

**Systematic lateral retinacular release does not reduce post-operative anterior knee pain after primary total knee arthroplasty with patellar replacement**

Study Protocol and Statistical Analysis Plan

September 1, 2019

## INTRODUCTION

Anterior knee pain (AKP) remains a common cause of persistent pain after total knee arthroplasty (TKA). The reported incidence varies from 8% to more than 50%, and it has a negative effect on patient quality of life and satisfaction. Many factors may contribute to AKP, but there is no clear consensus with regard to its etiology and treatment.

Lateral retinacular release (LRR) has been proposed as a surgical option to prevent AKP syndrome. This is based on the fact that excessive lateral patellofemoral pressure due to a tight lateral retinaculum contributes to patellofemoral disorders like AKP, patellar chondral lesions, or patellofemoral osteoarthritis. Some authors suggested that the origin of AKP can be found in the degenerative neuropathy seen in the lateral retinaculum of symptomatic patients. Therefore, its release would improve this pain by denervating the tissue.

Accordingly, the mechanism by which lateral release relieves pain may be the reduction of lateral tension decreasing the surface pressure, as well as the denervation of the retinaculum.

With TKA, forces and peak pressures significantly increase in the patellofemoral joint. For that reason, some authors are keen advocates of the lateral release with the intent to ease AKP. They perform it systematically even if the tracking is correct. A clinical randomized trial suggested that routine LRR can reduce AKP in TKA without patellar resurfacing.

### Objectives and hypothesis

The primary objective of this prospective randomized double-blind trial is to evaluate the effect of LRR on AKP after TKA with patellar replacement when compared to the resurfaced patella without release.

The secondary objectives are to assess and compare the functional and radiological outcomes between the groups after 12 months.

The hypothesis is that LRR would decrease the incidence of AKP after TKA with patellar resurfacing, as well as it would improve functional outcomes.

## MATERIALS AND METHODS

### Study design and eligibility criteria

A prospective, randomized, and double-blinded clinical trial is designed. All the patients that will undergo a primary TKA in our center from October 2019 through December 2020 are included.

The inclusion criteria are patients aged 40-90 years with a diagnosis of knee osteoarthritis who signed written informed consent.

The exclusion criteria are patients with a prior major surgery on the same knee (high tibial or distal femoral osteotomy, patellar realignment), important preoperative malalignment

(varus or valgus  $>15^\circ$  or flexion deformity  $>15^\circ$ ), and an inability to sign informed consent.

The study was approved by the Research Ethics Committee of our institution (2019/8993/I).

A total of 220 patients are randomized into either the LRR group (Group A) or non-release group (Group B).

### **Surgical procedure**

Computer-generated randomization sequencing will be conducted before the surgery.

All the procedures will be performed by five experienced surgeons from the knee unit of our institution, using a midline anterior approach and a medial parapatellar arthrotomy. An extramedullary guide will be used for tibial cutting and intramedullary guide for femoral cutting, following mechanical alignment technique. The prosthetic components will be implanted in a one-stage cementing technique after standard bone cuts. The patella is going to be always replaced with a symmetric implant.

In the release group (Group A), a retinacular release will be performed 2cm lateral to the lateral margin of the patella.

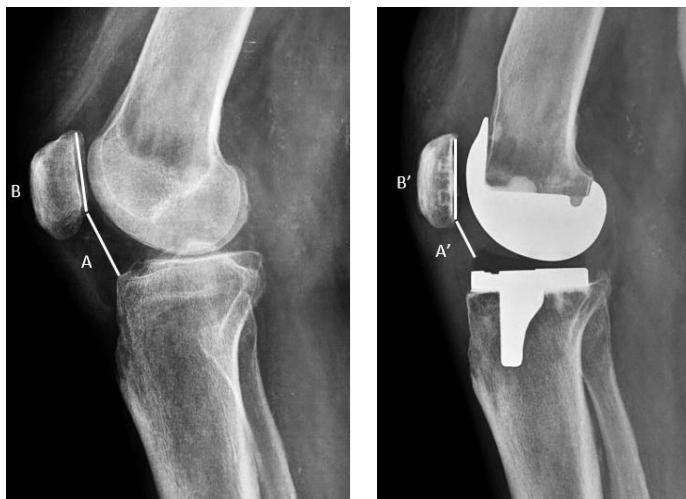
The postoperative rehabilitation protocol will be the standardized for every total knee arthroplasty in our hospital.

### **Data collection and outcome measures**

Preoperatively, demographic data regarding age, gender, body mass index and laterality will be recorded. At the preoperative visit and at the 1-year follow up, the following clinical and radiological data will be collected by an examiner blinded to the surgical technique performed:

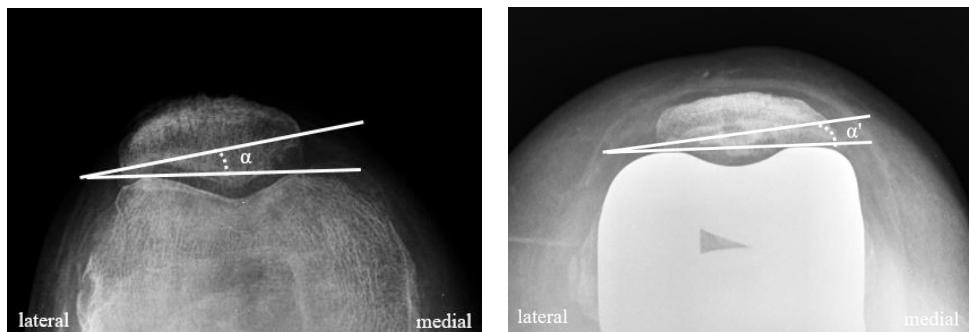
- Patellar pain and function are evaluated with the patellofemoral score designed by Feller et al. The score is distributed with a maximum of 15 points for the intensity of anterior knee pain, 5 points for quadriceps strength, 5 points for the ability to rise from a chair and 5 points for stair-climbing ability.
- The Knee Society Score (KSS) for both the Knee and the Function scores, 0 being the worst and 100 the best possible result in each section.
- The pressure pain threshold (PPT) determined using pressure algometry (PA). The PPT is assessed 3 times in each knee, with a calibrated electronic algometer (Algometer, Somedic Sales, Hörby, Sweden) with a  $1\text{cm}^2$  probe placed perpendicular to the skin in the center of the anterior aspect of patella. The evaluator increases the pressure 20 kPa/s until the sensation become painful and the patient says “stop”. The final PPT value taken is the average of the 3 measurements.
- The Visual Analogue Scale (VAS) referred by the patients at rest, when walking and when going up and downstairs.

- Patellar height. Measured in the lateral view using the Caton-Deschamps index and its application in TKA.



**Figure 1.** Patellar height measurement defined as the ratio of the length of the patellar articular surface (B) and the distance between the lower pole of patellar articular surface and the anterior border of the tibial plateau (A) preoperatively or the tibial component surface postoperatively (A').

- Patellar tilt. Defined in the axial view, as the angle subtended by the anterior intercondylar line and the equatorial line of the patella preoperatively or a line drawn through the prosthesis-bone interface postoperatively.



**Figure 2.** Patellar tilt measurement.

### Statistical analysis

The sample size calculation of 110 patients in each group was based on assuming a minimum difference of 1 point in the VAS value with a standard deviation of 2.5. A probability level of 0.05, a power of 80% and a drop-out rate of 10% were assumed.

Descriptive statistics were used for the demographic data. Continuous variables and measured scores were presented as mean and standard deviations and categorical variables as number and percentage. Between group comparisons were evaluated with the Mann-Whitney U test. These comparisons were performed with the preoperative and postoperative measurements. Differences between the groups in terms of changes or improvements (post vs. pre) were also assessed with the Mann-Whitney U test.

STATA version 15.1 (StataCorp, College Station, TX, USA) was used for the statistical analysis with p values of 0.05 being considered statistically significant.

For the calculation of intraclass correlation coefficients (ICC) two-way random-effects model approximation was performed, being in terms of *Shrout and Fleiss* notation ICC(2,1) for intrarater agreement and ICC(2,2) for interrater agreement.