# EPOS Discoid Meniscus (DiMe) Project: a Prospective Multicentric Cohort Protocol

**Short literature review:**

Discoid Meniscus (DM) is the most common congenital anatomic variation in pediatric knee. Compared to a normal meniscus DM is thicker and atypical in shape; these characteristics make it more prone to tear.[1] In recent times improvement in diagnostic capabilities, new classification systems and innovative arthroscopic techniques lead to a different and more specific approach to symptomatic DM.[2, 3] The impact of new classification systems in DM treatment has not been evaluated yet. Moreover, several techniques were currently proposed but a clear consensus still lacking about the best treatment option for skeletally immature patient with symptomatic DM[4, 5].

**Purpose:**

The aims of this Discoid Meniscus (DiMe) project were (1) to analyze DM tears characteristics in the pediatric European population (2) to describe current treatment options in symptomatic DM, and (3) to evaluate clinical outcomes.

To reach these objectives, a prospective database including symptomatic DM and variables associated with DM characteristics, type of tears, treatment, imaging and clinical follow-up will be implemented.

Data collection platform will provide future studies to understand the best treatment option for skeletally immature patient with symptomatic DM according to their history and lesion characteristics.

**Hypothesis:**

A Prospective Multicentric data collection about DM is the best way to provide adequate knowledge about a pathology with a relatively low number of patients treated in each hospital. An European prospective database will provide significant insights into several aspects of DM as the impact of this pathology to the European population, patient's characteristics, DM tears pattern, clinical outcomes and return to sport.

**Methodology:**

Patient inclusion and exclusion criteria:

INCLUSION CRITERIA: Patients with (1) symptomatic DM confirmed by a senior orthopaedic surgeon based on physical examination and MRI (2) age less than eighteen years (3) consent of the patient's legal representatives.

EXCLUSION CRITERIA: Patients with (1) concomitant or previous knee surgeries, (2) concomitant ligament knee injury that require a surgical treatment (3) concomitant fractures (4) inflammatory or arthritic diseases.

Study Design:

All pediatric orthopaedic units providing treatment to pediatric and adolescent symptomatic DM in Europe are eligible to participate by filling a formal application. They provide data on DM characteristics, treatments and clinical outcome using a dedicated web portal. The European Paediatric Orthopaedic Society (EPOS) Sports Study Group has endorsed the project and encouraged all members to participate. This is a multicentric prospective cohort study. Multicentric prospective cohort study design is a well-tested method of delivery of high-quality cohort studies in the field of pediatric sport medicine with the capacity to generate meaningful large-scale data with the potential to inform or change clinical practice [6, 7].

Data collection:

All eligible consecutive patients will be identified prospectively by the local participating clinical teams according to Inclusion/Exclusion Criteria. Prospective data entry is mandatory.

Data will be collected and stored online through a secure cloud-based platform Research Electronic Data Capture cloud (REDCap cloud).

REDCap cloud is a secure, cloud-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.

REDCap cloud allows collaborators to enter and store data in a secure system. A designated collaborator at each participating site will be provided with REDCap cloud login credentials, allowing them to securely submit data on to the REDCap cloud system. The REDCap cloud platform is managed by the Bicocca Clinical Research Office of the University of Milano-Bicocca, Italy. Only pseudo-anonymised data will be uploaded to the database.

Data collection will be conducted in three phases:

Phase 1 will register patients to the study, document symptomatic DM, collect the details of patient demographics, sport characteristics, PROMS, imaging classification and consent of the patient's legal representatives. Once the patient has reached the age of majority, the date of his/her own consent will be recorded.

Phase 2 will register surgical treatment and arthroscopic video and photographs collected during surgery, collect intraoperative DM instability, arthroscopic classification and surgical details. Post-operative complication will also be collected.

Phase 3 will collect short-, medium- and long-term outcome data. Short follow-up data collection will plan at 1 month follow-up then 3 and 6 months follow-up. Then annual data collection will performed.

The foreseen timeframe of follow-up will be 15 years for each patient. At the end of the 15-year follow-up, the data will be stored for an additional 10 years before being deleted. Data will be recorded if the patients are willing to comply with the annual data collection. Should the DiMe Project be terminated at one stage, the data will be stored for 10 years after termination of the project before being deleted.

<u>Full data description:</u>

- Consent of the patient's legal representatives and, once the patient has reached the age of majority, consent of the patient.
- Demographic and anamnestic information (age, gender, Weight, Height, BMI, discoid meniscus in patient's family, comorbidity, bilateral DM).
- History of symptomatic DM: average duration of symptoms, traumatic injury (Y/N).

- Pre-operative sports participation: Tegner activity level scale, Marx Activity Rating Scale[8], Children's Self-Perceptions of Adequacy in and Predilection for Physical Activity (CSAPPA)[9], Type of sport, Hours of sport/week.[10]
- Clinical evaluation: Pain / Loud click / Locking /Effusion /McMurray test, Bilateral and comparative knee range of motion, lower limb discrepancy (mm), lateral or medial DM, VAS, Pedi IKDC, Subjective Knee Value (SKV).[11] Puberty evaluation according to Tanner stage classification.
- MRI meniscal evaluation: Medial or lateral meniscus. Watanabe classification: (A) The complete type is the disc-shaped meniscus that completely covers the tibial plateau with a normal posterior attachment. (B) The incomplete type has a semilunar shape and normal posterior attachment (covers less than 80% of the tibial plateau). (C) The Wrisberg type lacks the posterior meniscal attachments (coronary ligament), and only the Wrisberg ligament connects the posterior horn of the lateral meniscus.

  Ahn MRI classification [2]: 1) antero-central shift type; 2) postero-central shift type; 3) central shift type; 4) no shift type. Other meniscal lesions (not described by Ahn classification): 5) bucket-handle meniscal tear: displaced longitudinal tear; 6) flap meniscal tear: displaced horizontal or longitudinal tears; 7) parrot beak meniscal tear: displaced radial tear; 8) complex tear: a combination of all or some of horizontal, longitudinal and radial-type tears.
- Intraoperative evaluation: Date of surgery, delay to surgery. Video recordings of arthroscopic diagnosis (including probing) and DM treatment. The arthroscopic findings will be analyzed. Meniscal arthroscopic evaluation according to Watanabe Classification and Ahn arthroscopic meniscal classification [2]. Ahn classification: (A) Meniscocapsular junction, anterior horn type (MC-A type); (B) Meniscocapsular junction, posterior horn type (MC-P type); (C) Posterolateral corner loss type. Description of DM tear (Type and location).

  Assessments of chondral associate damage according to Outerbridge classification[12]: Grade 0 – normal; Grade I - cartilage with softening and swelling; Grade II - a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter; Grade III - fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm; Grade IV - exposed subchondral bone. Description of eventual concomitant osteochondritis dissecans. Treatment: Saucerisation (Y/N) Suture

(Y/N) - Out in (Y/N) - In out (Y/N) - All inside (Y/N). Type and number of suture/anchor.

Intraoperative complications: intraoperative technical complications will be stratified into "minor" and "major" events, using the following definitions: (1)"Minor event": Any unexpected intraoperative event which deviates from the initial surgical plan and from an anticipated uneventful accomplishment of the procedure, but did not mandate a conversion to a different surgical technique, and did not bear the potential for patient harm or an unsatisfactory surgical result. (2)"Major event": Any unexpected intraoperative event which resulted in the necessity for conversion to a different surgical technique and/or had the potential for inducing patient harm or an unsatisfactory surgical result.

- Postoperative evaluation: VAS and Postoperative complications such as wound complications or infection will be recorded.
- Prospective follow-up evaluation: Clinical evaluation, PROMS (PediIKDC, VAS, SKV) and sport levels (Tegner activity level scale, Marx Activity Rating Scale, CSAPPA, Type of sport, Hours of sport/week) evaluated pre-operative will be monitored and collected at 3 and 6 months of follow-up. Then annual data collection will be performed. A standardized annual MRI will be performed to evaluate meniscal healing and chondral evaluation.

Data validation and management:

For quality assurance purposes, REDCap cloud's data quality rules will be implemented to find discrepancies and errors in the project data. In addition, in the lead up to publication, interim analyses will be performed to look for discrepancies in the data, and if identified, the study site will be contacted to validate that record. This is consistent with the quality assurance procedure used in other large collaborative audit projects.[13, 14]

Statistical analysis:

Task 1: to describe study population before surgical treatment to highlight potential patterns and risk factors according to different kind of DM lesion. Multivariate analysis techniques will be used to described pre-surgical intervention population and identify cluster of variables with a significant impact on different DM lesions.

Task 2: to analyze the surgical intervention in terms of surgical results, complications and observed adverse events by kind of DM lesions. Multivariate analysis techniques will be used adjusting by

significant patients characteristics find out in Task 1. Different surgical outcome measures will be considered.

Task 3: to evaluate clinical outcome at 1, 3, 6 and 12 months after surgical intervention by kind of DM lesion. A long term outcome will be evaluated at 5, 10 and 15 years from the surgery to evaluate the long term effect of surgical treatment on different lesions. Multivariate analyses will take into account patients characteristics and the applied surgery technique.

Longitudinal analyses will be applied to described the patients meniscal status over a 15-year follow-up.

Ethical / legal aspects:

EPOS PeDiMe Project will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to locally applicable legislation. This project and related documents will be submitted for review to Ethics Committee of the Hospital CUF Descobertas, Lisbon, Portugal.

The Study will be conducted only on the basis of prior informed consent by the patient's legal representatives and, once patients have reached the age of majority, consent of the patients to participate in the Study. Patients involved in the project will be the owners of their data. Partner institutions will act as their patients' data processors. Every patient has the right to access their own data as per request to the participating institution/hospital.

Hospitals willing to participate in the PAMI project will seek ethics clearance to their local or national ethics committee when applicable, in accordance with their national laws and regulations. Formal proof of ethics clearance is a prerequisite for participation in the EPOS PeDiMe Project.

**References:**


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