INFORMED CONSENT FORM

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

Version: 1.0 (January 30, 2024)
Institution: Fuzhou University Affiliated Provincial Hospital
Ethics Approval No.: K2025-10-005
Principal Investigator: Dr. Wei Xu
Main Researcher: Anning Liu, M.Med. (candidate)

Introduction

You are invited to participate in a research study titled “High-Strength Suture Modified Tension Band for Patellar Fractures.” Please read this form carefully and ask the research staff any questions you may have before deciding whether to participate. Participation is voluntary.

1. Background and Purpose of the Study

This study is conducted by Fuzhou University Affiliated Provincial Hospital. The purpose is to evaluate the clinical efficacy and safety of the high-strength suture modified tension band technique compared with the traditional screw–cable tension band fixation for patellar fractures. The study has been reviewed and approved by the Fuzhou University Affiliated Provincial Hospital Ethics Committee (Approval No. K2025-10-005).

2. Study Procedures

If you agree to participate, the research team will collect data generated during your routine clinical care, including: medical history, imaging (X-ray/CT), operative records, pain assessment (VAS), functional assessments (Lysholm score, knee range of motion), SF-36 questionnaire responses, and records of complications or reoperations. No additional tests or interventions beyond standard care are required solely for this research.

3. Duration of Participation

You will be followed for 12 months after surgery. Follow-up visits are scheduled at approximately 1 week, 1 month, 3 months, 6 months, and 12 months after surgery.

4. Confidentiality and Data Protection

All collected information will be de-identified. Your records will be assigned a study code; names and direct identifiers will be removed from research datasets. Data will be stored securely on password-protected computers accessible only to authorized research personnel. De-identified (aggregate) results may be published, but no individual participant will be identifiable in publications or reports.

5. Risks and Discomforts

This is a non-interventional (observational) study. Your participation will not affect the clinical care you receive. There are no additional risks beyond those associated with your routine clinical treatment.

6. Potential Benefits

There may be no direct benefit to you. However, the study may provide data that helps improve surgical treatment options for future patients with patellar fractures.

7. Costs and Compensation

Participation will not result in additional costs for you. If any study-related injury occurs, treatment and compensation will be provided according to applicable Chinese laws and institutional policies.

8. Voluntary Participation and Withdrawal

Your participation is completely voluntary. You may refuse to participate or withdraw at any time without giving a reason. Withdrawal will not affect your medical care or rights.

9. Contact Information

If you have questions about the study, contact the research team:
Research Team: +86-15259370989 or 0591-88617310

For questions about participant rights, contact:
Fuzhou University Affiliated Provincial Hospital Ethics Committee: 0591-88216023

10. Data Use and Sharing

De-identified data may be shared in aggregate form in scientific publications and presentations. Individual participant data will not be disclosed without your explicit consent except as required by law.

Consent Signature Page

I have read (or someone has read to me) the information in this informed consent form. I have had the opportunity to ask questions and all my questions have been answered. I voluntarily agree to participate in this study.

Participant Name (Print): _____
Participant Signature: _____
Date: _____ / _____ / _____

If the participant is a minor or otherwise incapable of consent:
Guardian Name: _____
Guardian Signature: _____
Relationship to Participant: _____
Date: _____ / _____ / _____

Witness (if applicable):
Witness Name: _____
Witness Signature: _____
Date: _____ / _____ / _____

Researcher Declaration

I have explained the study to the participant and answered all questions. The participant has agreed voluntarily to participate.

Researcher Name: _____

Researcher Signature: _____

Date: _____ / _____ / _____