Official Title:

Isokinetic Performance After Cruciate-substituting Ultra-congruent and Posterior Stabilized Total Knee Arthroplasties

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OBJECTIVE

Whether ultra-congruent (UC) or posterior cruciate ligament-stabilized (PS) inserts should be used in posterior cruciate ligament (PCL)-sacrificing total knee arthroplasty (TKA) remains debatable. Therefore, the aim of this prospective randomized controlled study is to compare the isokinetic performance and clinical outcomes of these inserts in PCL sacrificing TKA.

DESIGN AND METHODS

Sixty-six patients diagnosed with primary knee osteoarthritis will be randomly assigned to either the UC or the PS group. The Knee Society score (KSS) and isokinetic performance results for each patient will be recorded preoperatively and at 3, 6 and 12 months postoperatively. The physiatrist performing the isokinetic tests and the patients will be blinded to the study groups.

This study is approved by the institutional review board (IRB) by the "Ankara Numune Training and Research Hospital Clinical Research Ethics Committee" ethical committee (1585/2017) (Ankara, Turkey) and will be performed in accordance to the 1964 Helsinki Declaration and its amendments.

STATISTICAL ANALYSIS PLAN (SAP)

Sample size estimation is performed using the mean knee extensor peak torque at one year postoperatively, 53.9 Nm, and the standard deviation, 12, reported in a prior study [1] and G*Power (version 3.1.9.6.) software. A total of 66 patients is estimated to be needed to achieve a power of 95% in detecting a 10 Nm difference in the extensor peak torque, with a standard deviation of 12, 4 measurements, an effect size of 0.41 and a significance level (alpha) of 0.05 using two-way repeated measures ANOVA. All the data will be presented as means and standard deviations. Two-way repeated measures ANOVA will be used for the statistical analysis of the repeated measurements in the two groups. The statistical calculations will be performed with SPSS 22.0 software (IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.). Values of $p < 0.05$ will be considered statistically significant.

1. Kim JG, Lee SW, Ha JK, Choi HJ, Yang SJ, Lee MY (2011) The effectiveness of minimally invasive total knee arthroplasty to preserve quadriceps strength: a randomized controlled trial. Knee 18:443–447. https://doi.org/10.1016/j.knee.2010.08.008 11.