% (95%CI 0.38% to 0.92%)</li> <li>1 case series: 0.1% (1/1615 hips)</li> </ul> <p><i>Deep vein thrombosis (DVT)</i></p> <ul style="list-style-type: none"> <li>1 SR [Bolia]: 1.18% (95%CI 0.8% to 1.74%)</li> <li>RCTs: 0% (0/203)</li> <li>Cohorts: range, 0% to 3%</li> <li>Case series: range, 0.1% to 0.2%</li> </ul> <p><i>PE or DVT</i></p> <ul style="list-style-type: none"> <li>1 SR [Riff]: 0.1% (8/7241)</li> </ul> <p><u>Conclusion:</u> Thromboembolic events were rare as reported by 9 studies ranging from 0% to 1.2%. No study in pediatric patients reported these complications.</p> | ⊕⊕○○<br>LOW   |
| <b>Revision surgery</b>       | <p><u>Adults</u></p> <p>2 SRs of case series (N=9,222 hips)<br/>Riff 2019, Minkara 2019</p> <p>1 RCT (N=65)<br/>Mansell 2018</p>  | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><u>Adults</u></p> <ul style="list-style-type: none"> <li>SRs: 1.9% (38/1981) and 3.2% (233/7241)</li> <li>RCT: 7.7% (5/65)</li> <li>Cohorts: range, 0% to 12%</li> <li>Case series: range, 1.2% to 6.5%</li> </ul>   | ⊕⊕○○<br>LOW   |

| Outcome*  | Studies, Year, N<br>Timing*   | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE) |
|---|---|-------------------------|--------------------------|-------------------------|------------------------|--|---------------|
|   | <p>10 cohorts (N=23 to 201)<br/>Botser 2014, Buchler 2013,<br/>Cetinkaya 2016, Domb 2013,<br/>Larson 2012, Menge 2017,<br/>Redmond 2015, Rego 2018,<br/>Webb 2019, Zingg 2013</p> <p>3 case series (N=314 to 1870)</p> <p><u>Pediatrics</u><br/>1 SR of case series (N=435)<br/>de Sa 2014</p> <p>9 case series (N=18 to 108)<br/>Byrd 2016a, Byrd 2016b,<br/>Cvetanovich 2018, Degen<br/>2017, Larson 2019, Litrenta<br/>2018, McConkey 2019, Sink<br/>2013, Tran 2013</p> |                         |                          |                         |                        | <p><u>Pediatrics</u></p> <ul style="list-style-type: none"> <li>SR: 3.0% (13/435); all occurred following arthroscopy (4.0%; 13/354)</li> <li>Case series: Arthroscopy range, 0% to 5.9% (8 case series); Open hip dislocation, 13.6% (6/44) (1 case series)</li> </ul> <p><u>Conclusion:</u> Across all studies, the frequency of revision surgery ranged from 0% to 13.6%. The highest rates occurred following open hip dislocation surgery (12% in open arm of one cohort in adults; 13.6% in one small case series in children).</p>  |               |
| <b>Additional surgery (other than revision)</b> | <p><u>Adults</u><br/>4 cohorts (N=23 to 198)<br/>Botser 2014, Domb 2013,<br/>Rego 2018, Zingg 2013</p> <p><u>Pediatrics</u><br/>4 case series (N=24 to 44; 18 hips)<br/>Guindani 2017, Litrenta 2018, Novais 2016, Sink 2013</p>  | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><u>Hardware/screw removal</u><br/><u>Adults</u></p> <ul style="list-style-type: none"> <li>3 cohorts [Botser, Domb, Zingg]: 0% in arthroscopy arms (n=18 to 23) vs. 20%–80% across open hip dislocation arms (n=5 to 15).</li> </ul> <p><u>Pediatrics</u></p> <ul style="list-style-type: none"> <li>2 case series [Novais, Sink]: 12.5% (3/24), 20.5% (9/44); all open hip dislocation surgery</li> </ul> <p><u>Additional surgery</u><br/><u>Adults</u></p> <ul style="list-style-type: none"> <li>2 cohorts [Domb, Rego]: 1% (1/102) and 5% (1/20) in arthroscopy arms vs. 0% across open hip dislocation arms (n=96, 10).</li> </ul> <p><u>Pediatrics</u></p> | ⊕⊕○○<br>LOW   |

| Outcome*   | Studies, Year, N<br>Timing*  | Serious<br>Risk of Bias | Serious<br>Inconsistency | Serious<br>Indirectness | Serious<br>Imprecision | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE) |
|--|--|-------------------------|--------------------------|-------------------------|------------------------|--|---------------|
|  |  |                         |                          |                         |                        | <ul style="list-style-type: none"> <li>2 case series [Litrenta, Guindani]: 2.3% (1/43), 11% (2/18 hips); all arthroscopy</li> </ul> <p><u>Conclusion:</u> Hardware removal occurred exclusively following open hip dislocation surgery across 5 studies, range 12.5% (pediatrics) to 80% (open arms of cohort studies). Additional surgeries ranged from 1% to 11%.</p>  |               |
| <b>Other adverse events in pediatric populations</b> | 1 SR of case series (N=435) de Sa 2014<br><br>4 case series (N=18 to 108) Byrd 2016b, Cvetanovich 2018, Larson 2019, Tran 2013 | Yes <sup>1</sup> (-1)   | No                       | No                      | Yes <sup>4</sup> (-1)  | <p><i>Physal arrest or growth disturbance</i></p> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>4 case series: 0% (0/197)</li> </ul> <p><i>Acute iatrogenic slipped capital femoral epiphysis (SCFE)</i></p> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>1 case series: 0% (0/34)</li> </ul> <p><i>Iatrogenic instability</i></p> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> <li>1 case series: 0% (0/108)</li> </ul> <p><i>Various**</i></p> <ul style="list-style-type: none"> <li>SR: 0% (0/435)</li> </ul> <p><u>Conclusion:</u> No cases of physal arrest/growth disturbance, SCFE, iatrogenic instability or various other complications were reported by 5 studies in pediatric populations; sample sizes may not have been sufficient to detect rare events.</p> | ⊕⊕○○<br>LOW   |

Adj. = adjusted; FABER = Pain on flexion, abduction, and external rotation; FAdIR = Pain on flexion, adduction, and internal rotation; HAGOS = Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; MD = mean difference; NAHS=non-arthritis hip score; OHS = Oxford hip score; PASS = patient acceptable symptom state; RR = risk ratio; THA = conversion to total hip arthroplasty; UCLA = University of California at Los Angeles activity score.

\*Follow-up varied widely across the studies comparing different surgical treatments for FAI and across case series of surgical intervention (1.5 months to 120 months).

†The serious treatment-related adverse events included an overnight admission post-arthroscopy, scrotal haematoma requiring readmission, superficial wound infections that required oral antibiotics [2 patients], hip joint infection that required further surgery and ultimately a THA.



‡To include: lateral femoral cutaneous neurapraxia; femoral neurapraxia; pudendal neurapraxia; perineal neurapraxia; sciatic neurapraxia; and unspecified/other Neurapraxia.

§Included one case each of iliopsoas release due to new onset symptomatic internal snapping and compartment syndrome grade III.

\*\*Broken instrumentation, abdominal compartment syndrome, urinary/sexual dysfunction, chondral scuffing, labral penetration, or inadequate correction.

#### Reasons for downgrade:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details). Studies which did control for confounding via study design and/or statistical analyses (e.g. Adequate randomization and concealment, matching, multivariate regression, propensity matching) may not be downgraded for risk of bias depending other potential sources of bias (e.g. substantial loss to follow-up).
2. Inconsistency: differing estimates of effects across trials; if point estimates/effect size across trials are in the same direction, do not vary substantially or heterogeneity can be explained, results may not be downgraded for inconsistency. The consistency of single studies is unknown; evidence from single studies was not downgraded. Consistency may also be unknown if there is substantial differences between study populations across studies.
3. Indirect, intermediate or surrogate outcomes may be downgraded.
4. Imprecise effect estimate for an outcome: small sample size and/or confidence interval includes both negligible effect and appreciable benefit or harm with the intervention may be downgraded; If sample size is likely too small to detect rare outcomes, evidence may be downgraded twice. If the estimate is statistically significant, it is imprecise if the CI ranges from “mild” to “substantial”. If the estimate is not statistically significant, it is imprecise if the CI crosses the threshold for “mild/small” effects. Wide (or unknown) confidence interval and/or small sample size may result in downgrade.

### 5.3 Strength of Evidence Summary for Key Question 3: Differential Efficacy\*and Safety Results for Operative (Arthroscopy) versus Non-operative (Physiotherapy) Treatment for FAIS

| Outcome   | Time           | Studies, Year, N  | Serious Risk of Bias | Serious Inconsistency | Serious Indirectness | Serious Imprecision   | Arthroscopy vs. PT<br>Effect estimate (95% CI)<br>Conclusion   | Quality (SoE)        |
|---|----------------|---|----------------------|-----------------------|----------------------|-----------------------|--|----------------------|
| <b>Age</b> (years);<br><b>FAI type</b><br>(cam, pincer, mixed); <b>Sex</b> ;<br><b>KL grade</b> (0 or 1); <b>Study center</b> (1-6) | 8 to 12 months | 2 RCTs<br><br>Griffin 2018 (N=358; iHOT-33)<br>Palmer 2019 (N=222; HOS-ADL) | No                   | Unknown†              | No                   | Yes <sup>4</sup> (-2) | Greater improvement on the HOS-ADL at 8 months with younger age in one RCT (Palmer 2019): adj. interaction effect – 0.31 (–0.44, –0.18); the second RCT (Griffin) found no significant interaction for the effect of age (<40 vs. ≥40) on the iHOT-33 at 12 months.<br><br>There was no modifying effect seen for the following:<br><ul style="list-style-type: none"> <li>• FAI type (2 RCTs)</li> <li>• Sex, KL grade, baseline HOS-ADL, and study center (1 RCT, Palmer)</li> </ul> <u>Conclusion:</u> It is unclear whether age may modify treatment effect since outcomes, methods, and results across trials differ. | ⊕○○○<br>INSUFFICIENT |

Adj. = adjusted; FABER = Pain on flexion, abduction, and external rotation; FAdIR = Pain on flexion, adduction, and internal rotation; HAGOS = Copenhagen hip and groin outcome score; MCID = minimal clinically important difference; MD = mean difference; NAHS=non-arthritis hip score; OHS = Oxford hip score; PASS = patient acceptable symptom state; RR = risk ratio; THA = conversion to total hip arthroplasty; UCLA = University of California at Los Angeles activity score.

\*Additional domains considered in studies performing a formal test of interaction for subgroup modification (i.e., HTE) based on recommendations from Ofman<sup>152</sup> and Guyat<sup>71,72</sup>:

- Is the subgroup variable a characteristic specified at baseline or after randomization? (subgroup hypotheses should be developed a priori)
- Did the hypothesis precede rather than follow the analysis and include a hypothesized direction that was subsequently confirmed?
- Was the subgroup hypothesis one of a smaller number tested?

†Different methods were employed to evaluate the effect of age on treatment modification; one trial dichotomized age (<40 vs. ≥40) while the other evaluated age as a continuous variable which may have given it more power to detect a difference.

#### Reasons for downgrade:

1. Serious risk of bias: the majority of studies violated one or more of the criteria for good quality RCT (or cohort study) related to the outcome reported (see Appendix for details). Studies which did control for confounding via study design and/or statistical analyses (e.g. Adequate randomization and concealment, matching, multivariate regression, propensity matching) may not be downgraded for risk of bias depending other potential sources of bias (e.g. substantial loss to follow-up).
2. Inconsistency: differing estimates of effects across trials; if point estimates/effect size across trials are in the same direction, do not vary substantially or heterogeneity can be explained, results may not be downgraded for inconsistency. The consistency of single studies is unknown; evidence from single studies was not downgraded. Consistency may also be unknown if there is substantial differences between study populations across studies.
3. Indirect, intermediate or surrogate outcomes may be downgraded.
4. Imprecise effect estimate for an outcome: small sample size and/or confidence interval includes both negligible effect and appreciable benefit or harm with the intervention may be downgraded; If sample size is likely too small to detect rare outcomes, evidence may be downgraded twice. If the estimate is statistically significant, it is imprecise if the CI ranges from “mild” to “substantial”. If the estimate is not statistically significant, it is imprecise if the CI crosses the threshold for “mild/small” effects. Wide (or unknown) confidence interval and/or small sample size may result in downgrade.

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