Biobrace® BioPPD – Clinical Trial

Recruiting patients with an Acute Primary Lateral Patellofemoral Dislocation

Banff Sport Medicine is running a study to determine if the addition of Biobrace® to an MPFL repair will decrease the re-dislocation rate after an *acute* first-time patellofemoral dislocation.

Please call Dr. Laurie Hiemstra (403-688-9288) or Dr. Michaela Kopka (250-792-0428) to discuss any interested patients as soon as they are assessed, ideally within 5 days from injury. One of the surgeons will see patients on-call within 1 – 2 working days.

Upon determining study eligibility and willingness to participate, the patient will be booked for surgical stabilization within 14 days of the dislocation. Current non-operative standard management will be offered as an alternative, including bracing for 2-6 weeks and physiotherapy.

The Biobrace® implant is intended to strengthen soft tissues that are repaired by sutures during surgery like an MPFL repair. BioBrace® is a device containing collagen of animal origin (bovine type-I), poly-L-lactic acid (PLLA), and polyethylene glycol (PEG). It is designed to provide additional strength over time to the repaired MPFL.

Inclusion Criteria	Exclusion Criteria
❒ Aged 13 – 30 years ❒ Having a first-time patellofemoral dislocation that occurred within the past 7 days ❒ Closed or closing growth plates (confirmed on x-rays with no change required for surgical technique)	❒ History of previous patellofemoral dislocation on the index knee ❒ An osteochondral fracture of the patellofemoral joint that requires surgical repair ❒ Unable to complete computer-based outcome questionnaires ❒ Pregnant at the time of surgery

What is involved for patients?

1. The use of Biobrace® during MPFL repair surgery to reinforce the torn ligament
2. Standardized knee examinations, knee imaging (x-ray, ultrasound, MRI), and completion of online questionnaires
3. Follow-up visits at 2-4 weeks, 3 months, 6 months, 12 months, and 24 months after surgery

With the Patient's Permission, Please Call	For More Information:
Dr. Laurie Hiemstra Ph: 403-688-9288 Or Dr. Michaela Kopka Ph: 250-792-0428	Research Coordinator Banff Sport Medicine Foundation research@banffsportmed.ca Phone: 403-760-2897 ext 6

This study has been approved by the University of Calgary Conjoint Health Research Ethics Board (REB23-1095).

Sponsored by: *Biorez Inc., a wholly owned subsidiary of CONMED.*