# STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

**Official Title:** A Prospective Cohort Study of High-Strength Suture Modified Tension Band Technique for the Treatment of Patellar Fractures

**Institution:** Fuzhou University Affiliated Provincial Hospital
**Principal Investigator (PI):** Dr. Wei Xu
**Main Researcher:** Anning Liu, M.Med. (candidate)
**Ethics Approval Number:** K2025-10-005
**Version:** Version 1.0 — January 2024

This protocol has been approved by the Ethics Committee of Fuzhou University Affiliated Provincial Hospital (Approval No. K2025-10-005).

# 1. Study Objective

This study aims to evaluate the clinical efficacy and safety of the high-strength suture modified tension band technique for patellar fracture fixation compared with the conventional screw-cable tension band fixation. The primary outcomes include Lysholm knee function score, range of motion (ROM), and pain score (VAS) at 12 months postoperatively.

# 2. Study Design

This is a prospective cohort study conducted at Fuzhou University Affiliated Provincial Hospital from February 2024 to February 2026. Patients with AO/OTA 34-C1 or 34-C2 type patellar fractures will be assigned into two groups based on surgical technique: the suture fixation (SF) group and the screw-cable tension band (SCTB) group. Follow-up will be 12 months postoperatively.

# 3. Eligibility Criteria

Inclusion criteria include adults aged 18–55 years with confirmed patellar fractures (AO/OTA 34-C1 or 34-C2) and surgery within 2 weeks of injury. Exclusion criteria include pathological fractures, prior patellar surgery, active infection, severe comorbidities, or inability to complete follow-up.

# 4. Outcome Measures

Primary outcomes: Lysholm Knee Score, Knee ROM, and VAS pain score at 12 months after surgery. Secondary outcomes: fracture healing time, alignment quality, complication rate, reoperation rate, implant removal rate, SF-36 score, and patient satisfaction.

# 5. Statistical Analysis

Data will be analyzed using IBM SPSS Statistics 27.0. Continuous variables will be expressed as mean ± SD and compared using t-tests or Mann-Whitney U tests. Categorical variables will be analyzed using Chi-square or Fisher’s exact test. Time-to-event data will be analyzed by Kaplan-Meier method with log-rank test. Multivariate analyses may use linear or Cox regression. Statistical significance is defined as $p < 0.05$ (two-sided).

# 6. Ethical Considerations

This study follows the Declaration of Helsinki and Good Clinical Practice guidelines. All participants will provide written informed consent before enrollment. Patient confidentiality will be strictly maintained. Any adverse events or serious adverse events will be reported to the Ethics Committee within 24 hours.

# 7. Publication Plan

Results will be submitted to peer-reviewed journals in orthopedics or trauma surgery and presented at scientific meetings. Data will be reported in aggregate form only.

**Prepared by:** Dr. Wei Xu and Anning Liu
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