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Arthroscopic Labral Repair Versus Physical Therapy for Tears of the Acetabular Labrum

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DETAILED PROTOCOL

Title: Arthroscopic Labral Repair versus Physical Therapy for Tears of the Acetabular Labrum in Patients Age 40 and Older

I. BACKGROUND & SIGNIFICANCE:

Introduction

Tears of the acetabular labrum appear to be common with the prevalence of asymptomatic tears in the general population approaching 66% and 70% based on cadaveric dissection and magnetic resonance imaging, respectively.[1, 2] Despite this prevalence, there is no currently accepted justification for performing labral repair in an asymptomatic patient despite the many postulated biomechanical benefits that an intact labrum imparts to the hip joint.[3-6]

Representing a smaller proportion of all tears, symptomatic tears of the acetabular labrum present a therapeutic challenge. Current treatment modalities range from conservative measures to open surgical intervention. Conservative measures have typically included: activity modification, the use of non-steroidal anti-inflammatory drugs (NSAIDs), physical therapy (PT), core strengthening and improvement of sensory motor control.[7] In the past two decades, technological advances in the form of surgical instrumentation and traction devices have facilitated less invasive arthroscopic techniques to diagnose and treat hip problems and as such is now the preferred treatment modality for many orthopedic surgeons treating patients with hip pathology.[8-10]

Femoroacetabular Impingement (FAI) is a common cause of acetabular labral pathology. Over the past decade hip arthroscopy has become the established modality for treating this entity.[11-13] However, despite the widespread utilization of hip arthroscopy there is a paucity of evidence to validate the use of this procedure over conservative management or other forms of open surgery.[14] Several authors have suggested that while initial studies on the utilization of hip arthroscopy are promising, the current evidence base is lacking.[15] In particular there is a lack of high quality evidence evaluating outcomes for non-operative management of labral pathology.

Physical Therapy

There are only a few reports recommending the routine use of physical therapy in patients with tears of the acetabular labrum.[11,16] In particular, it has been emphasized that physical therapy should focus on improving strength resulting in fewer forces directed on the anterior portion of the hip, the site most commonly afflicted by labral tears[17,18]. Accordingly, there are just as few reports comparing the efficacy of physical therapy versus arthroscopic intervention for management of labral tears.

Two level IV cases series report evidence on the results of conservative management of acetabular labral pathology. Emara et al.[19] report 2-year follow-up data on 37 patients with FAI followed prospectively. These patients were found to have improved hip outcome scores but with much limited activities of daily living and non-improvement in hip motion. Here conservative therapy was defined as intensive physiotherapy, stretching, assessment of range of motion, and determination of problematic motion that patients were advised to avoid. Yazbek et al.[20] report on the non-surgical management of four patients with clinical evidence and magnetic resonance imaging confirmation of an acetabular labrum tear. These patients were managed with NSAIDs for pain control and multiphase physical therapy focusing on improving strength and range of motion. All four patients demonstrated decreased pain as well as functional improvements over a 6-month follow-up period. The authors concluded that patients with clinical evidence of acetabular labral tears could show meaningful improvement with non-surgical intervention.

There has been only one prospective study documenting the outcomes of patients treated with physical therapy for intra-articular conditions of the hip.[21] These conditions included mild FAI and mild developmental dysplasia of the hip. Here, physical therapy was given as a first line treatment. Those who did not make satisfactory improvements in pain or wished to have surgery were then scheduled for surgery to repair the defects. Patients saw improvement in validated outcome measures at one year. The authors attempted to eliminate cases of advanced arthritis based on Tonnis grading (see section IV) scores greater than 2. However, there was no mention of the degree arthritis seen at the time of arthroscopy and the presence of a labral tear due to the aforementioned pathology was not part of the inclusion criteria, rather it was a secondary data point.

Arthritis

Symptomatic, radiographic osteoarthritis (OA) affects over 27 million people in the United States; of this number, a significant proportion are affected by OA in the hip.[22] Additionally, it is well known that older patients presenting with symptomatic labral tears are more likely to have OA. In fact, it is estimated that 25% of the general adult population has some type of cartilage defect.[2] Despite its prevalence the influence of preoperative arthritic changes on surgical outcomes is controversial. A recent systematic review gave a grade Cc recommendation for hip arthroscopy for the treatment of mild to moderate hip arthritis (conflicting).[14] Another systematic review concluded that although some benefit is achieved in arthritic patients, the presence of cartilage defects at the time of surgery results in poorer outcomes than cases with normal cartilage.[23] There is an abundance of discussion in the literature with a specific focus on the influence of pre-existing arthritis on hip arthroscopy outcomes.[24-33] In order to highlight this influence, one group created a Kaplan-Meier survival analysis that showed a high rate of conversion to total hip replacement in patients aged over 50 years old, and within this cohort, patients with less than 2 mm of joint space (radiographic OA) were found to have an increased failure rate.[32]

The distinction between radiographic arthritis and arthroscopically (directly visualized) identified arthritis is important. Several radiologic-surgical correlation studies[34-36] in the knee have shown that direct visualization of joint tissues by arthroscopy is more accurate in diagnosing cartilage loss and meniscal damage, making an arthroscopic exam the gold standard of investigation before definitive treatment planning in the knee.[36] This standard has not yet been achieved in the hip.

A retrospective evaluation of arthroscopically identified arthritis and its influence on outcomes in patients undergoing periacetabular osteotomy, not primary arthroscopic labral repair, has been reported.[37] This study involving 121 patients was able to show that exposed subchondral bone (Outerbridge grade 4 change; see section IV) was predictive of accelerated conversion to total hip arthroplasty. Secondarily, it was postulated that standard radiographs of the hip are poor predictors of actual arthritic lesions due to the amount of arthritic change that was noted at arthroscopy in patients whose preoperative radiographs showed minimal evidence of OA. Furthermore, there has been only a single prospective study evaluating the influence of the degree of arthroscopically identified arthritis, using the Outerbridge scoring system, on validated patient outcomes following repair of a torn acetabular labrum. The results of this study involving 50 patients showed a negative correlation between the severity of arthritis and improved outcomes, drawing the conclusion that patient outcomes are directly influenced the presence and degree of arthritis.[38] Setting up the argument that direct visualization of the articular surfaces in the hip should be the gold standard for identification of arthritis, just as it is in the knee. However, before attempting to reach such a conclusion, the effects of cartilage defects on the progression of OA symptomatology in the hip needs to be further elucidated. Specifically, no evaluation to date has been conducted that specifically addresses size and location of osteochrondral defects and the effect these defects have on OA progression in the hip following repair of a torn acetabular labrum.

Age

Very little formal investigation has been performed to study the influence of age on hip arthroscopy outcomes; as such, there is currently no consensus on age as a predictor of outcome. Khanduja and Villar[12] recommend arthroscopy to be reserved for patients aged less than 50 years old. Philippon et al.[32] reported outcomes after FAI in patients aged 50 years or older at a minimum 1-year follow-up and found that patients primarily achieved surgical success, though with a 20% conversion to total hip replacement (with a higher incidence in patients with > 2 mm of joint space). Larson et al.[24] also showed a failure rate that was dependent on age; however, a formal comparison was not made. Byrd and Jones[39] showed worse outcomes in older men. Although there have been studies looking at age secondarily in patients with labral tears, there is no prospective evidence to endorse or refute a recommendation of hip arthroscopy for patients of any age being treated for a tear of the acetabular labrum.

Preliminary Data

Our group recently performed a large retrospective case-control series looking at the influence of pre-operative arthritis and age as predictors of long-term outcomes following arthroscopic labral repair.[40] Over the course of the study period, which spanned 8 years and 200 patients, our management evolved to reflect the current practice of abstaining from arthroscopy in patients with less than 2 mm of joint space on plain standing radiographs. In spite of this, we continue to routinely encounter cartilage defects intra-operatively. Such findings can be explained by evidence stating conventional radiographic measures are poor predictors of actual arthritis in the hip.[48] Although it is possible that focal cartilage defects seen at arthroscopy are incidental findings.[42]

Most studies attempt to eliminate radiographically evident severe arthritis by excluding patients who demonstrate less than 2 mm of joint space on standing antero-posterior hip radiographs at the time of surgery. However, based on our results, we suggest that the presence of Outerbridge grade 4 arthritic changes noted at the time of arthroscopy can be used adjunctively to identify patients who will fare poorly after hip arthroscopy for labral pathology. Interestingly, despite the apparent influence of arthroscopically identified arthritis portending worse outcomes (Odds ratio=2.5), our preliminary results suggest age is a stronger predictor (Odds ratio = 7) of diminished surgical outcomes.

Most recently, the authors involved in this study performed a retrospective investigation (unpublished data) to capture patients with clinically and radiographically confirmed acetabular labral pathology electing to undergo conservative management defined as the refusal of surgical intervention. Based on a retrospective review of 894 patients presenting to clinic over a 10-year period, we identified 22 patients with labral pathology that were treated non-operatively. Retrospective case control analysis was performed using outcome questionnaires administered to both surgical and non-surgical cohorts. We found that patients with labral tears managed non-operatively appear to score highly on hip function outcome scores, preliminarily indicating there may be some benefit in using conservative management alone in the treatment of labral pathology. Controlled comparative analyses between surgically and non-surgically managed patients suggested that non-operatively managed patients exhibit a non-significant tendency toward worse outcome.

Given the lack of current guidance for judicious use of hip arthroscopy for labral pathology in patients of increasing age with arthritic change, we propose that there is a need for high quality prospective comparative studies assessing hip arthroscopy against physical therapy as a non-operative form of management for tears of the acetabular labrum. Furthermore, preliminary evidence by our group and the published data of others described above highlights the necessity for continued investigation into

this topic with particular emphasis on the role of preexisting arthritic change in this select group of patients. Without prospective investigation into the role of arthritic burden and age, we cannot begin to fully assess their influence on outcomes following labral repair.

Implications:

Determining which patients, using age and arthritic burden as predictors, can benefit from labral repair is paramount for several reasons. Showing arthroscopic repair is of little or no benefit to a specific cohort can reduce the number of unnecessary surgeries performed, increase the use of conservative therapy (if validated) and reduce the interval between diagnosis and total hip replacement. Additionally, proving a benefit exists from arthroscopic repair in a certain subset of the population will substantiate the need for developing a treatment algorithm in older patients presenting with labral tears and some degree of pre-existing arthritis. Furthermore, conservative physical therapy may prove to be of equal or greater benefit than arthroscopic repair in select patients. If true, this study will be a landmark for providing the evidence needed to recommend conservative treatment as an efficacious alternative in addition to providing a foundation for future research on this topic.

II. SPECIFIC AIMS:

Specific Aim 1: To evaluate if physical therapy alone or arthroscopic labral repair and physical therapy is of greater benefit to patients presenting at age 40 with tears of the acetabular labrum.

Hypothesis 1.1: Physical therapy will result in a significant difference in mHHS scoring at 12 months when compared to baseline.

Hypothesis 1.2: Arthroscopic labral repair will result in a significant difference in mHHS scoring at 12 months when compared to baseline.

Hypothesis 1.3: Arthroscopic labral repair and physical therapy will be superior to physical therapy alone in improving function and alleviating symptoms at 12 months when compared to baseline, as judged by the mHHS.

Hypothesis 1.4: Hypotheses 1.1-1.3 will hold true at 24 months and beyond.

Hypothesis 1.5: Functional outcome scores collected at the completion of PT will not significantly differ from those collected at 12 and 24 months and beyond in the same group.

Specific Aim 2: To evaluate the effect of arthritic burden on short term outcomes following arthroscopic labral repair.

Hypothesis 2.1: In the surgical treatment group, subjects with arthroscopically proven severe osteoarthritis (Outerbridge grade 4) will do more poorly on validated outcome measures, specifically the mHHS, after arthroscopy than subjects with less severe osteoarthritis (Outerbridge grade ≤ 3).

Hypothesis 2.2: Cartilage defects at or near the chondrolabral junction are prognostic indicators of worse outcomes as determined by the mHHS.

Hypothesis 2.3: Subjects with any degree of joint space narrowing (classified by Tonnis and Kellgren-Lawrence grading, see below) on plain radiographs will have more pain, regain less function, and do more poorly based on validated outcome measures, specifically the mHHS, at 6 and 12 months than subjects without any degree of joint space narrowing on plain radiographs.

EXPLORATORY Specific Aim 3: To evaluate the relationship between joint space narrowing on plain radiography and arthroscopically proven osteoarthritis.

Hypothesis 3.1: Tonnis grading and Kellgren-Lawrence grading on plain radiography are not predictive of the severity of arthritis at the time of arthroscopy.

Specific Aim 4: To analyze the data of subjects crossing over from PT alone to PT and surgery.

Hypothesis 4.1: Primary outcome scoring (mHHS) at 12 and 24 months after cross to surgery and PT will differ significantly from those initially randomized to surgical treatment.

Hypothesis 4.2: Baseline scores on outcome measures of those subjects crossing over will not differ significantly from those obtained at the time of crossover.

III. SUBJECT SELECTION & ENROLLMENT:

Study Overview: This is a prospective randomized control trial (RCT), which will enroll subjects with a clinically diagnosed tear of the acetabular labrum. Subjects who have been diagnosed with a labral tear in clinic will receive conservative physical therapy treatment alone or arthroscopic surgical labral repair and physical therapy. If it is discovered that there is unexpected pathology at the time of arthroscopy for subjects in the surgery group, those subjects will be removed from the study. This is due to the possibility that the source of pain is less likely a result of the dysfunction of the labrum and more likely due to aberrant extra-articular biology. We will use validated outcomes measures that include the mHHS, LEFS, HOS, NAHS, and iHOT-33 (see below) and review the medical record for physical exam findings to track patient progress throughout their involvement in the study which will continue for as long as they are a patient of the PI. Study procedures will be complete when the last enrolled subject completes 24-month follow-up and completes the corresponding surveys.

Our Primary Outcome is change in the modified Harris Hip Score at 12 months and 24 months. Secondary outcomes include changes in other validated outcomes measures patient satisfaction, and degree of improvement on physical exam. The influence of OA severity (Outerbridge scoring) and location of OA will also be analyzed to determine if they have an effect on the aforementioned outcome measures. Satisfaction will be assessed by an exit questionnaire (See section IV). In addition to gauging satisfaction, this questionnaire will ask subjects how they felt about their participation in the study. (See section IV)

Inclusion and Exclusion Criteria:

Inclusion criteria	**Rationale**
Age 40 or greater	Higher likelihood of undetectable OA on imaging
Orthopedic surgeon determines symptoms are consistent with a labral tear.	Required for treatment
Availability of hip radiographs and MRI	Needed to assess eligibility and comparison for specific aim 3
Willingness to undergo randomization and ability to understand and sign informed consent document	Ability to understand study and consent willingly

Exclusion criteria	Rationale
Unexpected pathology at the time of arthroscopy	Source of pain less likely to due dysfunction of the labrum and more likely due to aberrant extra-articular biology
Same site surgery	Complex anatomy
Contraindication to surgery or physical therapy	Cannot tolerate either treatment grouping
Alternate form of PT for greater than 6 weeks	Will negatively augment results. May affect recruitment.

Selection and enrollment:

We will enroll 122 consecutive subjects meeting the aforementioned criteria. Subjects will be randomized into conservative or surgical treatment arms. All potential subjects on the clinic schedule of the investigator will be pre-screened for eligibility based on age, clinical assessment, and previous medical history.

All eligible subjects will be approached at an outpatient clinic visit. Those who initially meet inclusion criteria will be introduced to the study and given a research consent form that they have the opportunity to take home and to review.

The research coordinator will randomize the subjects into the study at this visit. Randomization will be assigned utilizing an electronic randomization program. Those receiving conservative management will be scheduled for physical therapy. Those receiving surgical management will be scheduled for surgery and the post-operative physical therapy protocol within 2 weeks of their operative date.

Efforts will be made to attain a mix of study participants, regarding gender and racial/ethnic representation reflective of the population of the greater metropolitan Boston area: 66% White, 14% African American and 10% Hispanic or Latino. More specifically, we anticipate that at least half of our subjects will be female and that we will have representation from Asian American, African American and Hispanic minority groups in our final cohorts.

Informed consent:

The informed consent document will be approved by the IRB at Partners HealthCare, which covers The Brigham and Women's Hospital, Faulkner Hospital, and the Brigham and Women's/Mass General Health Care Center at Foxborough. The informed consent process will be conducted by the PI.

Overview of sample size:

This randomized control trial includes 122 subjects age 40 or older with evidence consistent with tears of the acetabular labrum in the affected hip

Meeting recruitment targets:

As previously mentioned, the design of our study is similar to that of the MeTeOR trial [43] in which Dr. Martin and Dr. Safran-Norton were lead investigators. Dr. Martin was the highest referral base for the

MeTeOR subjects at the BWH site and Dr. Safran-Norton designed, delivered and managed the physical therapy protocol for both arms of the MeTeOR trial across 7 national trial centers. Based on a survey before that trial commenced, it was estimated that 20-25% of eligible subjects would agree to participate in the randomized controlled trial. Participation in the actual trial was 26%. We anticipate a similar recruitment percentage as our design is similar as are our inclusion criteria.

Study retention procedures:

Dr. Martin and Dr. Safran-Norton were investigators in a similarly designed multicenter trial involving meniscal tears in the knee.[43] In that recently published study, once enrolled, the patient retention rate was approximately 90%. We believe we will have similar success over the course of this study. Nevertheless, procedures will be in place to aid in maintaining subject participation over the course of the study. Outcome measures collected around formal visits can be collected remotely. Subjects can receive the surveys via email sent through REDcap. Study staff will conduct reminder phone calls around data collection time points.

IV. STUDY PROCEDURES:

Enrolled subjects will complete surveys around normal clinic visit intervals. Subjects will continue receiving surveys around their normal postoperative clinic visits until they request to stop receiving them. We are interested in long-term outcomes for these treatment arms, so we hope to collect patient-reported outcome measures for several years after randomization. These surveys can be completed remotely or at clinic visits. Follow up/reminder calls will be conducted to ensure subjects complete surveys.

Medical History:

The medical record may be reviewed for relevant medical history, imaging, physical exam, and surgical procedure from the subject's operative note, imaging, or clinic visit notes.

Patient-Reported Outcome Measures (PROMs) Surveys:
Pain/Physical Function:

Modified Harris Hip Score (mHHS): The MHHS is a validated condition specific outcome instrument that is used widely after hip arthroscopy. The eight questions measure domains of pain, gait function, and functional activities. Scores range from 0 (poor) to 100.1 (ideal).[45,46]

The Lower Extremity Function Scale (LEFS): The LEFS is a 20 item validated outcome measure that is commonly used by physical therapists to initially evaluate and subsequently monitor patient progress through the course of a rehabilitation program. The minimum level of detectable change is 9 points.[47]

Hip Outcome Score (HOS): The HOS is composed of the activities of daily living (HOS-ADL) subscale and the sports (HOS-sports) subscale. The HOS-ADL subscale contains 19 items pertaining to basic daily activities, and the HOS-sports subscale contains 9 items pertaining to higher-level activities, such as those required in athletics. In addition to the 5 potential responses, ranging from "unable to do" to "no

difficulty," a response of "not applicable" is an option to allow subjects to designate that something other than their hip problem limits their activity. Use of the HOS is supported for individuals with labral tears. Importantly, this includes individuals who underwent arthroscopic surgery, as well as those who did not.[48] A score change beyond 3 points represents a change beyond measurement error for the HOS-ADL and HOS-sports subscales. An increase in the score above 9 points and 6 points represents a meaningful increase for the HOS-ADL and HOS-sports subscales, respectively.[49]

The Nonarthirtic Hip Score (NAHS): The NAHS is a validated, self-administered 20-item questionnaire designed to assess non-arthritic hip pain in patients with high activity demands and expectations.[50]

International Hip Outcome Tool-33 (iHOT-33): Measure health related quality of life. The iHOT-33 includes 33 questions or items, each answered by marking a visual analog scale between 2 anchor statements. This can be done on a paper form (with a 100-mm scale) or as part of a computer-based system. The total score is calculated as a simple mean of these responses ranging from 0 to 100, with 100 representing the best possible quality-of-life score. It is most suited for research purposes.[51]

Psychiatric/Psychological Measures:

Short Form 36 (SF-36): The SF-36 is a self-administered questionnaire consisting of 36 items, requiring 5-10 minutes to complete. The 36 items generate a profile of scores across eight dimensions of health: physical functioning (10 questions), social functioning (two questions), role limitations (physical problems) (four questions), role limitation (emotional problems) (three questions), mental health (five questions), vitality (four questions), pain (two questions), general health (five questions). One question addressing health change (transition) is not scored nor represented in the eight dimensions.[53] SF-36 appears to be a valid instrument, responsive to changes in health status over time among unintentionally injured adult people. Thus it may be possible to use the SF-36 to describe changes in health due to injury. The applicability of this or similar measures for injured children remains to be established.[54]

Exit Questionnaires:

Patient Satisfaction: This questionnaire will be disseminated to subjects yearly starting around the time of their 1-year follow up clinic visit and yearly thereafter. The questionnaire will contain 3 items. The purpose is to gauge how satisfied with each subject is with 1) their specific treatment regimen during the study 2) their outcomes of their specific therapy and 3) if given the choice, would the subject undergo the same therapeutic regimen. (See addendum)

Participation questionnaire: This 6-item questionnaire was designed to assess how patients felt about their care during the study, if they would participate in a similar study, how well they feel the outcomes measures addressed their hip condition, and what factors, if any, would increase participation in a future study. (See addendum)

Study compliance monitoring, treatment credibility assessment, and data management:

Subjects will be given contact information for the IRB and study coordinator. Subjects will also be seen in clinic. In addition to regular clinical follow-up the purpose of these interactions is to identify adverse events, patient concerns, and to check on patient compliance with physical therapy regimen, which is particularly important over the first 3 months. At the end of the trial all subjects will complete an

exit questionnaire. All data is collected with RedCap electronic software, which reports on missing data and data outliers. We can also then quantify and analyze treatment compliance.

PHYSICAL THERAPY VISITS

Please see attachments for post-operative and non-operative physical therapy protocols as well as advancement criteria.

The physical therapy protocol was developed by an experienced board-certified physical therapist utilizing nationally recognized surgical post-op hip labral repair protocols in addition to an extensive literature review for best practice in treating patients with labral tears. The physical therapy protocol was specifically designed to be similar in both arms of the study with consideration for differences in those patients post-op. The intervention was designed to be a rigorous program that allows for individualization for patients with specific impairment and functional limitations yet standardized with specific guidelines for best practice. The three-stage structured program is designed to address inflammation, pain, range of motion, muscle strengthening, muscle length restrictions, aerobic conditioning (e.g. bicycle, elliptical, treadmill), functional mobility, proprioceptive/balance training. The program additionally recognizes and considers adjacent joints associated with hip pain e.g. lumbar spine, pelvic girdle and hip. The specific content of the PT program is outlined in a separate document. The three phases of intervention include: Acute Phase I with a focus on ROM, pain and edema, Sub-acute Phase II which introduces muscle reeducation and Phase III which addressed more advanced muscle strengthening, balance, proprioception and higher level functional mobility. Criteria for advancing from Stages I to II and II to III include the level of self-reported pain, observed strength, range of knee motion, knee effusion soft tissue restrictions, pelvic alignment symmetries and functional mobility. In each stage, the patient is recommended to attend 1-2 PT sessions up until 12 weeks depending upon physical therapy examination findings. The patient will also have an individualized home exercise program. Patients will use their regular health care insurance for these treatments, which is considered standard practice. The protocol is designed to accommodate the various types of insurances for all patients. The physical therapy documentation will be kept in a secure electronic medical record. The study physical therapists are not blinded to the study as they are treating every patient in the trial. Dr. Safran-Norton will train and assure competencies for each study physical therapist.

In order to objectively track each individual subject's progress enrolled in the PT alone group, we employ the use of "advancement criteria". These criteria will serve as a safety and quality control measure. Failure to meet these advancement criteria is a trigger for re-referral back to the orthopedic surgeon for potential cross over due to an inadequate response to PT. Non-achievement of the advancement criteria outlined for each phase of the physical therapy protocol is a cause for clinical concern that the PT intervention has been ineffective or not effective enough. We plan to use these advancement criteria for those subjects enrolled in the physical therapy alone arm of this randomized controlled trial as an objective measure to monitor subject progress and safety. At each treatment session, which will ideally take place every third day (1-2x/week) once enrolled, subjects will undergo complete evaluation by the physical therapist for clinical concern that the subject is not adequately responding to PT (page of the detailed protocol). Therefore, each subject who is compliant with the non-operative PT protocol will undergo formal evaluation at least once per week during the course of treatment. This is exactly what would be done in normal routine practice and our study procedures will not deviate from this. Progression through the advancement criteria will be documented in the subjects chart on a separate sheet of paper (attached) requiring the dating and signature of the physical therapist for advancement through the protocol or re-referral back to the surgeon, which is considered standard of care and common practice.

In addition, subjects can subjectively withdraw from PT any time point if they feel that it is not working for them the way they would like. However, in order to standardize the amount of time that lapses between enrollment and potential cross-over, subjects wishing to transition to surgical treatment cannot do so until 6 weeks after initial enrollment (see figure 5 of the study schema). There are several reasons for this: First, we want subjects to have enough time to see the benefits of PT, as they may not be immediate. Second, if the decision to cross over is made prior to 6 weeks, the remaining time allows for scheduling of a follow-up appointment in a timely manner that does not delay appropriate patient care. Lastly, subjects are not required to continue under the PT protocol, they can stop at any point and not receive further PT or medically directed care until their follow-up. This scenario is no different than if a patient, in a non-study setting, self discontinued a recommended course of PT and sought surgical consultation elsewhere. The advantage here is that subjects will already be known to both the hospital system and surgeon, which allows for quicker consultation.

SURGERY

While randomization is a research procedure for this study, the surgery itself is not a research procedure. This surgery is standard of care for patients with symptomatic labral tears, and the PI regularly performs labral repair in patients not enrolled in research.

POSTOPERATIVE PROTOCOL

All procedures are performed on an outpatient basis. Patients are allowed flat-foot full weight bearing immediately postoperatively. Patients are instructed in gait training, keeping a level pelvis and avoiding any lurching of their pelvis during ambulation. Patients are kept weight bearing as tolerated with crutches for 6 weeks postoperatively for a labral repair. Patients are allowed full active range of motion as tolerated immediately with avoidance of deep squatting and impact loading exercises for 4 months postoperatively. This is considered standard practice.

V. BIOSTATISTICAL ANALYSIS

Hypothesis 1.1-1.4:

The mean outcome scores of the mHHS in each treatment group at 12 months will be compared to baseline scores to assess for significant differences using paired sample t-test in SPSS 16 (SPSS, Chicago, IL). The mean outcomes scores of the mHHS between groups at 12 months will be compared using independent t-tests to assess for significant difference. We will use a Levene test to judge variance and proceed accordingly. If a statistically significant difference is detected during these analyses, we will calculate the effect size (ES) to determine how meaningful these results are outside of being statistically significant. The ES will be calculated by: [(mean mHHS score of surgical arm / mean mHHS of the conservative group) / standard deviation of the conservative group]. According to Cohen [58], an ES <0.1 is trivial, ES of 0.1-0.3 is minimal, ES of 0.3-0.5, is moderate, and ES >0.5 is large. We will repeat the same analysis at 12 months.

Hypothesis 2.1, 2.2, and 2.3:

Diagnosis and treatment of the prearthritic and early arthritic hip has been an area on intense interest. However, our most conventional method of assessment (plain radiography) does not provide us with enough diagnostic sensitivity.[41] Direct visualization on the articular surfaces in the hip is both sensitive and specific. Furthermore, emphasis is being placed on the location of arthritis as a prognostic indicator of good outcomes following hip arthroscopy. The value of arthroscopic techniques for primary

symptoms and/or prevention of OA secondary to labral tears remains unclear even though preliminary reports indicate there may be some benefit to repairing a torn labrum, even in cases of severe OA. Evaluation of arthritic change at the time of arthroscopy is important, particularly in subjects where there remains uncertainty about the efficacy of labral repair for those with articular or rim cartilage degeneration that the effects of those changes on long-term OA progression.[59]

We plan to track the effects of OA on outcomes through identification and localization of OA at the time of arthroscopy using a mapping technique (see diagram). After complete visualization of the intra-articular space, as is standard practice in hip arthroscopy, classification of any existing osteoarthritis will be done according to the Outerbridge grading scale. Using this system, we are able to categorically group subjects based on location and severity of disease. If multiple lesions are present, subjects will be characterized by the most severe grade. Furthermore, based on the data gathered through meeting hypotheses 1.1-1.4, we will subdivide primary outcome scores into four categories.[60] Category I, excellent outcomes (mHHS $\geq$90); Category II, good outcomes (mHHS $\geq$80); Category III, fair outcomes (mHHS$\geq$70), and Category IV, poor outcomes (mHHS <70). The likelihood of outcomes based on Outerbridge grading and outcome category will be determined through odds ratios. Analysis will be carried out using Chi-squared tests. Significance is set at $P<0.05$. Linear regression analysis will be performed to detect if any relationship exists between the severity of osteoarthritis and short-term outcome scoring.

Hypothesis 3.1:

This is an exploratory hypothesis whose assessment will no influence the other data sets. Prior work by other groups has demonstrated that evaluation of arthritic burden by conventional measures (Kellgren-Lawrence and Tonnis grading) are not indicative of the severity of arthritis found at the time of arthroscopy.[58] We will explore this phenomenon in our own cohort of subjects, specifically those in the surgical group and report our findings. We will correlate our findings for significance.

Power Analysis:

Specific Aim 1, Hypotheses 1.1-1.4: *To evaluate if physical therapy alone or arthroscopic labral repair and physical therapy is of greater benefit to patients presenting at age 40 with tears of the acetabular labrum.*

Using the data from our retrospective review of outcomes following labral repair, a 10 point or greater difference on the mHHS as significant, and a single-tail independent t-test to evaluate the difference between means with 80% power and a 5% significance level, 35 subjects are needed to demonstrate a statistically significant difference between the average mHHS of the conservative group and surgical group. Testing of hypothesis 1.5 will be an intragroup analysis looking for a significant difference in outcome measures from the time of completion of PT (non-crossover) when compared to the same data to be collected at 12 months and 24 months. The purpose is to determine the short-term durability of the response to PT, if one is found.

70 study completers should provide us with the necessary data needed to substantiate or reject our hypothesis. There has been no prospective trial to date testing these hypotheses in the hip, but we expected a 7.3-10.3% dropout rate based on the results of a similar study in the knee. However, as of July 2018, we had 47 patients that had passed the 2-year follow-up mark, of which 5 patients were no longer in the study (combination of lost to follow-up and proceeding to total hip arthroplasty), and another 11 had yet to complete their 2-year surveys even with multiple attempts to contact them and encourage them to do so. With a yield of 31 patients out of 47, or 65.95%, we increased our sample size to 122.

Therefore, we estimate needing 122 subjects to achieve 70 study completers, in the appropriate proportion of 35 subjects per treatment arm. We enroll until reaching at least 35 subjects in each group.

The results of the MeTeOR trial in the knee show that we can expect a higher drop-out rate in the surgical group. As such, this cohort may be our limiting factor.[40, 43, 61,62]

Specific Aim 2, Hypotheses 2.1-2.3: *To evaluate the significance of arthritic burden on short term outcomes following arthroscopic labral repair.*

Hypothesis 2.1 was powered on the basis of our prior work where 33% of study participants had grade 4 Outerbridge changes the time of arthroscopy. Dividing our cohort into two subgroups: 1) Those with grade 4 changes and 2) Those without. We will need 12 subjects with grade 4 changes in order to perform adequate sub-group analysis.[63] Powered to 80% and 5% significance level. Hypothesis 2.2 is another sub-group analysis that will be conducted in a similar fashion to that of hypothesis 2.1. However, the two groups will be categorized into: 1) cartilage defects at or near the chondro-labral junction and 2) cartilage defects not at or near the chondro-labral junction. We cannot control the heterogeneity of the subjects enrolled, but based on this analysis we expect to meet our target enrollment. Hypothesis 2.3 will be analyzed via linear regression and is appropriately powered.

Specific Aim 3 is exploratory. Since we are recruiting subjects for the main purposes of determining outcomes, we recognize that we may be underpowered for the definitive analyses of our radiographic correlation hypotheses. Nevertheless, we anticipate that we will enroll sufficient numbers of subjects to draw an association or at the very least, trend patient outcomes with degree of joint space narrowing, Kellgren-Lawrence grading, and Tonnis grading. There should also be sufficient numbers to preliminarily assess any correlations between pre-operative Kellgren-Lawrence and Tonnis grades with the Outerbridge classification at the time of arthroscopy.

VI. RISKS & DISCOMFORTS

Conservative Treatment: Subjects can expect the routine discomfort associated with any therapeutic procedure. Complications may include muscle soreness, pain, and increased edema or muscle fatigue.

Operative treatment: Since surgery is not considered a research procedure (only the randomization into the surgery group is considered a research procedure, as explained above) surgical risks are explained in the surgical consent process.
In the rehabilitation period, patients will be subject to the same potentials discomforts as those subjects in the conservative treatment group as the physical therapy protocols for both groups are identical. In both treatment groups every effort will be made to minimize the risk of adverse events and patient discomfort.

VII. POTENTIAL BENEFITS:

It is very likely that some of the subjects will derive direct benefit from participation in the study, such as improvements in pain and physical function. Outside of the estimated physical benefits from a surgical treatment or rehabilitation program, subjects may experience the monetary benefits in the forms of less missed work and increased productivity. There may also be the emotional benefit of being able to return to the normal activities of daily with a reduction in pain or no pain at all. Subjects who wish to continue their treatments at the conclusion of the study will be given the opportunity to do so through the Brigham Orthopedic Associates. It is anticipated that findings from these studies will help advance research in labral repair and patient outcomes in general. We also hope to derive a strong sense for the type of

patient age 40 and older who will benefit the most from either arthroscopic labral repair or physical therapy.

VIII. MONITORING AND QUALITY ASSURANCE:

The P.I., Dr. Martin, will oversee all data collection and ensure that data are collected and stored in a confidential manner consistent with all regulatory requirements.. This study will be approved by the Partners IRB, and any protocol deviations and/or adverse events will be reported in accordance with the Partners Human Research Policy. Research assistants will be trained to identify and to bring to the research team any complaints or adverse reactions among participants. Training will include appropriate steps to alleviate or remedy common problems. Dr. Martin will have contact with staff to monitor patient participation and any issues that emerge during the protocol, and will review and discuss human subjects' protection issues with staff as unique situations emerge during the progress of the study. Dr. Martin will meet with the research team regularly for a formal research meeting. Subjects will be given telephone numbers to contact the PI and the IRB to communicate any concerns that may rise during their participation in the protocol. Please see below for specifics.

1. The study staff will meet regurlarly with Dr. Martin to review study participants and the data that has been collected on them to date. If a subject becomes disqualified or must leave the study for safety concerns, Dr. Martin will personally inform them of the situation through the subjects preferred method of contact. Dr. Safran-Norton will be leading and administering the conservative arm of the study (subjects being treated non-surgically with physical therapy and subjects in the post-operative period receiving rehabilitative physical therapy). She will inform Dr. Martin of patient progress and any potential clinically significant events that may warrant further discussion and could ultimately result in the dismissal of a patient from the study.
    a. As this is a prospective study comparing the gold standard of treatment (labral repair) to a potentially equivalent therapeutic modality, qualifying subjects will never be denied the option to undergo labral repair via hip arthroscopy. The treatment schema allows for subjects in the non-surgical arm (physical therapy alone) to cross over to the surgical treatment group at any time (following physical therapy) from initial enrollment if they wish to do so. Subjects who decide to crossover or are indicated to crossover through the non achievement of advancement criteria will have the PT discontinued at that time point but must wait for official crossover at 6 weeks after initial enrollment. Participants can always decide to leave the study if this is not what they want. The decision to cross over will in no way affect the quality of healthcare current or prior study participants receive. All of this will also be explained to them during the consent.
    b. We will review all data continuously and should there be a obvious clinical detriment to specific treatment arm such as repeated poor outcomes or worsening function, further investigation will be initiated to determine if this is an isolated occurrence or if there is a significant trend which warrants cessation of study protocol and disenrollment of subjects.
        i. Stopping rules include a clear difference in morbidity, as measured by interval physical exams and outcomes questionnaires, between treatment groups
        ii. Any significant mortality possibly linked to study procedures will result in immediate suspension of the study protocol.
2. A data safety monitoring board (DSMB) or data monitoring committee (DMC) is not required for the purposes of this study because large numbers of subjects will not be used in this investigation, there are no blinded treatment study groups, we are not using multiple clinical sites (all are within Partners network), we are not using high risk interventions (hip arthroscopy has been shown to be a safe option for managing intra-articular and periarticular pathology of the hip;

physical therapy is low risk), we are not performing a controlled trial in which major morbidity or mortality are considered primary or secondary endpoints.

Adverse Events Reporting and Assessment:

Any protocol deviations and/or adverse events will be systematically documented and reported to the IRB. Adverse Event Reports and/or Case Report Forms will identify study participants by their initials and a unique study participant identifier.:

Severity grading scale:

Mild: adverse event of little clinical significance
Moderate: adverse event between mild and severe - causing some limitation of usual activities
Severe: adverse event that results in death, is life-threatening, requires or prolongs hospitalization, causes persistent or significant disability/incapacity, represents a significant overdose or breach of protocol, results in congenital anomalies/birth defects or produces cancer, or in the opinion of the investigator, represents other significant hazards or potentially serious harm to the research subject or others.

Attribution scale:

Not related: clearly NOT related to the study
Possible: may be related to the study
Probable: likely related to the study
Definite: clearly related to the study
Unable to assess

Any serious or unexpected adverse events will be reported to the IRB within the required timeframe, using the appropriate forms. The principal investigator will provide an interim report of all adverse events to the IRB at the time of continuing review. Although this proposed project is perceived to be relatively low-risk, the study may be terminated if the frequency of serious or unexpected adverse events is higher than that anticipated. Once this determination is made, a memo will be sent to the IRB explaining the reasons for the determination. For suspended studies, an action plan will be devised which will outline what evidence and/or conditions will be required to terminate or re-initiate the study.

Reporting Unanticipated Problems including Adverse Events

The principal investigator will report to the PHRC any unanticipated problems and adverse events that occur: 1) during the conduct of the study, 2) after study completion, 3) after subject withdrawal or completion. The reports will be submitted according to PHRC policy within 5 working days or 7 calendar days of the date the investigator first becomes aware of the problem.

Subject Confidentiality:

Precautions will be taken when contacting and communicating with subjects to ensure that their participation is kept confidential. Subjects will be assured that their decision to participate will not affect their medical treatment. Throughout the study, investigators will be alert to any complaints or adverse reactions and will take appropriate steps to alleviate the difficulties as soon as possible. Subjects will be given the names and phone numbers of individuals to contact in the event of an emergency or a complaint or question regarding the conduct of the study.

All data for presentation will be identified by a code number only. Prior to releasing data to the scientific community, all data will be de-identified. Explicit permission to share the de-identified data with the scientific community will be obtained as part of the Informed Consent procedures.

Safeguarding Specimens, Records, and Data:

All research materials are obtained directly from the participants by trained and supervised study staff. All study staff who interact with human subjects have completed the requisite training in research ethics and procedures, and are approved by the institution's IRB. Each participant in the study will be assigned a study ID number as a unique identifier. All records and research data will be kept in locked filing cabinets and on password-protected, secure computer systems. Databases that link Personal Health Information with research data will be kept on secure, Partners computer systems. Only summaries of group data will be reported in any publications or presentations, with no identification of individual.

IX. REFERENCES

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Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: February 2010

Protocol Title: Arthroscopic Labral Repair versus Physical Therapy for Tears of the Acetabular Labrum in Patients Age 40 and Older

Principal Investigator: Dr. Scott D. Martin

Site Principal Investigator: MGH and BWH

Description of Subject Population: Adults age 40 or greater with a tear of the acetabular labrum

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Why is this research study being done?

We are doing this study to learn whether physical therapy (PT) alone or surgery and PT is more effective at treating the symptoms of a torn acetabular labrum (torn fibrocartilage in the hip joint). PT and surgery are both considered standard medical care for your kind of hip injury.

We are asking you to take part in this study because you have a tear of the acetabular labrum.

This is a pilot study. Pilot studies are done on a small group of people to learn whether a larger study would be useful.

About 122 people will take part in this study. This study is being done at Massachusetts General Hospital, MGH West, Brigham and Women's Faulkner Hospital, and the Patriot Place Health Care Center at Foxborough.

Smith & Nephew is helping to pay for this study to be done.

How long will I take part in this research study?

Depending on what treatment you are assigned, the length of certain study procedures will differ. If you are assigned to physical therapy, you will have 3-4 months of physical therapy sessions 1-2 times a week followed by 3-4 months of self-directed home physical therapy. If you are in the surgery group, you will also undergo 3-4 months of physical therapy, which will start within two weeks of your surgery followed by 3-4 months of self-directed home physical therapy. If you switch from physical therapy to surgery, you will undergo 3-4 months of physical therapy after your surgery, meaning that you may undergo more than 3-4 months of physical therapy in total. After this, you will also undergo 3-4 months of self-directed home physical therapy. Participation in this study entails taking surveys at time points closely mirroring your postoperative follow-up schedule with Dr. Martin. These surveys will be sent to you for as long as you are a patient of Dr. Martin's or until you tell us that you do not want to receive any more surveys. Follow-up with Dr. Martin after your surgery will start out being a few times a year for the first year and will progress to once yearly or once every few years thereafter. Therefore, you will receive, at most, one survey a year after your first year of follow-up. Surveys take approximately 15-20 minutes to complete.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

After your normal clinical visit with Dr. Martin, he will let you know if you qualify for this research study. If you choose to participate, we will assign you to a study group. We will assign you by chance (like a coin toss) to the PT alone group or the surgery with PT group. You and the study doctor cannot choose your study group. You will have a 1 in 2 chance of being assigned to the PT alone group and a 1 in 2 chance of being assigned to the surgery with PT group. While you will have some PT no matter which group you are in, the exercises you will do at PT are different depending on whether you are having surgery or not.

We will have you complete a set of baseline surveys about your hip problem and your general health. We can email you these surveys so you can complete them at home.

The Partners standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

Hip Surgery (Surgery group only)

If you are assigned to the hip surgery with PT group, you will come in for surgery on your hip. This visit will take about 4-6 hours. After surgery, you will be monitored for 2-3 additional hours. The surgery will be performed as usual. We may videotape parts of your surgery.

Physical Therapy Visits

All participants, regardless of the treatment group you are in, will make up to 24 visits for PT during the study. These visits will take place once or twice a week for about 4 months and will take about one hour each. The physical therapist will meet with you at these visits and have you do exercises to increase the strength and flexibility of your hip. There are several differences in the type of PT each group receives:

- If you receive only PT: The PT will be immediately directed to improve strength, increase the range of motion at your hip, and reduce pain associated with your hip.
- If you receive surgery and then PT: The PT will be directed to improve strength, increase range of motion at your hip, and reduce pain associated with your hip. However, in the first four weeks after your surgery, we are careful to not reinjure your hip. For this reason, you will have restrictions on physical activity. After the 4 weeks, we will increase your activity

Crossover

If you are in the PT only group, you will be evaluated at every PT session to see how effective the PT is. If you, the physical therapist, or your doctors find the treatment to be ineffective the physical therapy will be stopped. We hope most people will try PT for 6 weeks before deciding to switch but you will be allowed to crossover to surgical treatment at any time point and remain in the study. However, surgery may be scheduled for a date that is at least 6 weeks after your PT start date. As part of the process to switch from PT to surgery, you will be scheduled for re-evaluation by the surgeon within two weeks of the last PT visit you went to.

Regardless of which treatment you are receiving, we will continue to send you surveys around your regular clinical follow up visits with Dr. Martin. We estimate these surveys will take about 20 minutes to complete.

Study Phone Calls

During this study, we may call you to follow up with questions about survey responses and to give you friendly reminders to complete the surveys.

Storage and Use of your Study Information

During this study, we will store your study information in a secure electronic database used for research.

We will label your study information with a code instead of your name. The key to the code connects your name to your health information. We will keep the key to the code on a password-protected computer. We will also collect your personal contact information which includes your name, address, telephone numbers, and email address. This information will be shared with staff participating in the study if you need to be contacted. This information will also be stored securely in REDcap. All paper study information forms will be kept in a locked file cabinet.

Future Studies

We would like to contact you 4 years after you finish your study treatment year, so that we can evaluate the long-term outcome of hip problems like yours. We will ask you to come to the clinic for a brief physical exam and to complete questionnaires. The questionnaires can be emailed to you one week before your clinic visit. The visit will take about 15-45 minutes depending on if the questionnaires were completed before coming to your visit.

Do you agree to be contacted and to complete an extra study visit one time, at 5 years after you start this study?

YES_____(Subject's Initials)
NO_____(Subject's Initials)

What are the risks and possible discomforts from being in this research study?

Risks of Hip Surgery

If you are assigned to the surgery group, you will be exposed to all of the clinical risks associated with your hip surgery. These risks include:

- Nausea
- Pneumonia (lung infection)
- Infection in the hip
- Blood clots in the lungs or legs
- Heart attack
- Injury to nerves
- Death

There is also a small possibility that you might have an allergic reaction to the bandage used after surgery. Signs of an allergic reaction include rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

Risks of Physical Therapy

Risks of PT include:

- Locking in your hip
- Muscle pain in the knee, hip, back, or neck
- Injury to tendons or ligaments

Unknown Risks

There may be other risks of this study that are currently unknown. We will tell you if we learn any significant new information about risks that may affect your willingness to stay in this study.

What are the possible benefits from being in this research study?

You may or may not benefit from taking part in this study. Whether you are assigned to PT alone or surgery and PT, it is possible that the pain in your hip might improve. The information from this study may help us to give the best treatment to future patients with tears of the acetabular labrum.

What other treatments or procedures are available for my condition?

You do not have to take part in this study to receive treatment for your acetabular labral tear. You can receive PT and surgery outside of the study.

Will I be paid to take part in this research study?

You will not be paid to take part in this study.

What will I have to pay for if I take part in this research study?

You and your insurance company will be responsible for the cost of the surgery and/or physical therapy you receive in this study because this would be needed for your care even if you are not in the study.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Giving you care does not mean that Partner's Hospitals or researchers are at fault, or that there was any wrongdoing
Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Scott D. Martin, M.D., Associate Professor of Orthopedic Surgery at Harvard Medical School is the person in charge of this research study. You can call him at (617)-732-5329, Monday through Friday from 9 a.m. to 5 p.m. He can be reached during evenings and on weekends by calling (617)-732-6660 at pager number 16414. You can also call Dr. Clare Safran-Norton, PT, PhD, OCS at 617-732-5304, Monday through Friday from 9 a.m. to 5 p.m. with questions about this research study.

If you have questions about the study, you can call the research coordinator at 617-643-0886, Monday through Friday from 8:30 a.m. to 5:00 p.m.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research

- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)

- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.

- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent _____ Date/Time _____

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject _____ Date/Time _____

Consent Form Version: 7.7.19 PA