**ROCK,** the Osteochondritis Dissecans Research Group, a multi-center study group formed in 2009 to prospectively study this condition. The primary objective of the **ROCK** group is to develop evidence based methods of treatment for this disease that affects a growing number of young, active people. To achieve this goal is we have developed collaborative approaches between institutions, including physicians, research departments and administrators, to develop specialized cartilage treatment centers that would be part of a Center of Excellence for the Treatment of Cartilage conditions.

**SPECIFIC AIMS**

Osteochondritis dissecans (OCD) is a focal condition of an articular surface, which involves separation of a fragment of subchondral bone and often the overlying cartilage as well. This osteochondral fragment may be in situ, incompletely detached, or completely detached at presentation. The knee is the most commonly affected joint (~75%). Symptoms typically arise in the second decade of life. Long-term (>15 year) outcomes of OCD of the knee are frequently poor. Treatment strategies vary widely and are based primarily on retrospective studies and expert opinion.

OCD, while diagnosed most commonly in children and young adults, has a significant lifetime impact on patients and their families. The development of early onset osteoarthritis has significant socio-economic costs. The more we know about the effectiveness of each intervention (non-operative and operative) for all types of OCD lesions, the greater the benefit to the patient. Currently, the best treatment option is unclear in many cases.

The long term goal of our projects is to determine the reasons why therapies for juvenile OCD fail and to use this knowledge to optimize clinical effectiveness of treatments. The overall objective of this application is to capitalize on the prospective multicenter cohort study of patients with an OCD lesion treated either operatively or non-operatively to determine the benefits of treatment with knee unloader bracing to further optimize outcomes that can maximize clinical management strategies for knee OCD. Once the aims of our projects are achieved, we will be positioned to disseminate evidence based treatment algorithms nationwide in order to identify patients who will benefit most from targeted and patient centered intervention for juvenile OCD. Through the innovations in this proposal, patients with knee OCD will be provided with an immediate objective, individualized, and clinically accessible probability ***at the time of diagnosis*** of their likelihood for healing with proposed treatment.

**Specific Aim 1:**  To identify the potential benefits of including unloader bracing as a component of care for knee OCD lesions.

H.1: The inclusion of unloader brace as a component of non-operative treatment of an OCD lesion will demonstrate improved radiographic lesion healing and patient-reported outcomes at 2 years post- treatment relative to patients not treated with unloader brace.

H.2: The inclusion of unloader brace as a component of rehabilitation from surgical treatment for salvageable knee OCD lesions will demonstrate improved radiographic lesion healing and patient-reported outcomes at 2 years post- treatment relative to patients not treated with unloader brace.

H.3: The inclusion of unloader brace as a component of rehabilitation from surgical treatment for non-salvageable knee OCD lesions will demonstrate improved radiographic lesion healing and patient-reported outcomes at 2 years post- treatment relative to patients not treated with unloader brace.

***Detailed Expectations:*** The **ROCK** research previously have published our prognostic algorithm used to determine probability for healing status outcome for patients with juvenile OCD. The *expected outcom*es from the work proposed in these Aims will utilize the highly generalizable multi-center results to optimize the accuracy of previous prognostic algorithms for OCD and will allow for robust identification of patient specific treatments. Following the development and external validation of the clinical prediction algorithms ***we will effectively be positioned to apply patient specific interventions that reduce morbidity associated with the disorder.*** In addition, the created infrastructure afforded with the development of the proposed data server and online prognostic tools will facilitate future innovative multicenter clinical trials to evaluate treatment of OCD and other surgical/medical conditions. Cumulatively, the achieved aims will significantly impact how we treat knee OCD with ease of use and immediate clinically relevant feedback that will foster optimal treatment approaches for children diagnosed with knee OCD.

**Significance**

Juvenile osteochondritis dissecans (OCD) is an acquired condition of skeletally immature children with that affects the subchondral bone and the articular cartilage and can lead to detachment of a bone fragment with its overlying articular cartilage. It occurs in 18-30 per 100,000 patients in the population, but the condition appears to be increasing in incidence, especially in young athletes. Currently, the treatment for juvenile OCD is controversial and difficult to study because the condition is relatively uncommon and progresses slowly. Most importantly, the relative success of non-operative treatments is basically equivocal creating outcome uncertainty at the time of treatment decision making. Specifically, conservative, nonsurgical therapies provide 50%-67% of children with stable OCD healing after 6 to 18 months. It is difficult to accurately predict which children with OCD lesions are destined to fail non-surgical management. Therefore, the patient may undergo over six months of non-surgical treatments, only to find out that they need surgery with another subsequent period of activity restriction. Conversely, some children with stable appearing OCD lesions may miss a surgical window of opportunity for healing that expires during the months of non-operative treatment/observation, leaving them with a lesion that is incurable. It would be extremely beneficial to determine an a priori probability that a patient with juvenile OCD will heal with non-operative treatment.

The fact that only 33-50% of children do not show healing after 6-18 months after non-surgical treatment is chosen suggests that a revised patient specific treatment algorithm may be necessary. Therefore, in order to test our new hypotheses, perform statistically powered, prospective research, and ultimately improve the care for these patients we must collect data from multiple centers. The current proposal is aimed directly at creating an affordable and efficient mechanism to coordinate research between multiple centers and thus provide the framework for comparative effectiveness studies in juvenile OCD. To date, there has never been a prospective study of the operative and non-operative treatment of OCD of the knee, involving skeletally immature and mature patients. Such a study would allow for more precise prognostication and more exact surgical indications.

**INNOVATION**

The research team has previous experience with recruiting and retaining study participants in existing orthopedic registries and the integrated infrastructure has already begun to yield impactful evidence to the literature. The **ROCK** group has recently initiated a multi-center randomized clinical trial for different surgical treatments for early stage OCD, which demonstrates the group’s ability to work together. The most salient innovation of the current proposal is the integration of prospective dynamic research database at 13 institutions uniquely positioned to conduct this research because of the presence of an OCD expert at each center within the group. Prior barriers to achieving the goals outlined in the above aims are related to the ability to attain targeted sample size include inadequate case volume per center. The integration of the multicenter prospective research database from the Study Group institutions provide a volume exceeding 200 cases/year. This multicenter proposal will overcome many of the potential barriers to enrollment by allowing us to quickly identify and enroll numerous subjects simultaneously, thus enabling us to reach conclusions and relay essential information to patients and clinicians in a timely manner.

**Budget and Justification ($50,000/year over 3 years)**

The funding support for the present proposal will be used toward ensuring adequate informatics and technical support. In addition, the funding will support a research assistant who will be responsible for data management, outcomes surveillance and technical support for participating institutions using the web-based portal. ***Detailed Budget Justification:* Application Specialist-** will be responsible for the development and maintenance of the web-enhanced data capture, management and analysis system which is to be implemented as part of each Specific Aim of this proposal. **Research Assistant-** will be responsible for data management, outcomes surveillance and technical support for participating institutions using the web-based portals and teleform data collection. Each reseach site has committed 10% physician effort annually to support participant recruitment, coordinator management and patient follow-up needed to ensure success of the proposed Aims.