Study Title: Postoperative Hip Bracing After Hip Arthroscopy

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RESEARCH PLAN

Abbreviations: FAIS – femoroacetabular impingement syndrome, IPT – iliopsoas tendonitis, NPRS – numerical pain ranking scale, HOOS-P – Hip disability and Osteoarthritis Outcome Score (Pain Subscale), PI – principal investigator

Global Hypothesis: Postoperative hip braces reduce patient pain and improve hip function after arthroscopic osteoplasty and labral repair for FAIS.

AIM 1, Primary goal: **To test whether postoperative hip bracing affects patient NPRS scores in the first 6 weeks after arthroscopic surgery for FAIS.** We will randomize 3-week continuous use of a postoperative hip brace (**Fig 1**) in patients who undergo arthroscopic surgery for FAIS. We will compare mean NPRS scores at the 3- and 6-week postoperative visit between groups. We hypothesize that at both time points, the Brace group will have lower mean NPRS scores compared to the No Brace group.

Figure 1

AIM 2, Secondary goals: To test whether postoperative hip bracing affects gait pattern, IPT symptoms, HOOS-P scores, or use of narcotic medication at 6 weeks after surgery. At the 6-week postoperative visit, a blinded investigator will assess patients for antalgic gait in clinic as well as for IPT signs through four established tests: 1) resisted seated hip flexion, 2) Stinchfield test, 3) psoas stretch test, and 4) hip flexor tenderness to palpation[1]. We will compare the rate of the antalgic gait pattern and flexor symptoms between groups. We will compare patient reported HOOS-P scores and the rate of narcotic prescription refills between Brace and No Brace groups. We hypothesize that compared to the No Brace group, the Brace group will have a lower rate of IPT signs, lower rate of antalgic gait, better HOOS-P scores, and lower refill rate of narcotics at 6 weeks postoperatively.

AIM 3, Long term goals: To test whether postoperative hip bracing affects NPRS, HOOS-P scores, IPT symptoms, and use of pain medication at 6-months after surgery. Patients will be followed to determine if the short period of brace wear has lasting effects on recovery after hip arthroscopy for FAIS. We will compare NPRS, IPT, and HOOS-P at 6 months after surgery. We will also compare between groups the rate of topical anti-inflammatory prescription or iliopsoas tendon/bursa cortisone injection within the 6-month postoperative period. We hypothesize that NPRS, IPT and HOOS-P scores will be the same between groups at 6 months postoperatively. We hypothesize that the No Brace group will have a higher rate of topical anti-inflammatory use and IP cortisone injection compared to the Brace group.

Background/Significance

Hip arthroscopy for treatment of FAIS involves reshaping of the osseous sources of impingement ("osteoplasty") and repair of impingement-associated labral tears. It is primarily done in patients under 50 years of age as a method of hip preservation. Diagnoses of FAIS and the incidence of hip arthroscopy have both increased dramatically in the last 20 years in the US[2,3]. In our study using IBM Marketscan to evaluate rates of hip arthroscopic treatment of FAIS, we found this incidence doubled from 1.2 to 2.1 per 100,000 person-years in just a 3-year period[4]. During an arthroscopic procedure for FAIS, the hip joint is subluxated to allow for entry of camera and tools. Pain from muscle soreness from hip distraction is common in the immediate postoperative period[5]. Furthermore, the standard portals for hip arthroscopy enter near or through the hip abductor muscles (gluteus medius & minimus) and this process causes initial abductor inhibition[6]. Postoperatively, patients are at risk to overuse hip flexors in gait and develop IPT[1,6]. Current postoperative hip arthroscopy rehabilitation is centered around muscle recovery and prevention of IPT[7]. Despite the increasing incidence of hip arthroscopy in the US, on a recent review we have found few evidence-based studies on postoperative care[8].

A particular area of debate is the use of postoperative hip braces (**Fig 1**). A survey of 27 high-volume orthopaedic surgeons specializing in hip arthroscopy found that 59% used a postoperative hip brace for an average of 3.4 weeks[9]. Among 31 hip arthroscopy postoperative protocols available online, 55% used a brace for a median of 2 weeks[10]. A survey of 48 surgeons at an international hip arthroscopy conference found that 40% of "expert" surgeons (>500 career hip arthroscopies) used a postoperative brace[11]. Postoperative hip braces are advocated to decrease postoperative pain by offloading hip musculature. They may also prevent overuse of the hip flexors by supporting the hip during gait. Additional cited benefits of postoperative hip braces include assisted normalization of gait in weight bearing[10], protection of capsular closure[7], and reduction in the risk of postoperative hip dislocation (which is low at 0.58%)[12]. However there are no studies looking at efficacy of hip braces after hip arthroscopy[8]. The utility of bracing is important because hip braces are expensive (averaging $350-$600):

if there are over 7000 hip arthroscopies performed nationwide and 50% of surgeons use hip braces, this amounts to over $2,000,000. We aim to test the cited benefits of postoperative hip bracing through NPRS pain scores, HOOS pain scores, use of pain medication, specific tests for IPT, and gait observation.

Approach

The proposed study design is an intent-to-treat, single-blind randomized controlled trial for treatment superiority. Inclusion criteria include any patient aged 14-60 at Husky Stadium Sports Medicine Center who is scheduled to undergo arthroscopic osteoplasty and labral repair for FAIS. We will exclude anyone who cannot follow up in our clinic for their 3- and 6-week postoperative visits. We will also exclude any patient with planned iliopsoas tendon release for tendonitis at the time of surgery. See **Fig 2** for flow chart of patient enrollment, treatment arms, and assessment.

The randomization sequence will be created in Excel with 1:1 allocation using random block sizes by an independent physician (co-investigator), and then assigned to patients in opaque, tamperproof envelopes with key stored in secure location by the co-investigator and unknown to the PI. The patients assigned to the Brace group will receive a standard postoperative hip brace at their preoperative visit with the Physician Assistant, billed to the Research Account (~$290/brace). Patients in the Brace group will be expected to wear their braces at all times for the initial 3-week period except shower and toilet, as per current standard of care. Patients in both groups will be prescribed our standardized physical therapy protocol for arthroscopic hip osteoplasty and labral repair. All data will be stored in a de-identified, secure server maintained by the research coordinator and PI (REDcap). As all patients will have discontinued their braces by the 6-week visit this will be a single-blinded trial; the PI - who will be analyzing patient reported outcome measures and performing each exam at the 6-week visit - will have no knowledge of patient assignment. Any patient care questions will be managed by the Physician Assistant and nursing team so as to ensure no accidental exposure of the PI to a question about bracing.

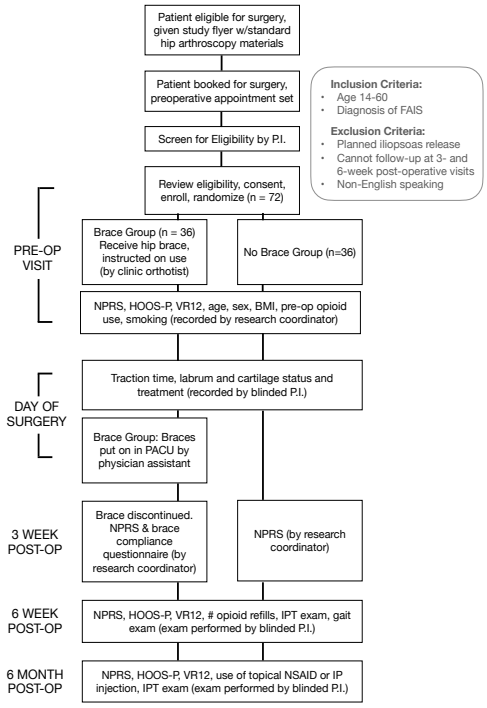

Figure 2. Flow chart of study design

Statistical Analysis, Feasibility, Safety: As short-term NPRS scores are absent in the literature for hip arthroscopy, sample size has been calculated using 2-years of pilot data on 6-week postoperative NPRS scores for FAIS patients (all wore braces) in the PI's practice, demonstrating a mean NPRS of 2.4 (SD 1.7). Given the cost of hip bracing, a treatment effect size of 50% increase in pain in the No Brace group (mean NPRS 1.2 higher) is used with 1:1 enrollment ratio and standard two-sided alpha of 0.05 and beta of 0.20, resulting in a total of 32 patients per group. Assuming a 10% drop out this would be 36 patients per group. Baseline and postoperative data will be compared using Fisher exact test and *t* testing.

The PI is the only provider in the UWMC system who performs hip arthroscopy and in order to contain cost this will be a single-center study. The PI currently performs approximately 50-75 hip arthroscopies for FAIS per year. A pilot feasibility questionnaire was administered to 18 hip patients over a 3-month period with 17/18 (94%) responding favorably to participate in the trial. We expect high follow-up rates at 6 weeks as in the PI's current practice this rate is 94.7% among FAIS patients. We thus anticipate enrollment and 6-week results to be complete within 2 years, with pilot data within 1 year. During the study period we will monitor for any serious adverse effects including hip dislocation, revision surgery, or intractable pain. These will be promptly reported to the IRB and trial sponsor.

Strengths & Weaknesses: This study is innovative as there are no evidence-based reports on bracing after hip arthroscopy. This study is important because of the cost of bracing and frequency of hip arthroscopy. There is excellent equipoise as approximately 50% of surgeons use postoperative hip braces. This study also would add to its field by providing short term postoperative pain data as well as high quality data on incidence of IPT after hip arthroscopy. If the null hypothesis is shown and there are no differences between groups, we could justify disuse of hip braces and reduce societal costs. The most obvious weakness lies in the ability to recruit and meet sample size requirements. In case of poor enrollment, we will use

these data as an internal pilot study, to refine group variability/event rates and expand to a multicenter trial (the PI has already received interest from several academic centers that wish to participate), with hope for extramural funding.

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