

**Pure Articular Knee Chondral Fractures in Pediatric Population
(PACK project):
Is There a Role for Surgical Fixation?**

A Multicenter EPOS Study

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Background - Short Literature Review:

Osteochondral injuries are common in young population.¹ Pure articular chondral knee (PACK) fractures are considerably less frequent compared to osteochondral defects.² Even if pure chondral fractures are infrequent, their clinical consequences especially in a young patient are relevant.^{3,4} Historically physicians believed that a pure chondral fragment has a very limited healing potential. Difficulties in stabilizing a cartilage fragment due to its low thickness, together with less reliable healing of the bone-cartilage interface, supported the belief that fixation of a pure chondral fracture is not recommended.⁵ Recent studies showed good clinical results of chondral fragment fixation, especially in skeletally immature patients with a well-known higher healing potential compared to adults.⁶⁻⁸ Even though several studies recently describe repair techniques for articular cartilage fragments, data are not supported by large cohort studies.

Purpose:

The purpose of this study is (1) to describe the population of skeletally immature patients with a diagnosis of pure chondral knee fracture, together with information regarding injury characteristics, (2) to describe the treatment strategy and type of surgery, and (3) analyze the clinical outcomes.

The present multi-center retrospective study will provide data on a cohort of skeletally immature patients who underwent surgical repair of a knee joint full-thickness cartilage fragment. These data will implement the scientific knowledge to better understand which treatment is recommended in young patients with pure chondral lesions.

Hypothesis:

Our hypothesis is that pure chondral lesions in skeletally immature patients can heal if treated with surgical fixation of the cartilage fragment. The greater healing potential of young patients supports this thesis. A retrospective European database of patients with pure chondral lesions will provide information on the safety of these procedures and could highlight which patients can benefit most from surgical cartilage fixation.

Methods:

Patient Inclusion and Exclusion Criteria:

INCLUSION CRITERIA: Patients with (1) diagnosis of acute pure full-thickness chondral fracture without subchondral bone attached confirmed by a senior orthopedic surgeon based on physical examination and MRI (confirmed during arthroscopic surgery), (2) surgical fixation of the chondral fragment (arthroscopic or arthrotomic), (3) age less than eighteen years at time of diagnosis, (4) consent of the patient's legal representatives.

EXCLUSION CRITERIA: Patients with (1) concomitant or previous knee surgeries, (2) other type of treatments (removal of the fragment, osteochondral tissue transfer, cell-based regeneration techniques, cartilage auto- or allograft, use of synthetic scaffold), (3) tibial spine cartilaginous avulsion fractures, (4) concomitant bone fractures, (5) inflammatory or arthritic diseases.

Study Design:

The present study is a multicenter retrospective study. Pediatric orthopedic units where patients were treated according to inclusion and exclusion criteria in Europe are eligible to participate by filling a formal application. Institutional review board approval will be required from all institutions. The European Paediatric Orthopaedic Society (EPOS) Sports Study Group has endorsed the project and encouraged all members to participate.

Data Collection:

All eligible patients will be verified by the local clinical team participating in the study according to inclusion and exclusion criteria. For all eligible patients, the consent of the patient's legal representatives is required to proceed with data entry.

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-anonymized data will be uploaded to the database.

Full Data Description:

- 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, comorbidity, Tanner stage classification, physis status (open, closing, closed – according to X-ray evaluation)).

- Onset of symptoms: traumatic injury (Y/N), contact/non-contact, traumatic circumstance (sport, road accident, recreative activity), type of sport.
- Pre-operative sports participation: Tegner activity level scale, Marx Activity Rating Scale⁹, Children's Self-Perceptions of Adequacy in and Predilection for Physical Activity (CSAPPA)¹⁰, type of sport.¹¹
- Preoperative MRI meniscal evaluation: chondral defects location (patella, trochlea, medial/lateral femoral condyle), dimension of the chondral fragment (mm), displaced/non-displaced fragment,
- Intraoperative evaluation: time trauma to surgery (months), surgical fixation of the fragment (arthroscopic vs. mini-open surgery), type of device used to fix the chondral fragment (bioabsorbable implants (chondral darts, nails, screw) vs. metal screw fixation), number of devices, non-bleeding vs. subchondral bone bleeding stimulation (micro perforations), other procedures.
- Intraoperative adverse events: chondral chip fragmentation, unstable fragment fixation.
- Postoperative treatment: weight bearing vs. non-weight bearing, immobilization (cast or brace) vs. early mobilization, weeks of immobilization, time to full weight bearing, time to return to sport.
- Post-operative follow-up: follow-up time (months), clinical evaluation, PROMS (PediIKDC, VAS) and sport levels (Tegner activity level scale, Marx Activity Rating Scale, CSAPPA, Type of sport), new traumatic events, new surgery required. If available
- Post-operative MRI evaluation: MRI performed 3-6 months after surgery (radiographic evidence of healing vs. non-healing of chondral defect).

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.^{12,13}

Statistical Analysis:

Descriptive statistics: study population to highlight potential patterns and risk factors, surgical intervention, complications, and adverse events. Description of the clinical outcome after surgical intervention (% of healing, % of new surgical intervention).

Ethical and Legal Aspects:

PACK 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 Milano-Bicocca University, Milan, Italy.

The Study will be conducted only based on prior informed consent by the patient's legal representatives. Patients involved in the project will be the owners of their data. Partner institutions will act as their patient's 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 PACK 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 PACK Project.

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