**Collaborator IRB Packet**

[Retro versus Trans Articular Drilling for Juvenile Osteochondritis Dissecans of the Knee: A Multicenter, Randomized Controlled Study](http://rc-cherpprod/CHERP/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5bE636BC125E4B0A4F8D5FED00DE41BD9A%5d%5d)

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**Protocol**

**TITLE:** [Retro versus Trans Articular Drilling for Juvenile Osteochondritis Dissecans of the Knee: A Multicenter, Randomized Controlled Study](http://rc-cherpprod/CHERP/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity%5bOID%5bE636BC125E4B0A4F8D5FED00DE41BD9A%5d%5d)

**A. Specific Aims/Objectives**

The purpose of this study is to compare the clinical, functional, and radiographic outcomes associated with trans-articular drilling versus retro-articular drilling, two commonly employed techniques of operative treatment for stable forms of juvenile osteochondritis dissecans (JOCD) lesions. This study also aims to better define the natural history of this condition in its most commonly identified pathological state (as a stable lesion) following surgical intervention by determining the rate of radiographic healing and any need for secondary surgery.

**B. Background and Significance**

Osteochondritis Dissecans (OCD) of the knee is a localized pathologic process in which an area of subchondral bone undergoes metabolic changes or diminished blood supply and may progress to separate, along with its overlying cartilage, from the surrounding bony tissues. Paget first described it as a “quiet necrosis” in 1870 ([Paget 1870](#_ENREF_25)) and Konig later coined the term ‘OCD’ in 1888 ([Konig 1887-1888](#_ENREF_20)). Despite the historical recognition of the entity, its precise etiology and natural history remain largely speculative. While ischemia, genetics, acute trauma, and inflammation have all been postulated in the past, increased youth participation in sports and the rising incidence rate of OCD in skeletally immature athletes support a theory of overuse and repetitive microtrauma ([Cahill, Phillips et al. 1989](#_ENREF_6); [Flynn, Kocher et al. 2004](#_ENREF_11); [Donaldson and Wojtys 2008](#_ENREF_9)). OCD lesions may be identified at various points along a pathologic spectrum, ranging from bone changes or mild softening of the overlying articular cartilage to frank osteochondral separation and loose body formation ([Hughston, Hergenroeder et al. 1984](#_ENREF_15)). Knee OCD is generally detectable radiographically, but newer magnetic resonance imaging (MRI)-based classification systems describe low-grade lesions appreciable only through advanced imaging ([Hefti, Beguiristain et al. 1999](#_ENREF_14)). Most (70-80%) OCD lesions are located in the postero-lateral aspect of the medial femoral condyle, with less than 30% of cases appearing at others sites in the knee, which may include the lateral femoral condyle, patella or trochlear groove ([Kocher, Tucker et al. 2006](#_ENREF_19)).

Treatment of JOCD can include conservative and/or surgical management. Failure of a stable lesion (one that has intact overlying cartilage) to demonstrate radiographic healing and persistence of clinical symptoms despite non-operative measures for 3 to 6 months, which is not uncommon, are indications for surgical intervention ([Flynn, Kocher et al. 2004](#_ENREF_11)). While lesions that prove to be unstable on intra-operative inspection generally undergo fixation, arthroscopically confirmed stable OCD lesions generally undergo drilling by one of two techniques, trans-articular or retro-articular drilling. Both techniques are designed to create channels into subchondral bone for revascularization and bony union of the osteochondral fragment. Trans-articular (also referred to as ‘retro-grade’ or ‘intra-articular’ in the past) drilling penetrates the articular cartilage through multiple sites to create subchondral penetrations. Concerns with this technique involve the uncertain long term implications for cartilage health created by articular cartilage drill sites. By contrast, retro-articular (also referred to as antero-grade’ or ‘extra-articular’ in different reports) drilling spares the articular surface and physes by drilling through the cortical margin of the affected condyle. However, the technique necessitates fluoroscopic guidance and its technical difficulty raises the risk of incomplete lesion drilling, possible displacement of the OCD fragment and/or inadvertent soft tissue injury around the knee.

We hypothesize that there is no difference in short term outcomes between these techniques and propose a prospective, multi-center randomized equivalence trial to compare the two procedures. Robust demonstration of clinical equivalence could have a significant impact on surgical treatment of JOCD, and may represent compelling evidence to utilize the retro-articular technique, which avoids damage to the native articular cartilage, in place of trans-articular techniques.

**C. Preliminary Studies**

Currently, few high quality studies exist to guide clinicians on most diagnostic, prognostic and therapeutic decisions. In 2009, the American Academy of Orthopaedic Surgeons established a committee (eight members of which are surgeons who will be investigators for the proposed trial) and sponsored development of the Clinical Practice Guideline (CPG) for “The Diagnosis and Treatment of Osteochondritis Dissecans of the Knee” ([Chambers, Shea et al. 2011](#_ENREF_8)). The committee conducted a systematic review, between May 2009 and March 2010, of the best available literature related to OCD and formulated 16 recommendations. The evidence was deemed to be ‘inconclusive’ for 10 of the recommendations and ‘weak’ for 2 recommendations. Four of the recommendations could not be based on evidence available from the literature, but the committee felt there was substantial clinical importance to support the recommendation based on ‘consensus’ by the group. The inability of this group to develop a strong, evidence-based CPG for this condition demonstrates the obvious need for more rigorous research on this topic.

Despite the lack of definitive evidence, several trends regarding non-operative management of JOCD have emerged from the available literature. JOCD lesions with intact overlying cartilage (stable lesions) may respond well to non-operative measures including activity modifications, restricted weight bearing and knee immobilization, though controversy exists regarding which methods and for what duration they should be prescribed. The effectiveness of these measures varies greatly with studies reporting radiographic healing at rates ranging from over 90% ([Linden 1977](#_ENREF_22); [Sales de Gauzy, Mansat et al. 1999](#_ENREF_27)), to less than 60% ([Cahill, Phillips et al. 1989](#_ENREF_6); [Pill, Ganley et al. 2003](#_ENREF_26); [Wall and Von Stein 2003](#_ENREF_28); [Cepero, Ullot et al. 2005](#_ENREF_7)). Additionally, successful non-operative treatment may take up to 6 to 18 months to achieve healing, which can lead to atrophy, stiffness, and poor treatment adherence, thereby complicating a patient’s course and precluding normal activities of daily living and delayed returns to athletic participation ([Hughston, Hergenroeder et al. 1984](#_ENREF_15); [Cahill, Phillips et al. 1989](#_ENREF_6); [Aglietti, Buzzi et al. 1994](#_ENREF_2); [Hefti, Beguiristain et al. 1999](#_ENREF_14)).

To date, the available evidence on surgical technique has been limited largely to retrospective level IV case series, with no studies directly comparing the two techniques. Comparisons of level IV reports have demonstrated no large differences in rates ofx-ray healing for JOCD lesions (defined as resolution of the lesion’s sclerotic rim and/or resolution of the radiolucent zone behind the OCD lesion) drilled by retro-articular or trans-articular techniques, with respective healing rates of 86% ([Kocher, Micheli et al. 2001](#_ENREF_18)) and 91% ([Edmonds, Albright et al. 2010](#_ENREF_10)) in two of the largest series. Of the 12 studies using x-ray to examine lesion healing, seven also reported results on *time to healing* ([Aglietti, Buzzi et al. 1994](#_ENREF_2); [Anderson, Richards et al. 1997](#_ENREF_3); [Kocher, Micheli et al. 2001](#_ENREF_18); [Kawasaki, Uchioa et al. 2003](#_ENREF_17); [Donaldson and Wojtys 2008](#_ENREF_9); [Adachi, Deie et al. 2009](#_ENREF_1); [Edmonds, Albright et al. 2010](#_ENREF_10)). One study using a retro-articular approach ([Edmonds, Albright et al. 2010](#_ENREF_10)) reported healing as a percentage, by comparison of preoperative and postoperative radiographs. Using this definition, lesions would require considerably more time to achieve “100% healing”. Within the remaining 6 studies, JOCD lesions drilled trans-articularly healed an average 0.8 months sooner than lesions treated with retro-articular techniques.

There have been few reports of complications related to retro-articular or trans-articular drilling in any of the major studies that specifically describe drilling outcomes. Of the 13 studies included in the Research OsteoChondritis of the Knee (ROCK) study group’s unpublished systematic review, 8 reported no perioperative complications ([Bradley and Dandy 1989](#_ENREF_5); [Aglietti, Buzzi et al. 1994](#_ENREF_2); [Anderson, Richards et al. 1997](#_ENREF_3); [Donaldson and Wojtys 2008](#_ENREF_9); [Adachi, Deie et al. 2009](#_ENREF_1); [Hayan, Gicquel et al. 2009](#_ENREF_13); [Edmonds, Albright et al. 2010](#_ENREF_10); [Ojala, Kerimaa et al. 2011](#_ENREF_24)) and 5 did not report on complications ([Guhl 1979](#_ENREF_12); [Lee and Mercurio 1981](#_ENREF_21); [Kocher, Micheli et al. 2001](#_ENREF_18); [Kawasaki, Uchioa et al. 2003](#_ENREF_17); [Louisia, Beaufils et al. 2003](#_ENREF_23)). All studies lacked follow-up of a duration sufficient to assess development of degenerative joint disease, lesion recurrence, or limitations in long term function or activity level.

A variety of approaches to reporting outcome of OCD have been used, some of them centered around non-validated metrics, and none of them with measures validated for use in children, despite the study populations being mostly under 18 years of age. Four of the 13 studies that were deemed appropriate for systematic review on both retro-articular and trans-articular drilling reported results using pain scores ([Lee and Mercurio 1981](#_ENREF_21); [Bradley and Dandy 1989](#_ENREF_5); [Aglietti, Buzzi et al. 1994](#_ENREF_2); [Edmonds, Albright et al. 2010](#_ENREF_10)) and two studies defined their own patient-oriented outcome scales ([Guhl 1979](#_ENREF_12); [Donaldson and Wojtys 2008](#_ENREF_9)). Validated composite scores were used in the remaining studies; six studies used the Hughston clinical score ([Anderson, Richards et al. 1997](#_ENREF_3); [Kawasaki, Uchioa et al. 2003](#_ENREF_17); [Louisia, Beaufils et al. 2003](#_ENREF_23); [Adachi, Deie et al. 2009](#_ENREF_1); [Hayan, Gicquel et al. 2009](#_ENREF_13); [Ojala, Kerimaa et al. 2011](#_ENREF_24)), one study used the International Knee Documentation Committee form (IKDC) ([Anderson, Richards et al. 1997](#_ENREF_3)), and three studies used the Lysholm score ([Kocher, Micheli et al. 2001](#_ENREF_18); [Kawasaki, Uchioa et al. 2003](#_ENREF_17); [Adachi, Deie et al. 2009](#_ENREF_1)). Studies using a retro-articular technique reported a total of two poor outcomes and one failure. The two studies using a trans-articular technique reported a total of one poor result. Lysholm scores were used to evaluate outcomes for JOCD lesions in two studies using retro-articular techniques (35 lesions) ([Kawasaki, Uchioa et al. 2003](#_ENREF_17); [Adachi, Deie et al. 2009](#_ENREF_1)) and one study using a trans-articular technique (30 lesions) ([Kocher, Micheli et al. 2001](#_ENREF_18)). All three studies reported high final Lysholm scores.

In 2008, an international multicenter study group was formed with the goal of improving the understanding, diagnosis and treatment of, and outcomes associated with OCD of the knee. The group, known as ROCK (Research OsteoChondritis of the Knee), is made up of 15 orthopaedic sports medicine and pediatric orthopaedic surgeons at 13 clinical centers across North America, as well as several musculoskeletal radiologists, physical therapists and PhD researchers. A major undertaking of this group is to develop and validate plain radiograph, MRI and arthroscopic classification systems that will ultimately be used by the group to standardize all future research on this condition. Specifically in preparation for the proposed study, ROCK members completed a review of the literature related to trans-articular and retro-articular drilling techniques. Of the 65 studies reviewed, only 13 met the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria for inclusion in the review. The dearth of publications based on higher levels of evidence and the inability of the AAOS committee to develop robust CPG recommendations have served as a major impetus for the ROCK group to carry out rigorous, prospective multicenter studies.

**D. Design and Methods**

1. **Study Design**

Prospective multi-center randomized trial comparing retro-articular and trans-articular drilling techniques for surgical management of stable JOCD.

1. **Patient Selection and Inclusion/Exclusion Criteria**

To be eligible for this study, a patient must meet all of the following criteria:

* Diagnosis of JOCD,
* Lesion located on the lateral aspect of the medial femoral condyle,
* Lesion considered stable, based on MRI,
* Patient deemed skeletally immature based on: 1) MRI or 2) bone age film (female <16 years, male <14 years) Patients will therefore be between the ages of 8 and 18 years.
* Completed a course of conservative therapy

To be eligible for this study, a patient must meet none of the following criteria:

* Lesion healed sufficiently and surgery is not recommended,
* Prior surgery on the affected knee,
* Diagnosis of metabolic bone disorder (e.g. osteogenesis imperfecta),
* Diagnosis of sickle cell disease,
* History of prolonged corticosteroid or chemotherapy treatment,
* Who undergo a surgical technique involving lesion fixation of any type, and not simply drilling, will not be eligible for this study.

**(3) Description of Study Treatments or Exposures/Predictors**

The ROCK group surgeons met formally to discuss details of the trial and develop standardized treatment protocols (outlined below) to reduce variability across sites/physicians. Additionally, forms for each of the treatments/exposures/predictors listed below will be developed by the ROCK group to ensure the same protocols are followed and the same information is collected by each surgeon.

*Conservative Therapy*. All patients will be required to complete an acceptable course of conservative therapy before surgical treatment and official study participation can be offered. The standardized therapy regimen agreed upon by the group requires 3 continuous months of avoidance of athletic activity/participation *and* one of the following:

* Minimum of six weeks of cylinder casting, OR
* Minimum of six weeks of locked extension hinged-knee bracing OR
* Minimum of six weeks non-weight bearing with crutches, OR
* Some combination of the above 3 options for a minimum of 6 weeks

Patients who heal over the course of conservative therapy are not eligible for the study.

*Operative Management*. All patients will undergo surgery according to their surgeons’ preferred general technique of room setup, sterile prep and drape, and diagnostic arthroscopy; however, the surgical drilling technique performed will be determined by randomization. (Only cases that involve drilling alone as the surgical treatment will be included; cases that involve fixation of any type will be excluded.) Below are the standardized features of each surgical technique.

* *Trans-articular drilling*:
  + Drilling must be performed, under arthroscopic visualization, directly through the articular cartilage, with no additional drilling in ‘retro-articular’, ‘extra-articular’, or trans-condylar (through the intercondylar notch) fashion
  + Use of a 0.045 K-wire for drilling (currently, most commonly used wire size amongst the study surgeons)
  + A minimum 4 wire passes per square centimeter (to insure adequate disruption of sclerotic bone margin of OCD lesion), with a maximum of 5 wire passes per square centimeter (to prevent unnecessary disruption of the articular cartilage)
* *Retro-articular drilling*:
  + Drilling must be performed under AP and lateral fluoroscopic guidance, as described by Edmonds et al. ([Kocher, Micheli et al. 2001](#_ENREF_18); [Edmonds, Albright et al. 2010](#_ENREF_10)) and Boughanem et al. ([Boughanem, Riaz et al. 2011](#_ENREF_4)), with no additional drilling in ‘trans-articular’, or intra-articular trans-condylar fashion. Use of a 0.045 K-wire for drilling (as described by Boughanem et al. ([Boughanem, Riaz et al. 2011](#_ENREF_4)), thereby providing standardization of instrumentation between the two groups)
  + Minimum of 8 wire passes per square centimeter (to insure adequate disruption of sclerotic bone margin of OCD lesion) with no maximum number of wire passes (as additional wire passes are not theorized to be disruptive to the health of the articular cartilage, as described in previous techniques ([Kocher, Micheli et al. 2001](#_ENREF_18); [Boughanem, Riaz et al. 2011](#_ENREF_4)).

Patients who end up needing fixation due to the finding of an unstable lesion and do not undergo drilling, or who undergo the drilling technique that was NOT indicated on the randomization card will no longer be eligible for the study.

*Standardized Postoperative Physical Therapy*. All patients will be prescribed formal outpatient physical therapy, beginning within one week of surgery, to include the following features:

* Weeks 0-6: Non-weight bearing with crutches.
* After 6 weeks: weight-bearing as tolerated.
* Due to variability in institutional resources and insurance coverage amongst patients, continuous passive motion (CPM) machines, hinged knee braces, and pool therapy will not be used
* When non-weight bearing, patients will be allowed full range of motion of the affected knee, strength training will be allowed within the weight-bearing guidelines, including stationary bike on low resistance
* Recreational swimming following confirmation of wound healing (minimum 2 weeks post-op) will be allowed, but breast stroke and ‘whip kicks’ will not be permitted

We expect that each surgeon will contribute approximately 5-10 patients to the study for a total of around 120 study subjects. Surgeons at larger institutions may contribute more based on seeing more JOCD patients, so we expect that around 10-15 will be enrolled from Children's Hospital Boston.. The randomization of the surgeries will be done by surgeon so that each surgeon performs both the retro-articular and trans-articular drilling techniques throughout the course of the study in approximately equal numbers. Participants will be randomly allocated at the time of surgery to their treatment group via a secure web portal accessed by the surgeon or site designee. At the beginning of the study, every surgeon will be given the information to access a secure web portal that will carry out the randomization and surgical forms for both types of surgery to fill out for each surgery accordingly.

The surgeon maintains the right to do what he/she deems best during the surgery, and may deviate from the surgery indicated by randomization if the lesion is found to be unstable and needs to be treated with pinning (patient no longer eligible), if there are any unforeseen complications, or the technique indicated by randomization proves to be more challenging and risky than the other option.

1. **Definition of Primary and Secondary Outcomes/Endpoints**

Primary Outcome:

* Physical functioning at one year post-surgery as measured by the Pedi-IKDC total score

Secondary Outcomes:

* Physical functioning at two years post-surgery as measured by the Pedi-IKDC total score
* Activity level as measured by the Marx Activity Scale
* Pain level as measured by Pedi-IKDC

Additionally, we will use information collected from the follow-up clinical assessments, x-rays, and MRIs to assess healing and complications.

1. **Data Collection Methods, Assessments, Interventions and Schedule (what assessments performed, how often)**

Patients that agree to participate will complete a minimum of eight clinic visits and one surgical visit during the trial. The schedule of follow-up visits was designed to correspond with standard postoperative clinical visits so that patients do not have to complete additional visits solely for research. We will consent patients once they have been identified as eligible and completed their course of conservative therapy. Randomization will occur immediately prior to the surgery in the OR. The table below outlines the visit schedule and measures to be completed at each visit.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **Baseline** | **Postoperative Follow-Up** | | | | | | |
| **Time 0** | **6 wks** | **3 mos** | **6 mos** | **9 mos** | **1 yr** | **18 mos** | **2 yrs** |
| Medical history | X |  |  |  |  |  |  |  |
| Physical exam | X | X | X | X | X | X | X | X |
| X-ray | X | X | X | X | X | X | X | X |
| MRI | X |  |  | X1 |  | X1 |  | X1 |
| Bone Age | X |  |  |  |  |  |  |  |
| Questionnaires | X |  |  | X |  | X |  | X |

X1 – performed at centers where MRI is considered standard of care, and at other centers if clinically indicated

*Medical History and Physical Exam*. At the baseline visit, when the subjects are identified and consented, or another following pre-surgical clinic visit, surgeons will complete a standard medical history and perform a physical exam. Pre- and post-operative physical exams will include evaluation of the affected knee’s range of motion (with comparison to the contralateral knee), presence or absence of effusion and mechanical signs (such as clicking, snapping, or locking during range of motion testing).

*Plain Radiographic Assessment of the Knee*. Standardized knee radiographs with 3 views (AP supine, lateral supine, tunnel/notch supine) will be obtained at baseline and at every postoperative follow-up visit. These will be read immediately by the surgeon to guide clinical management of the patient and later by one of the designated study radiologists. Radiographs will be used to assess and describe characteristics of the OCD lesion such as size, location and healing status.

* *Assessment of Healing*. Healing will be determined by the findings on serial radiographs by the study radiologists only. A lesion will be deemed to be “healing” if the previously radiolucent area of the lesion shows progressive radio density in any view to more closely resembles the surrounding normal/healthy bony. A lesion will be deemed to be “healed” if the previous site of the margins of the lesion are indistinct/identical to the surrounding normal/healthy bone in all three views.

*MRI Assessment of the Knee*. MRIs will be performed at baseline for every patient to confirm study eligibility, i.e., stability of the lesion and skeletal immaturity. Patients enrolled at clinical centers where MRI is considered standard of care during the postoperative period will undergo an MRI at 6 months, 1 year and 2 years. Centers that do not do standard postoperative MRIs will order them for study patients only when it is clinically indicated.

* *Diagnosis of JOCD*. The diagnosis of juvenile OCD will be based on MRI findings, as described by Kocher et al. ([Kocher, Tucker et al. 2006](#_ENREF_19)) and Flynn et al. ([Flynn, Kocher et al. 2004](#_ENREF_11)).
* *Assessment of Skeletal Maturity*. Patients will be deemed “skeletally immature” if continuously open physes are seen on all coronal and sagittal MR images.
* *Assessment of Lesion Stability*. Lesion stability, for the purpose of study eligibility, will be determined based on MRI findings, which may include features described for Type 1, Type 2 or Type 3 lesions, as described by Hefti et al. ([Hefti, Beguiristain et al. 1999](#_ENREF_14)).
* NOTE: Each surgeon will be required to assess lesion stability intra-operatively, by probing the lesion, to confirm the absence of a breach in the articular cartilage at the margin and the absence of motion of the lesion. Patients who are randomized, but during surgery are found to have an unstable lesion, will be withdrawn from the study. The rationale for withdrawal is that these patients will require a different type of surgical intervention.

*Bone Age.*A bone age scan of the hand will be obtained at baseline to ensure the patients have a bone age appropriate for the parameters of this study as listed in D(2).

*Outcome Questionnaires*. A battery of three outcome questionnaires will be self-administered, filled out by patients at every study visit, and should not take more than 30 minutes to complete.

* *Pedi-IKDC.* The Pedi-IKDC form will be used to evaluate knee symptoms and function.
* *Marx Activity Scale*. The Marx Activity Scale will be used to assess patient activity level.
* *Lysholm*. The Lysholm will also be used to assess knee symptoms and function. Although this instrument is not validated for use in children, it will be used in this study specifically so that our results can be compared to those obtained in previous studies.
* *HRQOL*. We will use part of this questionnaire to assess quality of life.

*Need for Secondary Surgery*. The number and type of additional surgeries that may be pursued for the affected knee following drilling surgery will be recorded and analyzed.

All radiographs, MRIs, and other imaging records completed during the study period will be read locally for clinical purposes but will also be read centrally for research. Each clinical center will be responsible for deidentifying their imaging studies and sending them to the Core Laboratory for central reading by one of the two study/ROCK musculoskeletal radiologists. They will conduct all formal research-related readings for the trial.

Additionally, ROCK is starting an OCD registry in which these patients will have the option to be included. An additional consent form will be given to patients to be included in the registry.

1. **Study Timeline (as applicable)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Task** | **AOSSM Grant** | | **ROCK Group Funding** |
| **Year 1** | **Year 2** | **Year 3** |
| Accrual and surgery |  |  |  |
| Complete through 1-Year visit *(analyze primary outcome, Pedi-IKDC, and secondary outcomes)* |  |  |  |
| Complete 2-Year visit |  |  |  |

**E. Adverse Event Criteria and Reporting Procedures**

The monitoring of adverse events will be conducted on an ongoing basis for the duration of the study. If an adverse event occurs, it will be reported immediately to the IRB and the investigators will re-assess the risk/benefit ratio of the study and submit any modifications deemed necessary to the IRB for approval.

**F. Data Management Methods**

Every center participating in the trial has a research coordinator on staff that will be responsible for screening and consenting patients, collecting and scanning/entering data, and deidentifying and sharing data with the data coordinating center (see paragraph below). Each institution will be given an identifying number, which will be the beginning of each patient’s study identification number. Therefore, the patient study identification numbers will be linked to the patients’ institution and MRN. Each surgeon will also be given a study identification number. Only members of the study group at each institution will have access to the links, which will be destroyed once all of the data is collected.

The ROCK group has finalized plans for the implementation of a multicenter database system, RedCAP, which is fully HIPPA compliant. The DCC for the trial (Boston Children’s Hospital) will have a full-time research coordinator performing data management services for all ROCK data, including data collected for this trial, such as surgeon procedure forms, de-identified radiological imaging files, and patient-based questionnaires. Sites can enter their own data into RedCAP, however Boston Children’s Hospital will be checking this data once sites send their data to Boston for quality purposes.

At the local level, all hard copies of questionnaires patients fill out or forms that the surgeons or research staff fills out with identifying information on it will be stored in a locked research cabinet in the principle investigators office at Children’s Hospital Boston and entered into databases only accessible by members of the research staff. A subject's identity on these records will be indicated by a study ID number (a unique identification number created using an algorithm the study administrators will define) rather than by name and the information linking these study ID numbers with the subjects identity will be separate from the research records and research databases. Only the researchers listed in this protocol will have access to a subject's research records, with the exception of the informed consent from, a copy of which will be kept in the medical record of each subject as this study involves a treatment based protocol.

**G. Quality Control Method**

Procedures for all care have been developed by ROCK as mentioned in section D3 and D5. This was done to limit potential complications and between-surgeon and between-institution differences that might otherwise occur. As previously mentioned, upon finding out which surgery will be performed by the randomization envelope, the surgeon will also be provided with a surgical form for the surgery indicating the standards of each procedure to follow and fill out.

All radiographs and MRIs completed during the study period will be read locally for clinical purposes but will also be read centrally for research purposes to standardizing readings. Each clinical center will be responsible for deidentifying their imaging studies and sending them to the Core Laboratory (University of Cincinnati) for central reading by one of the two study/ROCK musculoskeletal radiologists. They will conduct all formal research-related readings for the trial.

**H. Data Analysis Plan**

Interpretation of the results will focus primarily on a two sided 95% confidence interval for the difference in Pedi IKDC means at 12 months, based on the t distribution. Equivalence will be interpreted as the entire CI lying within ±11.5, the assumed margin of equivalence based on Irrgang (Irrgang, Anderson et al. 2001). Unlike superiority trials, an intention to treat (ITT) analysis in an equivalence trial typically inflates Type I error so both per protocol (ITT) and per treatment analyses will be conducted. The results will not be considered definitive if conclusions disagree. If equivalence is not rejected we will test for superiority, with a two-sided t test.

While there may be patient characteristics that are associated with the outcome, including age (independent of skeletal immaturity), lesion size (although we do not expect large variation in lesion size between patients), surgeon, and contralateral lesion, we expect that the randomization process will distribute these and other covariates evenly across the two surgical groups. Stratification of the randomization by site will partially control for surgeon variation. We will examine possible imbalances of several characteristics between the two groups and will explore the associations between patient characteristics and outcomes using multiple regression, with a view toward adjusting the estimated treatment effect for potential confounders using linear regression. (A factor cannot confound the treatment effect unless it associated with the outcome and is also imbalanced between groups.) The effects of patient characteristics is not a primary aim of the study, and there will be no adjustment for multiple testing in the regression analyses although results will be interpreted cautiously.

Analogous analyses will be conducted for secondary endpoints. In addition, repeated measures models will be used to assess outcome trajectories over time and how relative treatment effects change over the two year follow up period.

**I. Statistical Power and Sample Considerations**

The study is designed as an equivalence study, with the aim of showing that trans articular drilling and retro articular drilling have similar outcomes. The Pedi IKDC total score at 12 months is the primary outcome. We use a difference in means of ±11.5 points as the margin of equivalence, based on Irrgang (Irrgang, Anderson et al. 2001), and assume a within-group standard deviation (SD) of 21 points, based on normative data from subjects with problems in both knees (Anderson 2006).In order to reject a difference of ±11.5 points with a two sided α=.05 t test and 80% power requires 54 patients per group or 108 total. Assuming a 10% dropout, we will target 120 patients.

**J. Study Organization**

This is a multicenter study. As previously mentioned, while individual sites are responsible for data collection and management, all data (deidentified) will be entered and stored in RedCAP with oversight from Boston Children’s Hospital. The principal investigator will conduct an evaluation of the progress of the research study on a monthly basis including assessments of data quality and timeliness, participant recruitment, accrual, and retention, and outcomes and adverse events to determine whether there is a need to reassess the original benefit-to-risk ratio of study participation. Thus, the study will maintain proper organization and follow the steps outlined in this protocol.

**K. References**

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**Informed Consent Form**

**Why is this research study being conducted; What is its purpose?**

You are being asked to be in this research study because you have Osteochondritis Dessicans (OCD). Some patients with OCD may need to on to surgical treatment if rest and physical therapy do not work well enough. Your doctor has recommended that you have surgery.

OCD is caused by a reduced blood supply to a small area of bone just beneath the cartilage. This loss of blood flow can cause the bone to become weaker or, at times, can create a piece that separates from the rest of the healthy bone.

There are two surgical methods that are seen as equally successful in treating OCD. In each, the surgeon makes tiny channels that allow more blood to flow to the affected area, which improves healing. The differences in the

methods are in where the channels are made and in how the surgeon sees the area during surgery. Each technique may have different advantages and disadvantages:

• Using one method, called the “trans-articular technique,” the surgeon makes tiny channels through the cartilage directly into the damaged bone with direct vision of the area using arthroscopy. This method is not seen as damaging to the cartilage, but there is concern about the long-term health of the cartilage.

• Using the other method, called the “retro-articular technique,” the surgeon makes tiny channels from behind through the healthy bone and stops just before reaching the cartilage. This technique uses x-ray to see the area during the surgery instead of direct visualization.

The main goal of the research study is to compare how patients do after surgery when each of these techniques is used so that we can better understand the advantages and disadvantages associated with each technique.

**Who is conducting this research study, and where is it being conducted?**

This study is being partially funded by the American Orthopaedic Society for Sports Medicine (AOSSM) and will be conducted at Children's Hospital Boston (CHB) and the 12 other medical centers across the United States and Canada that make up the Research in OsteoChondritis Dissecans of the Knee (ROCK) group, an international multi-center study group created to improve treatment of OCD. The Principal Investigator is Dr. Benton Heyworth, in the Department of Orthopedic Surgery at CHB, who is a member of the ROCK group.

**How are individuals selected for this research study? How many will participate?**

To be in this study, patients must have Juvenile OCD, meaning that they have open growth plates in their knee(s). Patients must also be between the ages of 8 and 16 years and have an OCD site that is stable and located at the end of the thigh bone.

Patients must also have completed a minimum of six weeks of non-operative therapy before they can enroll in this study. Eligible participants are identified by their attending physician or by members of the research staff through clinic schedule and chart review.

The goal is to enroll a total of 120 patients in total from all centers. At Boston Children's Hospital, we expect that 10-15 patients will be enrolled from here.

**What do I have to do if I am in this research study?**

If you/your child are eligible and choose to participate, all of the clinical care that you/your child receive will be standard for the treatment of OCD, meaning that it is exactly what would happen if you decided not to be in this study.

The schedule of visits for the study is designed to match up with your normal clinical care so that you/your child will not have to make additional visits just for research and there will be no additional costs as a result of participation.

What will be different is that you will be randomized (like flipping a coin) to determine which method the surgeon will use and that you will be asked to fill out questionnaires several times.

There are seven visits during which we are interested in collecting data: one before the surgery, when you/your child give consent to be in this study; one surgical visit; and five post-operative visits. All clinic visits and surgeries will be completed at Boston Children’s Hospital, or at one of the Boston Children’s Hospital satellites depending on which office you/your child usually visit.

On the first visit as a study member (today), you/your child will be consented to participate and asked to fill out several questionnaires. Together, these questionnaires should take no longer that 15 minutes to complete, and can be completed while waiting to see your/your child’s doctor so will not add time to the visit. They will contain questions about your knees and how your injury affects your daily life.

Your/your child’s next visit will be for surgery. The surgery you/your child receives, either trans-articular or retro-articular drilling, will be randomly decided. Randomization will happen on the day of your/your child’s surgery. All surgeons are trained and familiar with both types of surgery.

If your surgeon decides during surgery that the technique assigned by randomization is not the best choice because a screw or pin needs to be used, the surgeon will pick the technique (s)he thinks is best. The need to

use a screw or pin will mean that you are no longer eligible to be in the study. The surgeon may also decide not to use the randomized technique if (s)he decides during surgery that the use of this technique is not in your best interest.

If you/your child undergo surgery without the use of pins or screws, participation will continue. The only part of your/your child’s follow-up care that will be different than usual will be filling out the questionnaires; everything else will be the same as if you/your child were not in the study. Please see the chart below for a schedule of follow-up care.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Measure** | **Baseline** | **Post-operative Follow-Up** | | | | |
| **Time 0** | **6 wks** | **3 mos** | **6 mos** | **1 yr** | **2 yrs** |
| Medical history | X |  |  |  |  |  |
| Physical exam | X | X | X | X | X | X |
| X-ray | X | X | X | X | X | X |
| MRI | X |  |  | X |  | X |
| Bone Age | X |  |  |  |  |  |
| Questionnaires | X |  |  | X | X | X |

Some people have OCD in both knees and require surgery on each. If you/your child need to have surgery on the second knee because of OCD and that knee is also eligible to be followed in this study, we will also collect data for and follow the progress of that knee. Like the first knee, this will not require that you complete any extra visits or testing. Study visits will take place according to the schedule listed above. You/your child does not need to participate in this trial with the second knee if you/your child do not want to. If you/your child decide to participate in this trial with the second knee, you/your child will sign a new consent form.

We expect that it will take about one year to recruitment and enroll the number of patients we hope to, about one year to complete all of the surgeries, and about two years to complete all follow-up visits. Over all, your/your child ‘s involvement will take around 2 years, approximately the same length your/your child’s care for OCD would take should you/your child decide not to participate in the study.

**What are the risks of this research study? What could go wrong?**

Briefly, trans-articular drilling may lead to less healthy cartilage in the long term because the cartilage is being drilled through. Retro-articular drilling runs the possible risk of not drilling in the best location because the surgeon is using x-rays to see the area. In addition, there are potential risks associated with x-rays. For both techniques, the benefits include a healed OCD lesion.

You/your child will not be exposed to any additional physical risk because of participation in this study. You/your child will receive the same care as a patient who is not in the study. The only differences will be that the technique used will be decided by randomization and that you will be asked to fill out questionnaires. There are risks and benefits associated with both retro-articular and trans-articular drilling, but they are neither increased nor decreased by being in this study. There is also a risk of a breach of confidentiality associated with collecting information from patients for the registry. This would occur if a person gained access to any information he or she was not supposed to have access to, and could include identifiable or non-identifiable information being shared with a person at Boston Children's Hospital or a participating institution, or any other person, who is not involved with the study, or identifiable information being shared with people at participating institutions who are involved with the study. The research staff associated with this study will take all possible precautions to prevent this. All printed copies of study materials will be kept in locked cabinets by the coordinator. All digital records will be kept by the study coordinator in files only he/she has access to. All databases constructed for this study will be de-identified with each patient getting a unique study ID, and only research staff at Boston Children's Hospital will have access to the link between your/your child’s name and study ID, and therefore to your/your child’s personal information. In this manner it will be unlikely that others within the hospital, an insurance company or employer would ever learn of your/your child’s participation.

**What are the benefits of this research study?**

Your child will likely not receive any direct benefit from participating in this study. We hope that the data collected as part of this study will allow us to determine if one of the surgical drilling techniques being investigated is better than the other. This information would help us provide better care to patients in the future who present with a JOCD lesion.

**Are there costs associated with this research study? Will I receive any payments?**

There will be no additional costs to you/your child and you/your child will not receive any payments as a result of your/your child’s child participating in this study.

**If I do not want to take part in this research study, what are the other choices?**

The choice to participate in this study is completely up to you. You/your child can choose to participate or not to participate and no one will hold it against you/your child either way. The care that you/your child receive at Children's Hospital will be the same, regardless of participation status. Likewise, your/your child’s agreement, refusal, or wish to end participation will not affect your/your child’s future care at Boston Children’s Hospital. This study is an evaluation of the currently accepted treatments for stable JOCD and there are no alternative procedures known to be better than those used in the study that would be available to you/your child if you/your child choose not to participate. At any point during the study, you/your child have the right to terminate your/your child’s participation with no change to your/your child’s care or course of treatment.

**What are my rights as a research participant?**

Once again, know your/your child’s participation in this study is completely voluntary, you/your child have the right to withdraw at any point, and at no point will your/your child’s decision to participate or not, or withdraw, affect the care you/your child receive at Children's Hospital Boston. Whatever your/your child’s decision, there will be no penalty or loss of benefits to your/your child’s care.

We expect that it will take around three years to complete data collection, and we are more than happy to update you/your child to our findings. We will inform you/your child of any changes to the study, or if for any reason the study must be terminated. While we do not expect it, if there are any significant new findings during the course of the research which may relate to your/your child’s willingness to continue participation or affect you/your child positively or negatively, we will let you/your child know.

A copy of this consent form will be provided to you/your child for your/your child’s records. A copy of this consent form will additionally be kept in your/your child’s medical record as this study involves you/your child undergoing surgical treatment, which you/your child is agreeing to, but not obligated to complete, by signing this consent. Inclusion of this consent in your/your child’s medical record will not affect other care.

**Are there other things I should know about?**

The monitoring of adverse events will be conducted on an ongoing basis for the duration of the study. If an adverse event occurs, it will be reported immediately to the IRB and the investigators will re-assess the risk/benefit ratio of the study and submit any modifications deemed necessary to the IRB for approval.

As the lead site, Boston Children’s Hostpital will be collecting deidentified copites of all information collected from all participating sites except for consent forms. This will not affect your participation in the study, your confidentiality or your privacy.

**Why would I be taken off the study early?**

**It is possible that you/your child would be taken off this study early under several circumstances that were mentioned previously, including (1**) your/your child’s lesion is found to be unstable in surgery and you/your child need to undergo pinning, not drilling, (2) the surgical drilling technique you/your child end up undergoing is not the one indicated on the randomization card, or (3) you/your child wish to withdraw from the study.

**Standard HIPAA Language.**

**What information do I need to know about the Health Insurance Portability and Accountability**

**Act (HIPAA)?**

**Who may see, use or share your health information?**

A copy of this consent form will be placed in you/your child’s medical record.

Medical information collected during this study will become part of your/your child's hospital record, if the information is determined to be pertinent to the care you/your child receive at Children's Hospital. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at Children's Hospital and may be reviewed by Hospital staff in their course of carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your/your child's medical record may not be given to anyone unaffiliated with Children's Hospital in a way that could identify you/your child without written consent, except as required or permitted by law. Information collected during the study that does not become part of your/your child's medical record will be stored in separate research files maintained by the investigator. These research records will not be made available to any individuals who arenot part of the research team unless you so request or as required by law. If you/your child withdraw from the research study, information that has already been collected will become part of the research data, however, you/your child will not be identified.

A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov/), as required by U.S. law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at anytime

You/your child’s health information is protected by a law called the Health Information Portability and accountability act (HIPAA). In general, anyone who is involved in this research including those funding and regulating the study may see the data, including information about you. For example, the following people might see information about you:

* Research staff at Boston Children’s Hospital involved in this study

 Medical staff at Boston Children’s Hospital directly involved in your care that is related to the research or arises from it.

 Other researchers and centers that are a part of this study, including people who oversee research at that hospital.

 People at Boston Children’s Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program

 People from agencies and organizations that provide accreditation and oversight of research.

 People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others.

 Sponsors or others who fund the research, including the government or private sponsors.

 Companies that manufacture drugs or devices used in this research.

 Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities

 People or groups that are hired to provide services related to this research or research at Boston Children’s Hospital, including services providers, such as laboratories, and others

 Your health insurer for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children’s Hospital, we cannot promise that it will remain private. If you/your child decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this you may contact the Boston Children’s Hospital Privacy Officer at 857-218-4680 which is set up to help you understand privacy and confidentiality.

Because research is ongoing we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your name or identifying information will not be used without your specific permission.

**Your privacy rights**

If you or your child do not want to participate in this study, you do not have to. If you do want to participate, however, you must sign this form.

If you do not sign this form, it will not affect your care or your child’s care at Boston Children’s Hospital now or in the future and there will be no penalty or loss of benefits. You/your child can withdraw from the study and end your permission for Boston Children’s Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information will need to do so in writing.

You/your child may have the right to get some the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To request the information, please contact the Hospital’s Privacy Officer at 857-218-4680.

**Data Collection Forms**

|  |  |
| --- | --- |
| **Form 1c**  **Screening & Eligibility**  collected on all **Screened** pts  Have these patients fill out 1a as well to get more info asthis is the only data you will have on pts who are ineligible or refuse consent | * Patient ID   Date of screening  INCLUSION CRITERIA  To be eligible for this study, a patient must meet all of the following criteria:   * Diagnosis of JOCD, * Lesion located on the lateral aspect of the medial femoral condyle, * Lesion considered stable, based on MRI, * Patient deemed skeletally immature based on: 1) MRI or 2) bone age film (female <14 years, male <16 years) * Completed a course of ~~conservative~~ non-operative therapy   EXCLUSION CRITERIA  To be eligible for this study, a patient must meet none of the following criteria:   * Any concomitant knee pathology (AVN, fx, inflammatory arthritis) * Lesion healed sufficiently and surgery is not recommended, * Prior surgery for OCD on the affected knee, * Diagnosis of metabolic bone disorder (e.g. osteogenesis imperfecta), * Diagnosis of sickle cell disease, * History of prolonged corticosteroid or chemotherapy treatment, * Eligible (Y/N) * Consent (Y/N)   + If no, why     - Doesn’t want to be randomized     - Lives too far away/will have post-op care closer to home     - Not willing to follow post-op activity restrictions (wants to return to sports)     - Doesn’t want to be in two studies (Registry and RCT)     - No reason given     - Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Form 5b**  **Randomization and Surgery** | * Patient ID * Date of surgery * Surgeon ID * Which surgical technique was patient randomized to (Trans/Retro)   INTRA-OP LESION ASSESSMENT   * Was lesion stable (Y/N) **🡺** *If no, withdraw pt from study (complete Form 8a)* * Did lesion require fixation (Y/N) **🡺** *If yes, withdraw pt from study (complete Form 8a)*   SURGICAL INFORMATION   * Which surgical technique was performed (Trans/Retro)   + If not technique randomized to, why? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Fluoroscopic time during sugery \_\_ \_\_ minutes * Number of total K-wire passes performed: \_\_ \_\_ * WAS OCD lesion inavertantly destabilized/displaced during surgery (Y/N)   + If yes, how far \_\_ \_\_ mm * Were there any iatrogenic chondral injuries (Y/N)   + If yes, how many \_\_   + Size of injury \_\_ \_\_ mm * Did anything happen during surgery that you think may have an adverse effect on healing (Y/N)?   + If yes, describe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Did you notice anything about the lesion or knee, in general, that you think may have an adverse effect on healing (Y/N)?   + If yes, describe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Form 9b**  **Closeout** | * Patient ID * Date form completed * Did patient complete study (Y/N)   + If no, primary reason     1. Lesion found unstable, required fixation during surgery     2. Surgeon request to withdraw (reason:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)     3. Patient request to withdraw (reason:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)     4. Patient lost to follow-up * Date patient completed/withdrew from study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |