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# The medium-term results of Arthroscopic Hip Surgery compared with Physiotherapy and Activity Modification for the Treatment of Femoroacetabular Impingement Syndrome:

# A Multi-Centre Randomised Controlled Trial

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**Abstract:**

**Objective:** To report three-year follow-up from the FemoroAcetabular Impingement Trial (FAIT), comparing arthroscopic surgery with physiotherapy in the management of femoroacetabular impingement (FAI) syndrome for the dual primary outcomes of radiographic hip osteoarthritis and patient reported outcome measures (PROMS) of Activities of Daily Living (ADL).

**Methods:** Two-group parallel, assessor-blinded, pragmatic randomised controlled trial across seven sites. 222 participants aged 18 to 60 years with FAI syndrome confirmed clinically and radiologically were randomised (1:1) to receive arthroscopic hip surgery (n = 112) or physiotherapy (n = 110). Dual primary outcome measure was minimum Joint Space Width (mJSW) on Anteroposterior Radiograph at 38 months post randomisation and Hip Outcome Score ADL (HOS ADL) (higher score indicates superior outcomes). Secondary outcome measures were Scoring Hip Osteoarthritis with MRI (SHOMRI) (lower score indicates less pathology).

**Results:** mJSW, HOS ADL, and MRI data were available for 45%, 77%, and 62% of participants at 38 months, respectively. No significant difference in mJSW was seen between groups at 38 months. HOS ADLwas higher in the arthroscopy group (mean (SD) 84.2 (17.4)) compared with the physiotherapy group (74.2 (21.9)), difference 8.9 (95% CI 7.0, 10.8)). SHOMRI score total at 38 months was lower in the arthroscopy group (mean (SD) 9.22 (11.43)) compared to the physiotherapy group (22.76 (15.26)), differences (95% CIs) -15.94 (-18.69, -13.19).

**Conclusions:** No difference was seen between groups on radiographic measures of OA progression. Patients with FAI syndrome treated surgically may experience superior pain and function outcomes, and less MRI-measured cartilage damage compared with physiotherapy.

**Trial Registration:** ClinicalTrials.gov identifier: NCT01893034.

**Feasibility Study:**

https://www.ncbi.nlm.nih.gov/pubmed/23610700

**Protocol:**

https://www.ncbi.nlm.nih.gov/pubmed/25431439

**Ethics Approval:**

The trial protocol was approved by Health Research Authority, National Research Ethics Services Committee South Central – Berkshire (REC reference: 13/SC/0154) and local research and development departments at each participating site.

**Funding:**

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**Summary Box:**

***What is already known on this topic:***

- Femoroacetabular Impingement (FAI) syndrome is a symptomatic hip condition that results from a mechanical abutment of the femoral neck against the rim of the hip socket. This condition has been shown to be strongly associated with the development of osteoarthritis and the need for future hip replacement.
- Arthroscopic surgical treatment for FAI syndrome is an established procedure shown to be effective in treating short-term symptoms compared to non-operative treatment such as physiotherapy; however, limited long-term outcomes are available.

***What this study adds:***

- This study suggests that arthroscopic FAI syndrome surgery may offer some disease modifying potential in slowing down the progression to osteoarthritis based on MRI measures. However, this finding is not conclusive as the majority of radiographic measures used did not show a difference between groups and longer-term studies are required.
- Arthroscopic surgery for FAI syndrome provides a beneficial treatment effect in symptomatic relief compared to physiotherapy 38 months post-randomisation. However, symptoms in both arthroscopy and physiotherapy groups continued to improve over time.

***How this might affect research, practice, or policy:***

- Slowing the progression of osteoarthritis and therefore the need for hip replacement has patient-related and cost implications. Given that over 80,000 hip replacements are performed in the UK alone each year, even a moderate reduction would have a significant economic impact. However, these results should be interpreted with caution given the mid-term outcome assessment, loss to follow-up of the initial cohort, and lack of radiographic differences.
- Larger and longer-term studies are required to understand how best to prevent osteoarthritis progression in patients with FAI syndrome. We recommend surgeons make a decision to operate following a trial of non-operative intervention with the goal of improving symptoms rather than the prevention of osteoarthritis.

**Introduction:**

Femoroacetabular Impingement (FAI) syndrome (1) is a common symptomatic mechanical condition of the hip, where hip morphology predisposes to premature osteoarthritis (OA) (2-5). Hip morphology predisposing to FAI syndrome is present in approximately 25% of the general population(6), but is far more prevalent among athletes, with estimates ranging between 50-90% depending on sport(6-9).

The primary treatment goal in FAI syndrome is to improve pain and function. Physiotherapy (including physiotherapist-led incremental exercise rehabilitation, education, and activity modification) is the initial treatment for FAI syndrome; however, arthroscopic surgery is an established procedure for treating patients who have failed to respond to non-operative treatments(10). The aim of the surgery is to reshape the hip to modify its biomechanics to relieve impingement symptoms and address any chondro-labral damage. Arthroscopic hip surgery has been shown to be safe(11) and provide, in selected patients, superior symptomatic relief in the short term compared to best practice non-operative treatments such as physiotherapy(12, 13). The longer-term outcomes of hip arthroscopy are not known, both in terms of its ability to improve symptoms and modify disease progression. The Australian Fashion Trial(14) showed no effect of hip arthroscopy on disease progression at 12 months, and this study represents the longest follow-up period within the literature to date.

The aim of the Femoroacetabular Impingement Trial (FAIT) is to compare arthroscopic hip surgery with physiotherapy and activity modification in patients with FAI syndrome referred to secondary or tertiary care in the UK(15). The trial has two co-primary outcomes(15). We have reported the primary end-point of patient-reported outcome measures (PROMS) of activities of daily living (ADL) through the Hip Outcome Score (HOS ADL) at eight months post-randomisation in a previous manuscript(10). In this manuscript, we report the primary end-point of radiographic osteoarthritis progression in addition to HOS ADL at 38 months post-randomisation.

## Methods:

### *Design and participants:*

Details of the study protocol and eight-month results have been previously published(10, 15). In summary, adults aged 18 to 60 with FAI syndrome confirmed clinically and by imaging were randomised equally to receive arthroscopic hip surgery or physiotherapy and activity modification. Randomisation was performed using an automated computer-generated minimisation system including a random element making future allocations unpredictable and therefore ensuring allocation concealment. Minimisation factors (age (<40 vs. ≥40), sex, baseline HOS (<120 vs. ≥120) and randomising site).

### *Outcomes:*

The primary endpoint for the long-term follow-up was the Semi-Automated Minimum Joint Space Width (mJSW) on anteroposterior radiograph at 38 months post randomisation. Semi-automated mJSW is more reproducible than manual mJSW measurements (see supplementary data). A lower mJSW value suggests greater cartilage loss. Measurements were performed by trained readers (SF and AP) on standing anteroposterior pelvic radiographs using a validated software package (HipMorf 2.0, University of Oxford, Oxford, UK). mJSW was also measured at 14 and 26 months.

Scoring hip osteoarthritis with MRI (SHOMRI)(16) data was used as a secondary outcome measure to provide quantitative categorical information for evidence of pathology to articular cartilage, bone marrow oedema, subchondral cyst, labrum, paralabral cysts, intra articular bodies, effusion/synovitis, and ligamentum teres. A higher SHOMRI score suggests greater pathological change. These categorical data are presented separately and also combined to produce a total SHOMRI score for whole joint scoring. Additional radiographic outcomes (manual mJSW, alpha angle, lateral centre-edge, joint space width at lateral sourcil, joint space width at medial sourcil, average semi-automated joint space width, Kellgren-Lawrence grade), were measured at 8, 14, 26 and 38 months.

Assessors were blinded to treatment allocation during imaging and PROMs outcome assessment through anonymised patient identifiers. However, it was recognised that visible evidence of surgical intervention in some follow-up imaging would be unavoidable All imaging was read paired with knowledge of timepoint.

The HOS ADL at eight months was the primary outcome for the short-term follow-up previously reported(10), and PROM collection continued throughout the duration of follow-up. A higher HOS ADL score suggests superior patient outcomes. PROMS included HOS ADL, HOS Sports, Non-Arthritic Hip Score (NAHS), international Hip Outcome Score (iHOT), Copenhagen Hip and Groin Outcome Score (HAGOS), Oxford Hip Score (OHS), Pain Detect, Hospital Anxiety and Depression Scale (HADS), EQ-5D-5L), and were collected at 5, 8, 11, 14, 20, 26, 32, 38 months.

Details on further interventions, and unscheduled visits were also collected. Additional outcomes (not reported here) include serum and urinary biomarkers of osteoarthritis, and health economic data. The minimally clinically important difference (MCID) was defined as 0.5 mm for the mJSW (17, 18) and 9 points for the HOS ADL(19). Reproducibility data was excellent for all imaging outcomes and is reported in the supplementary data. Imaging protocols are reported in the supplementary data.

***Statistical analysis:***

*Sample size:*

The original sample size calculation of 51 participants per arm (102 in total, or 120 after allowing for 15% loss to follow-up) was based on the minimally important difference of nine points in the HOS-ADL at 8 months(19), and an associated standard deviation of 14,(20) but was also sufficient to detect a clinically important difference in mJSW of 0.5 mm (21)(standard deviation 0.62)(22) with 90% power at a 5% two-sided significance level(10). The sample size was subsequently increased from 120 to 214 to allow for a larger than expected standard deviation in the HOS ADL (18, as observed during a Data Monitoring and Ethics Committee review), and up to 20% loss to follow-up.

*Statistical analysis:*

Analyses were performed in line with our published protocol and statistical analysis plan, which was approved by trial statistician and chief investigator ahead of the final analysis.

Analyses were performed on the as-randomised population, regardless of adherence to the randomisation allocation, and all participants with at least one follow-up time point were be included in the analyses. Adjusted treatment effects and corresponding 95% confidence intervals (CIs) for continuous outcomes were obtained from multilevel mixed-effects models including repeated measures of the outcomes at each relevant time point (level 1) nested within participants (level 2, random effects). The models were adjusted for gender, age at randomisation (used as a continuous variable) and the baseline value of the relevant outcome variable. The inclusion of the baseline values

of the dependent variable instead of the baseline HOS-ADL was pre-specified as the former were thought to increase the precision of the models, and concerns over multicollinearity. Sensitivity analyses were performed to assess the effect of adding the baseline HOS-ADL scores to all models. Clustering of outcomes by randomising centre was accounted for using the 'cluster' option in Stata's 'mixed' command to generate robust standard errors. Time was added to the model as a categorical variable (i.e. categories are used to indicate the protocol stipulated follow-up time points), and interactions between randomised treatment and time were included. Missing semi-automated MJSW data where participants had undergone total hip replacements (THR) before the expected follow-up radiograph were excluded from the primary analysis. These individuals have been included in a sensitivity analysis where mJSM is set to zero, as a joint space width of zero represents end stage osteoarthritis which is an indication for a THR. Sensitivity analyses for the primary endpoint included the per-protocol population, variations on the observations replaced with zero depending on the timing of THRs and exploring the effects of missing data on the trial results considering missing not at random scenarios, whereby those with missing outcomes were assumed to have had outcomes better or worse than those with available data (Supplementary figure 1 and supplementary table 5). No other missing outcome data were imputed. Where relevant, missing baseline data were handled via mean imputation. Categorical data were summarised; no statistical tests were performed on these data. The assumptions underlying the statistical models were checked and found to be adequately met for the results presented in this publication.

Descriptive responder analysis for the HOS-ADL, semi-automated mJSW, and SHOMRI reported the frequency and percentage of participants classed as deteriorated, unchanged, and improved.

Statistical analysis and presentation of data were consistent with the CHAMP statement(23).

***Patient and public involvement:***

A feasibility study included patient questionnaires to determine outcomes they thought were most important, treatment preferences, acceptable study design, and anticipated recruitment numbers(24).The study design was based on these findings. A patient representative provided guidance throughout the study, including an evaluation of the burden of intervention and assessments.

***Equity, Diversity, and Inclusion statement:***

The study population was recruited across seven NHS England sites, covering a wide geographical region encompassing a diverse mix of socioeconomic and racial groups, with equal gender distribution. The author group includes individuals from all aspects of the study, from research nurses and academics to statisticians and surgeons. Participant's accessibility needs were accounted and provided for where possible in the study visits.

**Results:**

Baseline data, details of the interventions, and short-term results of the FAIT trial have been reported previously(10). 222 participants were recruited between 24 May 2013 and 30 September 2016, and there was a statistically and clinically significant benefit of arthroscopy over physiotherapy in the HOS ADL eight months post-randomisation. Superiority of arthroscopy over physiotherapy was confirmed also in secondary PROMS. Data for the 38-month follow-up were collected between September 2016 and November 2019.

Figure 1 presents the CONSORT flow chart for the study. 222 participants were included in the trial, 112 in the arthroscopy arm, 110 in the physiotherapy arm. Radiographic data, including the primary endpoint (semi-automated mJSW), were available for 101 participants at 38 months (45%) (n=53 (47%) in arthroscopy arm and n=48 (44%) in physiotherapy arm) HOS ADL and MRI data were available for 77% and 62% of randomised participants, respectively. Supplementary tables 1 to 3 detail data availability for all outcome measures at each timepoint.

During the trial follow-up, six participants in the arthroscopy arm received further arthroscopy, one participant received a Total Hip Arthroplasty (THA), and 22 participants received intra-articular hip injections. In the physiotherapy arm, 43 participants received arthroscopies after 8 months, 7 underwent THA, and 26 received intra-articular hip injections (Figure 1). Appointments for pain and stiffness were recorded for 23 and 30 participants in the arthroscopy and physiotherapy arm respectively (37 and 43 visits). Other unscheduled events are reported in supplementary table 4.

***Radiological findings:***

The primary outcome, mJSW at the final trial follow-up, did not show statistical significance between groups (arthroscopy group (mean (SD)) (3.40 (0.91)) compared to the physiotherapy group (3.36 (0.84)); adjusted mean difference of 0.17, p=0.152). Only in the sensitivity analysis when using imputation of missing mJSW of 0 for participants who had missing outcomes after receiving a THA at any point was mJSW significantly higher in the arthroscopy group (mean (SD) 3.34 (1.01)) compared to the physiotherapy group (2.99 (1.33)); adjusted mean difference of 0.48, p=0.017. (Table 1)

Other radiographic outcomes did not show statistically significant differences between treatment arms. (Supplementary table 5). The KL grading was also comparable between groups at each time point, further suggesting no radiographic difference between groups. (Supplementary table 9)

22% of participants in the arthroscopy arm, and 7% in the physiotherapy arm showed improvement in mJSW greater than the MCID of 0.5mm. 24% of participants in the arthroscopy arm, and 44% in the physiotherapy arm showed deterioration in mJSW greater than the MCID. (Supplementary table 6)

The total SHOMRI score was significantly lower in the arthroscopy arm with a score of 9.22 (11.43), compared to the physiotherapy arm, where the score was estimated to be 22.76 (15.26) at 38 months, with a difference of -15.94 (-18.69, -13.19), p-value < 0.001 (Table 2). The categorical SHOMRI data followed a similar pattern where mean cartilage, labrum, bone marrow oedema, and subchondral cyst scores at 38 months were significantly lower in the arthroscopy arm (3.99 (5.93), 2.96 (3.64), 1.19 (2.76), and 0.94 (2.50) respectively) than in the physiotherapy arm (9.34 (7.14), 4.31 (2.61), 4.67 (4.90), and 3.74 (4.17) respectively), P<0.001 for all comparisons. (Supplementary table 7)

***Patient Reported Outcome Measures:***

Difference between groups for the HOS ADL remained statistically significant throughout the duration of follow-up; outcomes at 38 months were 84.2 (17.4) and 74.2 (21.9) in the arthroscopy and physiotherapy arms, respectively, with the adjusted mean difference estimated as 8.9 (95% CI 7.0, 10.8, p-value < 0.001) (Table3). Other PROMs outcomes showed similar effects, except for the HAGOS symptoms, HAGOS pain, HADS anxiety, EQ-5D VAS, where differences were not statistically significant at all time points (Supplementary table 8).

67% of participants in the arthroscopy arm, and 48% in the physiotherapy arm displayed improvement in HOS ADL greater than the MCID of 9 points. 9% of participants in the arthroscopy arm, and 20% in the physiotherapy arm displayed deterioration in HOS ADL greater than the MCID. (Supplementary Table 6).

Sensitivity analyses adding baseline HOS-ADL scores to the analysis models for x-ray, SHOMRI, and PROMs data resulted in only negligible changes in the point estimates and CIs.

No serious adverse events were reported during the follow-up.

## Discussion:

### *Principal findings:*

This trial demonstrates that the statistically superior symptomatic improvement in the HOS-ADL score provided by surgery compared with physiotherapy in the treatment of patients with FAI syndrome at eight months is sustained at three years post-randomisation. However, the point estimate of the difference falls below the threshold set for clinical importance in the sample size calculation. The confidence interval includes the clinical important difference, and therefore it is uncertain if this difference in outcome between the groups equates to a therapeutic benefit.

There were high rates for missing date for radiographic outcomes. The between group differences in mJSW fell consistently below the threshold pre-specified for clinical importance (0.5 mm). Confidence intervals included the clinically important difference, reflecting uncertainty around the benefit of surgery versus physiotherapy. Differences in favour of surgery were only observed when individuals who underwent total hip replacement were assumed to develop a mJSW of 0mm. The statistical significance of MRI findings in this study suggests individuals treated with surgery may experience less joint degeneration than those treated with physiotherapy, however the clinical significance of this difference remains uncertain.

### *Imaging findings:*

*mJSW:*

The smallest detectable difference for JSW is 0.21mm(25) and a reduction in mJSW greater than or equal to 0.50mm at any location is thought to be clinically relevant(17, 18). 24% of participants in the arthroscopy arm, and 44% in the physiotherapy arm showed clinically significant deterioration in mJSW greater than 0.50mm. However, the difference in mJSW between groups failed to reach statistical significance in the primary analysis. Statistical significance was only found between groups (p=0.017) when the analysis included patients who had progressed to THA at any point, when it was assumed mJSW was 0mm (K-L 4). However, with a treatment effect of 0.48mm this still failed to reach the clinically relevant threshold.

The most statistically and clinically appropriate way to handle missing data from patients who have undergone THA remains uncertain. Inclusion or exclusion of these patients, and how missing data is handled, in the analysis may bias results. Full thickness cartilage loss is perhaps the primary indication for THA within the NHS where this trial was conducted, hence our decision to assume mJSW=0mm. However, there are a number of other indications for THA where mJSW may be

preserved, such as focal cartilage pathology. Moreover, global practices for indication to proceed to THA may be more heavily focussed on symptoms rather than mJSW. Our assumptions, therefore, may not remain valid within other healthcare systems. We hope that presenting different ways of handling missing data from THA may help inform any decision making in future trials that may encounter the same issues.

*SHOMRI score:*

Differences in measures of OA severity between groups were identified on MRI. The SHOMRI score showed there was more progressive joint degeneration in the physiotherapy group than the arthroscopy group. The total SHOMRI score demonstrated a treatment effect of 15.94 in favour of hip arthroscopy ($p<0.001$), with significantly less articular cartilage damage at 38 months post intervention (TE 6.13, $p>0.001$). There was also significantly less bone marrow oedema and subchondral cyst formation in the arthroscopy group. Although the difference between groups is statistically significant, its clinical relevance remains unclear as the MCID of the SHOMRI score is yet to be established. Indeed, the physiotherapy group displayed improved PROM scores despite a worsening SHOMRI score over time. It may be that the improvement seen in some categorical SHOMRI scores over time may reflect measurement error rather than the outcome from intervention. Alternatively, the worsening SHOMRI score in the physiotherapy group may reflect sub-clinical levels of disease progression or new pathology that is yet to become symptomatic or reflect MRI appearances following arthroscopy rather than underlying pathology (14). It is worth noting that of the 68 participants with valid data for the total SHOMRI score at 38 months, 34 (50%) had a hip arthroscopy after 8 months into the trial, which may also explain this finding. Longer term follow-up of this cohort, possibly in conjunction with compositional MRI analysis, is necessary.

*Disease Progression:*

Although there was a six times higher likelihood of receiving a hip replacement in the physiotherapy group within the follow-up period the absolute number of individuals undergoing THA within the study remained small. Seven participants (6%) in the physiotherapy group received a total hip replacement at a median of 38 months post intervention (range 14-57months). One participant (0.9%) in the arthroscopy group underwent a total hip replacement at 29 months post intervention. A substantial proportion (39%) of patients in the physiotherapy group received a hip arthroscopy after the initial primary end point. Cross-over was not permitted before the primary end point. The late cross-over may reflect a proportion of the patients in the physiotherapy group continued to experience symptoms. Five percent (n=6) of the patients in the arthroscopy group received a second

hip arthroscopy within 36 months of randomisation due to continued pain or recurrent symptoms. Although these observations may suggest differences in disease progression between arthroscopy and physiotherapy arms, the study was not powered to detect this difference between groups based on these outcomes. We are therefore unable to extrapolate these findings to suggest surgery has a disease modifying effect.

The effect of both arthroscopy and physiotherapy in terms of preventing or slowing OA progression on imaging, and in progression to arthroplasty within three years, remains inconclusive. The differences observed between groups may not be sufficiently robust to conclude that there is disease modifying potential of either intervention at present. Longer-term follow-up pooled across different studies are required. The more convincing difference between groups seen in the SHOMRI score over mJSW suggests that only early OA changes are observed at this timepoint post-intervention

***Patient Reported Outcome Measures:***

Individuals randomised to surgery reported greater improvement in HOS ADL compared to physiotherapy, with a treatment effect of 8.9 points between groups ($p<0.001$) (95% CI 7.0 - 10.8). We reported a 10 point difference between groups at 8 months post randomisation(10). Within the individual, 67% of patients randomised to arthroscopic hip surgery and 48% of patients randomised to physiotherapy reported an improvement in HOS ADL that exceeded the MCID of 9 points at 38 months post randomisation. At 8 months post randomisation the values were 51% and 32% respectively(10), suggesting continued symptomatic improvement in both groups over time.

***Comparison with Other Studies:***

No high quality data exist on the effect of interventions on OA progression in FAI syndrome. The Australian Fashion Trial compared the effect of hip arthroscopy and physiotherapy on changes in joint soft tissue quality and morphology over time using delayed Gadolinium Enhanced Magnetic Resonance Imaging of Cartilage (dGEMRIC) and the Hip Osteoarthritis MRI Scoring system (HOAMS)(14). They found no difference between hip arthroscopy and physiotherapy in cartilage quality at 12 months post-intervention with dGEMRIC imaging. However, their morphological semi-quantitative MRI findings using the HOAMS score suggested significantly greater deterioration in soft tissue morphology in the arthroscopy group at 12 months compared with physiotherapy. This contrasts with our SHOMRI score morphological findings which suggest significantly greater soft tissue deterioration in the physiotherapy group at 38 months (supplementary table 6). The difference in findings between studies may be explained by difference in population, cohort size, or

follow-up period. However, it is worth noting that three different compositional and morphological MRI assessments of soft tissue across the two studies provided three different conclusions with regards to effect of intervention on soft tissue deterioration. This suggests the choice of MRI scoring system to quantitatively assess joint soft tissue may significantly impact results. It remains unclear whether features of soft tissue deterioration used in MRI scoring systems can improve over time, and the criteria used in these scoring systems for clinical trials of disease modifying treatments still needs to be defined (26).

Previous cohort studies have shown an improvement in short-term outcomes with both arthroscopic hip surgery(27, 28) and physiotherapy(29). Published RCTs have only reported outcomes up to 12 months follow-up(30), with on-going trials aiming to report at two years follow-up(31). To our knowledge, this is the first trial to report medium term outcomes at three years.

***Strengths and limitations:***

One of the major strengths of this study is recruitment from different hospital settings, comprising District General and University Teaching Hospitals. Care was delivered by surgeons performing a high volume of arthroscopic hip procedures, ensuring reproducible outcomes with lower complication rates(32, 33).

A significant limitation of this study is the high loss to follow-up experienced. The most common reasons given were work commitments, moving out of area and no available time, likely reflecting a younger, more mobile population. However, 38 month follow--up is the longest of controlled trials investigating the management of FAI syndrome reported in the literature. Our findings may be subject to bias from missing data, and we have presented comprehensive sensitivity analyses to explore how varying assumptions about the missing data mechanism may have affected the trial results, and put point estimates and corresponding CIs into the context of the minimal important clinical differences pre-specified in the sample size estimation. We also report high cross-over rates, with 39% of individuals randomised to physiotherapy undergoing hip arthroscopy after the initial primary endpoint. For this reason, we also performed per-protocol analyses (see supplementary data) to assess how groups would compare when only considering participants who received their allocated treatment within the first 8 months of the trial. Point estimates in these scenarios increased slightly in magnitude, but only reached clinical importance in the scenario making the strongest assumptions about missing data.

Major limitations exist with regards to the imaging outcome measures used in this study. We chose mJSW as our primary outcome measure of radiographic progression of OA as it remains the only

structural end-point accepted by the European Medicines Agency and Food and Drug Administration to prove efficacy of disease-modifying osteoarthritis drugs(34). It is also offers a more sensitive and reliable scoring system that those proposed by Kellgren and Lawrence((35) and OARSI(36, 37). However, a significant limitation of this measure is that it lacks the sensitivity to diagnose localised or early disease that is achievable through MRI(38-42). Moreover, the 3 year follow-up period reported in this paper may be too short to adequately assess OA disease progression radiographically. Further limitations also exist with regards to how to handle missing data, as discussed earlier. It is for this reason that we also chose the SHOMRI score, which has been found to be highly reproducible and correlate significantly with established clinical and radiographic markers of hip OA(16).

The physiotherapy intervention in this trial was designed to reflect what was feasible in NHS practice (maximum of eight sessions over a five-month period). This intervention does not necessarily reflect best practice, which may have influenced patient outcomes. Furthermore, it is unclear if physiotherapy patients received maintenance exercise rehabilitation (either physiotherapist-led or as a home programme). It is recognised that not maintaining or adhering to a physiotherapy programme can significantly affect outcomes(43).

***Clinical implications:***

This trial and others(30) have demonstrated the clinical benefit of hip arthroscopy and physiotherapy in improving symptoms in FAI syndrome. Our results are inconclusive as to whether hip arthroscopy may confer disease-modifying potential. Clinicians must interpret these findings with caution due to the high loss to follow-up and uncertainty as to the clinical relevance of the imaging results. The decision to intervene surgically should be based on the goal of symptomatic improvement rather than the prevention or delay in development of OA. Further long-term trials and registry data are required.

***Conclusions:***

In this trial, arthroscopic surgery compared with physiotherapy provides superior symptomatic relief in patients with FAI syndrome up to three years post intervention. It is unclear if patients with FAI syndrome treated surgically also experience a delay in the development or progression of osteoarthritis on imaging. MRI measures demonstrated a difference in the rate of OA progression between groups but it is unclear if this progression is of clinical relevance. Further evidence of disease modifying potential is required to recommend changes to current clinical practice.

***Oversight Committees:***

Trial Steering Committee: Mr Oliver Pearce (Consultant Orthopaedic Surgeon, Milton Keynes University Hospital NHS Foundation Trust), Mr Timothy Theologis (Consultant Orthopaedic Surgeon, Oxford University Hospitals NHS Foundation Trust), Mr Sunil Auplish (Consultant Orthopaedic Surgeon, Barking, Havering and Redbridge University Hospitals NHS Trust). Data Monitoring Committee: Dr Karen Smith (Principal Statistician, NIHR Research Design Services, University of Leicester), Mr Muthu Ganapathi (Consultant Orthopaedic Surgeon, NHS Wales University Health Board). Mr Peter Lovell (Lay Representative).

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**Competing Interests:**

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare support from Arthritis Research UK and NIHR Oxford Biomedical Research Centre for the submitted work. There was independence between the researchers and funders. Unrelated to the submitted work, VK received support from Stryker and Smith and Nephew for educational consultancy, AA received support from Stryker, Smith and Nephew, and Zimmer Biomet for lectures, and SGJ received research grants and fees for lectures from Zimmer Biomet, Corin, and ConMed, and research grants from Neurotechnics, Johnson and Johnson, and Siemens.

**Contributors:**

AJRP and SGJ designed the study and the protocol was developed with VAG, IR, SJD, SW, TCBP, AWM, KLB, AJMDA, AJC, and DJB. IR and SJD performed the statistical analyses. AJRP, VAG, SF, RM, SW, VK, TCBP, AJMDA, and SGJ recruited patients and acquired data. AJRP, VAG, SF, IR, and SGJ drafted the manuscript. All authors revised manuscript drafts, approved the final manuscript, and contributed intellectually important content. SGJ attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. SGJ is the guarantor of the paper and takes responsibility for the integrity of the work from inception to published article.



**Data sharing**:

Anonymised patient level data can be made available on reasonable request after approval from the trial management committee and after signing a data access agreement. Proposals should be directed to the corresponding author. Consent was not obtained for data sharing but the presented data is anonymised and the risk of identification is low.

**Transparency:**

The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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Figure 1. Consort Flow Diagram

*[%]5 participants commenced but did not complete their physiotherapy programme.*

*[$]Six participants started but did not complete their physiotherapy and received arthroscopies within 8 months from randomisation. One participant withdrew from their randomised intervention before commencing physiotherapy and received an arthroscopy within eight months of randomisation.*

*[+]Four participants received their trial arthroscopy within the first 8 months from randomisation and had a subsequent arthroscopy (revision) recorded during the trial follow-up. One participant had two subsequent arthroscopies (revisions) recorded after their 8 months follow-up. One participant did not receive their randomised arthroscopy during the first 8 months from randomisation but received the procedure later on. They had initially withdrawn from the trial intervention.*

*[%]One participant had a second (revision) arthroplasty. Three participants had two arthroplasties (revisions) reported over the follow-up. The remaining 39 participants had their first arthroplasty after 8 months post randomisation.*

***Injections are reported for any time during the trial follow-up*

**imaging data were collected for up to 66 months post randomisation, PROMs data for up to 72 moths post randomisation*

**TABLE 1:** SEMI-AUTOMATED MINIMUM JOINT SPACE WIDTH ON ANTEROPOSTERIOR RADIOGRAPH AT 38 MONTHS

| | Arthroscopy (n=112) | | Physiotherapy (n=110) | | Treatment effect | |
|---|---|---|---|---|---|---|
| | n | mean (sd) | n | mean (sd) | Mean difference (95% CI) | p |
| **SEMI-AUTOMATED MINIMUM JOINT SPACE WIDTH ON ANTEROPOSTERIOR RADIOGRAPH (EXCLUDING INDIVIDUALS WHO UNDERWENT THA)** | | | | | | |
| **Baseline** | 105 | 3.53 (0.73) | 105 | 3.63 (0.75) | | |
| **14 months** | 67 | 3.60 (0.79) | 61 | 3.63 (0.72) | 0.06 (0.00, 0.12) | 0.035 |
| **26 months** | 8 | 3.08 (1.07) | 15 | 3.52 (0.70) | | |
| **38 months** | 53 | 3.40 (0.91) | 48 | 3.36 (0.84) | 0.17 (-0.06, 0.41) | 0.152 |
| **SEMI-AUTOMATED MINIMUM JOINT SPACE WIDTH ON ANTEROPOSTERIOR RADIOGRAPH (WITH 0 IMPUTED FOR PARTICIPIANTS WITH MISSING DATA WHO HAD A THR AT ANY POINT)** | | | | | | |
| **Baseline** | 105 | 3.53 (0.73) | 105 | 3.63 (0.75) | | |
| **14 months** | 67 | 3.60 (0.79) | 61 | 3.63 (0.72) | 0.08 (0.02, 0.13) | 0.005 |
| **26 months** | 8 | 3.08 (1.07) | 16 | 3.30 (1.11) | | |
| **38 months** | 54 | 3.34 (1.01) | 54 | 2.99 (1.33) | 0.48 (0.09, 0.88) | 0.017 |

*Note: outcome data for the 26-month time point were not included in the analysis model due to the sparsity of data available at this follow-up.*

*JSW is given in mm.*

*Multilevel mixed effects models were used to account for repeated observations per participant. Models were adjusted for randomisation factors (age, gender, clustering by site was accounted for using robust standard errors).*

*The minimal clinically important difference for the minimum joint space width was defined as 0.5mm, as specified in the published protocol(14).*

**TABLE 2: RESULTS FOR THE TOTAL SHOMRI SCORE DATA – CONTINUOUS SUBSCALES**

| | Arthroscopy (n=112) | | Physiotherapy (n=110) | | Treatment effect | |
|---|---|---|---|---|---|---|
| | **n** | **mean (sd)** | **n** | **mean (sd)** | **Mean difference (95% CI)** | **p-value** |
| **Baseline** | 90 | 7.01 (5.88) | 90 | 5.72 (5.33) | | |
| **8 months** | 73 | 6.74 (8.65) | 75 | 9.84 (7.73) | -4.70 (-5.25, -4.15) | <0.001 |
| **14 months** | 35 | 12.54 (8.99) | 32 | 15.34 (11.23) | -3.88 (-5.32, -2.45) | <0.001 |
| **26 months** | 8 | 15.13 (5.06) | 12 | 21.00 (12.02) | | |
| **38 months** | 65 | 9.22 (11.43) | 68 | 22.76 (15.26) | -15.94 (-18.69, -13.19) | <0.001 |

*Note: outcome data for the 26-month time point were not included in the analysis model due to the sparsity of data available at this follow-up.*

*Total SHOMRI score calculated as sum of all components.*

*Articular cartilage considered the outcome of main importance.*

**TABLE 3: RESULTS FOR THE HOS ADL DATA**

| | Arthroscopy (n=112) | | Physiotherapy (n=110) | | Treatment effect | |
|---|---|---|---|---|---|---|
| | **n** | **mean (sd)** | **n** | **mean (sd)** | **mean difference (95% CI)** | **p-value** |
| **Baseline** | 112 | 66.1 (18.5) | 110 | 65.7 (18.9) | | |
| **5 months** | 84 | 77.7 (18.7) | 79 | 68.4 (21.0) | 11.1 (6.7, 15.6) | <0.001 |
| **8 months** | 103 | 80.3 (19.2) | 90 | 68.8 (19.7) | 11.8 (8.0, 15.7) | <0.001 |
| **11 months** | 72 | 82.2 (19.7) | 69 | 71.2 (19.6) | 11.5 (8.2, 14.8) | <0.001 |
| **14 months** | 77 | 80.6 (19.2) | 76 | 67.8 (21.9) | 13.5 (10.9, 16.0) | <0.001 |
| **20 months** | 57 | 84.8 (17.1) | 44 | 71.7 (21.3) | 12.4 (8.9, 16.0) | <0.001 |
| **26 months** | 45 | 82.3 (22.9) | 46 | 79.6 (18.0) | 6.3 (2.3, 10.3) | 0.002 |
| **32 months** | 37 | 83.6 (17.5) | 36 | 72.8 (21.1) | 9.3 (4.2, 14.5) | <0.001 |
| **38 months** | 86 | 84.2 (17.4) | 85 | 74.2 (21.9) | 8.9 (7.0, 10.8) | <0.001 |