

Randomized Controlled Trial of Hip Arthroscopy Surgery vs Physical Therapy: Letter to the Editor

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Dear Editor:

We read with great interest the recent article published in *AJSM* by Mansell et al titled “Arthroscopic Surgery or Physical Therapy for Patients With Femoroacetabular Impingement Syndrome: A Randomized Controlled Trial With 2-Year Follow-up.”⁹ This trial is one of several ongoing randomized controlled trials (RCTs) on this well-deserving topic. The authors should be congratulated for performing an RCT of this nature to attempt to answer this important question. However, we have a number of concerns regarding the authors’ methods, results, and conclusions, and the potential for readers to misinterpret the presented results. These major concerns include (1) a high rate of crossover, (2) a significantly underpowered “as treated” analysis, (3) very small improvements in patient-reported outcomes (PRO) after surgery (which is inconsistent with the previous peer-reviewed literature), and (4) inclusion of patients with less than 2 years of follow-up in the primary analysis.

RCTs represent the highest level of evidence given their ability to limit the effect of bias. However, RCTs are not immune to the effect of bias. In fact, some RCTs of lesser quality or with less than 80% follow-up are better classified as level 2 evidence according to the Centre for Evidence-Based Medicine (CEBM) guidelines followed by *AJSM*. One major source of bias in RCTs is patient crossover, which has the potential to obscure the effect of an intervention. While some patient crossover is unavoidable, efforts to minimize crossover in an RCT are important. Intention-to-treat analyses are commonly used to counteract the effects of patient crossover but become invalid in the setting of excessive patient crossover. While no exact threshold of crossover percentage that invalidates a trial is known, with a 0% crossover being theoretically ideal and a 100% crossover rate completely invalidating a trial, the CEBM suggests a “rate of greater than 20% is a rough guide to the number that may invalidate the final results.” The 70% rate of crossover in the current study, with patients crossing over on average less than 3 months after their surgical counterparts, is concerning and should be interpreted as a “fatal flaw” of the study. The outcomes of the physical therapy (PT) group in this study are heavily dependent on the outcomes (at all time points) of the majority of patients ultimately having surgery. This results in a comparison of a group in which 95% had

surgery to a group where 70% had surgery. This is an unfortunate result of the current study design and setting. Other similar studies have made efforts to limit early crossover in this setting.² The crossover rate of this study alone confounds the data and limits the reader’s ability to draw any significant conclusions. As a comparison, the METEOR RCT comparing arthroscopic partial meniscectomy to PT was criticized for a high rate of crossover (27%).⁵ The authors and reviewers of the study concluded that the lack of difference between the 2 groups in the setting of this crossover “suggest that an initial course of rigorous PT ... may not compromise surgical outcome.” This conclusion is perhaps better suited to the current study.

Second, after crossover and loss to follow-up, only 11 patients remained in the PT group (compared to 63 for surgery). No data are provided to better understand if deterioration, no change, or another factor was the reason for crossover, which occurred on average less than 3 months after the surgical group, after the patients have evaluated their improvement after PT. The authors did perform an “as treated” or sensitivity analysis, in addition to the intention-to-treat analysis, and stated it “did not change the outcome” with no mention of the power of this comparison. However, in the “as treated” analysis, the advantages of the RCT are lost at this point, as shown in the significantly different characteristics of the patient groups (as seen in pain chronicity 62% vs 14%; no *P* value noted). In a trial comparing surgery and PT, the inclusion of patients from the surgery group (*n* = 2) who did not undergo surgery in the comparison group also doesn’t seem appropriate because they did not cross over to the structured PT group but rather had no intervention at all. With only 11 patients remaining in the actual PT group (35% of the number of patients needed based on power analysis), the study is at a high risk of type II error. Detailed assessment of the cohorts by established minimal clinically important difference (MCID) standards is not well reported in the current study; instead, the authors rely on the global rating of change (GRC) assessment tool. Most studies currently favor use of MCID change in PROs for assessing change due to the potential recall bias of GRC in remembering a health state several years prior.³ While “no statistically significant difference between the surgery and no surgery groups” was present, the surgery group demonstrated a significant increase in Hip Outcome Score (HOS) activities of daily living (ADLs), while a negative nonsignificant trend was present in the no surgery group. The results of this underpowered analysis are better described as “not finding a statistical difference” rather than “there being no difference” between the 2 groups.

The external validity of RCTs is an additional important factor for the reader. In the current study, the single surgeon and military setting of the study should be considered. The military population has unique issues and challenges and is similar to a workers’ compensation population. The use of narcotic pain medication in both cohorts for an average of 16 months is concerning and not typical of most femoroacetabular impingement (FAI) patients. The PROs after surgery in this study are low compared with the multiple published reports on hip arthroscopy for FAI

syndrome. A recent systematic review of level 3 and 4 studies demonstrated mean improvements in the HOS-ADL of 23.6 and HOS-Sport of 41.3, with similar trends for the modified Harris Hip Score and the International Hip Outcome Tool (iHOT).^{7,12} This study reports improvements of 7.4 (HOS-ADL), 4.7 (HOS-Sport), and 20.9 (iHOT). Numerous authors have reported that hip arthroscopy provides lasting and MCID improvements in high-demand professional athletes.^{1,6,10,13-15} Furthermore, improvements after hip arthroscopy have lasted beyond 2 years, and recent studies have reported sustained improvements in outcomes at 5 and 10 years after hip arthroscopy.^{2,4,11} The low PROs in the surgical group and high complication and revision rates (8.2%) are concerning regarding the quality of the surgical intervention in this study because these outcomes are not consistent with the results of other studies on the effectiveness of hip arthroscopy for FAI. A variety of surgeon and patient factors likely play a role in patient outcomes after FAI surgery, including technical expertise/experience, treatment decisions (labral repair vs debridement, capsulotomy vs capsular closure, adequacy of FAI correction), and intraoperative findings (acetabular cartilage damage). The current study fails to provide information on any of these aspects. In addition, the reported 10.8% rate of osteoarthritis at 2 years after surgery in this study is very concerning. Future multicenter studies including RCTs will perhaps provide more generalizable results.

The authors' prior publication of the protocol for the RCT should be applauded and sets the stage for the eventual results of the study.⁸ It outlines the primary outcomes and time points for the study analysis and documents inclusion of patients with an alpha angle greater than 50° or a crossover sign on plain radiographs, as well as a minimum joint space width greater than 2 mm. In the "Results" section of the current study, no data regarding the pre- or postintervention radiographic outcomes or surgical observations are reported. Furthermore, the authors indicate that patients with only 1-year (or even 6-month) outcome data (missing 2-year data) were included in the primary analysis, with advanced statistical techniques used to accommodate for data assumed to be missing at random. This change is not apparent in the title, abstract, methods, or discussion of this RCT "with 2-year follow-up." This change in methodology increases the follow-up rate from 77.5% to 92.5%, but the exact reason for this alteration is not discussed. At multiple points in the article, it is apparent that PROs "at 2 years" are in fact not the case.

We again applaud the authors on their efforts to perform the RCT but feel that clarification of the above aspects of the study is important for its proper interpretation within the sports medicine community and beyond.

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Randomized Controlled Trial of Hip Arthroscopy Surgery vs Physical Therapy: Response

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Authors' Response:

There is much yet to learn about the ideal management for femoroacetabular impingement (FAI) syndrome, and engaged discussion by all stakeholders is extremely important to this progress. Therefore, we are grateful for the concerns raised by Dr Faucett and the other 43 physicians and the physical therapist listed on the recent letter to the editor regarding our clinical trial comparing surgery to physical therapy for FAI syndrome.⁴ In the words of Thomas Paine, "It is error only, and not truth, that shrinks from inquiry."

We fully agree that there are limitations to this study and had sincere attempts to display full transparency of these limitations in our report. Most of the points brought up in the letter to the editor were also ones we outlined and discussed as limitations. We would like to address the 4 major concerns, as we also feel they are and should be valid concerns for readers:

(1) A high rate of crossover and (2) a significantly underpowered "as treated" analysis: The CONSORT statement for reporting clinical trials,⁷ endorsed by *AJSM*, and the critical appraisal checklist for clinical trials from the Centre for Evidence-Based Medicine recommend that high-quality trials should analyze subjects according to original randomization (intention to treat). Crossover is not unique to these types of trials,^{2,12} and a continued challenge is having patients believe that either treatment is truly equitable, especially after spending time with the surgeon discussing a mechanism that lends itself well to a surgical explanation. The possibility of not having surgery was the primary reason patients turned down enrollment in our study. We very much agree that these are problems (devoted first 2 paragraphs of the "Discussion" and again in the "Limitations" section to these issues).

(3) Very small improvements in patient-reported outcomes (PROs) after surgery (which is inconsistent with the previous peer-reviewed literature): We were also surprised by these findings. Certainly, part of this could have been a single-surgeon issue with perhaps less experience, as other published data indicate that outcomes improve with more experienced surgeons.⁵ The surgeon for our study is sports fellowship trained, with a 50% hip arthroscopy practice, and estimates that the subjects in our trial fell somewhere between 100 and 230 of his current count of 650. The military population is definitely unique. Despite being military service members, they are not the equivalent to athletes studied in other settings. In some cases, showing recovery is believed to be associated with loss of potential disability benefits and could influence outcomes.⁶ However, randomized clinical trials, specifically those that are high quality and pragmatic (multiple surgeons and multiple rehabilitation clinics), allowing for potentially high rates of crossover, are essential specifically because we do not have conclusive evidence about the outcomes for this condition. A recent scoping review of surgery for FAI syndrome that included 163 studies (14,824 subjects) concluded that "current surgical outcomes are limited to midterm surgical follow-up time frames and inconsistent outcome reporting."⁸ The most recent Cochrane review concludes that "there is no high quality evidence examining the effectiveness of surgery for femoroacetabular impingement,"¹¹ meaning we are limited to mostly observational research or trials comparing one type of surgery to another. There is also low- to moderate-quality evidence showing that physical therapy is effective,^{1,13} and our results would also be inconsistent with those findings. Ultimately, unexpected findings should provide an opportunity to learn something profound, rather than be disregarded because they are not what was expected. They are a good reminder that there is still a lot we do not know about who benefits most from surgery and what optimal rehabilitation before surgery, or instead of surgery, should look like.

(4) Inclusion of patients with less than 2-year follow-up in the primary analysis: All subjects were followed from enrollment at baseline out to 2 years. Because the mean time from enrollment to surgery was 5.5 months (4.4 for those assigned to surgery), outcomes at 2 years for surgical patients reflect data 18 to 19 months from the actual surgery date. This does not mean that the patients were not followed for 2 years. Of those on active duty, 45.8% were no longer in military service at 2 years, and 24 (33%) of these left specifically because they were medically discharged from military service due to their hips. In light of mobilization rates, training, and common changes in duty station, which make it challenging to track down patients, our 78% follow-up for outcomes at 2 years was fairly remarkable.

In the end, we must acknowledge that there is much still to be learned about optimal management for FAI syndrome. Some patients in both groups had excellent outcomes

(with surgery and without surgery), and we believe that there could be an appropriate role for both surgery and physical therapy in the appropriate patient. But that is where the devil more likely lies, in determining which patient is best for each clinical pathway. Efficacy trials attempt to understand how an intervention works, while pragmatic trials attempt to understand if it will work under normal conditions.¹⁰ Many efficacy trials exist, often well-controlled and with very specific subject selection. However, when replication is attempted in regular, uncontrolled settings of daily clinical practice, the results are not always the same.³ Unfortunately, our study does not conclusively answer the question about effectiveness of arthroscopy or physical therapy, and it may very well be that these results are unique to our military setting (as stated in our “Limitations” section). The good news is that an arthroscopy versus sham surgery trial is currently in progress,⁹ and 2 other much larger registered trials comparing surgery to nonsurgical management for FAI syndrome have reportedly been completed. The very near future should better elucidate how similar or distant our findings were compared to other settings and raise new opportunities to learn more about these patients.

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