Official Title:

Robot-Assisted Arthroscopic Anterior Cruciate Ligament Reconstruction: A Prospective Randomized Controlled Trial

NCT Number:

[To be filled after registration]

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Study Design and Methods

1. Type of Study

This is an interventional trial.

2. Study Hypothesis

This study adopts a randomized controlled trial design. The experimental group will receive robot-assisted ACL reconstruction, while the control group will undergo conventional ACL reconstruction. The hypothesis is that both groups will achieve similar clinical outcomes; however, the femoral tunnel position in the experimental group will more closely approximate the anatomical point as measured by the Bernard quadrant method, and the graft isometry will be superior.

3. Study Protocol

Experimental Group: Patients will undergo ACL reconstruction with a dedicated robotic system. Preoperative CT and MRI will be used to plan femoral and tibial tunnel positions. The robot will assist in assessing the feasibility of the planned trajectory, predict graft isometry and impingement risks, aid in tunnel drilling, and perform quantitative axial shift testing.

Control Group: Patients will receive standard arthroscopic ACL reconstruction using manual techniques. Femoral tunnels will be created with offset guides, and tibial tunnels with traditional ACL aiming devices. Graft fixation and assessments will be performed manually.

4. Study Population

Inclusion Criteria: Patients aged >14 years with ACL rupture, closed growth plates, full cognitive capacity, signed informed consent.

Exclusion Criteria: Combined ligament injuries, bilateral ACL injuries, poor skin/soft tissue condition, active infection, or systemic diseases requiring priority treatment.

Withdrawal Criteria: Patient-requested withdrawal, study termination, unacceptable risk as judged by the investigator, or other circumstances requiring withdrawal.

Elimination Criteria: Subjects not meeting eligibility criteria, or who withdraw early, or exhibit poor compliance. Case elimination is discussed and confirmed prior to data analysis by the PI and statistician.

5. Outcome Measures and Follow-Up Plan

Primary Outcome: Side-to-side difference measured by KT-1000 at 2 years post-op.

Secondary Outcomes: Lysholm, Kujala, and Tegner scores preoperatively and at 2 years; CT and MRI imaging at discharge and 2 years; physical examinations at the same time points.

Follow-Up Schedule: At baseline and 2 years post-op, conducted face-to-face.

6. Sample Size Calculation

Based on Lysholm scores from prior navigation-assisted studies, the experimental group is expected to score 87.6±16.0 and control 77.4±15.0. Using $\alpha=0.05$, $\beta=0.1$, and a 1:1 allocation ratio, each group requires 49 patients. Accounting for 20% loss to follow-up, 60 patients per group will be enrolled.

7. Statistical Methods

Software: SPSS 22.0.

Continuous Variables: Normal distribution: mean±SD, analyzed using ANOVA with Bonferroni post-hoc if variances are equal, or Dunnett T3 if not. Non-normal data: median and IQR, analyzed via Kruskal-Wallis test.

Categorical Variables: Chi-square or Fisher's exact test.

Repeated Measures: Paired t-test or repeated measures ANOVA for continuous variables; Cochran's Q test for categorical variables. $P<0.05$ is considered significant.

8. Experimental Procedures

Preoperative Planning Module: Enables surgeon-robot collaboration via 3D CT/MRI reconstruction. Tunnels are planned using Bernard quadrant method, IDEAL positioning, anatomical landmarks, and contralateral MRI as reference. The module predicts graft path and impingement risk.

Intraoperative Module (Motion Tracking): Integrates surgeon guidance with robotic precision. The robot acts as an extension of the surgeon's arm, enabling precise tunnel drilling without changing habitual surgical behavior. The robot tracks limb motion and adjusts accordingly.

Biomechanical Evaluation: Quantifies axial shift via a 6-degree-of-freedom optical tracking system. This approach represents a novel, domestically developed technique with leading international potential.

9. Data Management and Quality Assurance

Standardized training for research staff on eligibility criteria.

Implementation of standardized workflow and staff training.

Independent blinded evaluators trained at study initiation.

Dedicated personnel assigned to verify the accuracy and completeness of study data.
