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Outcomes of two surgical approaches for tibial eminence fractures

Submission date	Recruitment status	[ ] Prospectively registered
06/07/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/07/2026	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/07/2026	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Clinical efficacy between arthroscopic suture bridge fixation and cannulated screw fixation for tibial eminence fractures: a randomized controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/11/2025, Ethics Committee of Changji Hui Autonomous Prefecture Hospital of Traditional Chinese Medicine (110 Jianguo West Road, Changji, 831100, China; +86 0994-2345763; C19990215062@163.com), ref: MEC-2025112001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Comparison of tibial eminence fracture treatments

Interventions
This trial is a single-center, prospective, parallel group, randomized controlled superiority trial without crossover, factorial or single-arm design. Participants are allocated 1:1 to an intervention group or a control group. Blinding of participants and outcome assessors is performed; surgeons cannot be blinded because of the distinct surgical instruments and procedures involved, and therefore they are excluded from follow-up scoring and statistical analysis. Randomization and allocation concealment are carried out using a computer-generated random number table and sequentially numbered, opaque, sealed envelopes. Standardised surgical, rehabilitation and follow-up procedures are applied throughout the study, with baseline and multiple time point knee function and safety outcomes collected. This description follows the TIDieR checklist recommendations.

A complete set of standardized operating documents covering preoperative preparation, two types of arthroscopic surgery, postoperative care, staged rehabilitation, follow-up assessment, data collection and adverse event reporting was formulated. All operations were implemented uniformly in accordance with instruments and procedures specified in the manuscript without individualized adjustments.

Unified Preoperative SOP
All subjects received epidural anesthesia in the supine position with knees flexed at 90°. A sterile

thigh tourniquet was inflated to the patient's systolic blood pressure plus 100 mmHg, with a single maximum inflation time of 90 minutes; a 5-minute break was mandatory if the limit was exceeded. A STORZ 30° arthroscope system with 60 mmHg normal saline irrigation pressure was used for all cases. Preoperative X-ray and 3D CT were performed to evaluate fracture displacement and comminution, and 2g cefazolin was intravenously administered 30 minutes before incision for prophylactic anti-infection treatment. Intraoperatively, a 2.0 mm Kirschner wire was used for provisional reduction under C-arm fluoroscopy before definitive fixation.

Intervention Group (Suture Bridge) Surgical SOP
Anterolateral arthroscopic portal and anteromedial working portal were established. Intra-articular hematocele, synovial debris and free bone fragments were thoroughly debrided. Fracture displacement was confirmed by referring to ACL insertion anatomical markers on MRI. Under fluoroscopic guidance, two 4.5 mm bone tunnels were drilled 2 cm medial to the tibial tuberosity (avoiding patellar tendon insertion) along the 45°–60° anatomical axis of the ACL tibial footprint with a 5 mm inter-tunnel gap. Smith & Nephew UltraBraid high-strength sutures (2.0 mm diameter, tensile strength ≥2500 N) were passed through tunnels via DePuy suture passer. A suture hook threaded the double sutures beneath the ACL fibers under fragments to form a spanning bridge construct. A 10 mm × 2 mm titanium washer was placed at the anterior tibial tunnel outlet. Sutures were tensioned and fixed with a sliding knot reinforced by a surgical knot via a knot pusher. Final arthroscopic confirmation of anatomical reduction, uniform suture tension and no soft tissue entrapment was performed before joint irrigation and layered wound closure.

Control Group (Cannulated Screw) Surgical SOP
Intra-articular debridement, Kirschner wire provisional reduction and fluoroscopic verification were identical to the intervention group. A 4.5 mm cannulated reamer was advanced over the guide wire to penetrate 1–2 mm beneath the fragment cortex. A 4.5 mm DePuy cannulated lag screw (length 18–22 mm, thread length 8–10 mm) was selected according to fragment size and inserted via a guide sleeve, ensuring full thread crossing of the fracture line and 1–2 mm screw tip penetration of sub-fragment cortex. Arthroscopy confirmed no intra-articular screw penetration or fragment splitting before irrigation and layered closure.

Postoperative Care SOP
All patients received elastic knee compression bandaging for 6 hours with limbs elevated above the cardiac level. Partial weight-bearing (≤5 kg) ambulation was permitted 6 hours postoperatively. Intravenous antibiotics were discontinued after 24 hours, and oral celecoxib 200 mg twice daily for 7 days was prescribed for pain control.

Unified Staged Rehabilitation SOP
Weeks 1–2: Quadriceps isometric contraction and ankle pump exercises (3 sets × 20 times daily), active knee flexion limited within 30°.
Weeks 2–6: Continuous passive motion training once daily, range of motion increased gradually from 30° to 90°, weight-bearing capped at 5 kg.
Weeks 6–12: Active knee flexion targeting 120°, progressive full weight-bearing plus straight leg raise and gluteus medius training.
After 12 weeks: Low-impact aerobic exercise (jogging, swimming) allowed; competitive contact sports (basketball, football) prohibited. Return to competitive sports was approved only after combined imaging and functional assessment at 6 months postoperatively.

Supplementary Follow-up & Quality Control SOP
Standardized telephone inquiries regarding incision redness, swelling and severe pain were conducted at 1 week post-op. X-ray + 3D CT scanning, blinded Lysholm scoring and guided IKDC

self-assessment were completed during 3/6/12-month outpatient visits. Supporting SOPs for data entry, monthly quality control and adverse event reporting were formulated. All staff must complete training and assessment before participating in trial implementation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Physical function measured using the Patient-Reported Outcomes Measurement Information System Physical Function Computer Adaptive Test (PROMIS PF-CAT) at baseline, 3, 6, 12 and 18 months post-randomization

Key secondary outcome(s)

Completion date
20/01/2026

Eligibility

Key inclusion criteria
1. Aged 18 to 60 years old, any gender
2. Diagnosed with fresh Meyers–McKeever type II or III tibial eminence fracture
3. Surgery performed within 14 days after injury without mature callus formation
4. ASA physical status grade I or II
5. Normal cognitive and mental status, capable of completing full rehabilitation and outpatient follow-up
6. Fully informed of trial content and voluntarily signed informed consent
7. No high risk of loss to follow-up, such as relocation

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
74

Key exclusion criteria
1. Combined ipsilateral multi-ligament rupture, grade III meniscus tear, femoral or tibial plateau fracture

2. Severe osteoporosis, defined as DXA T-score ≤ -2.5
3. Continuous oral glucocorticoid administration for at least 4 months within the past 6 months
4. Prior ipsilateral knee surgery, Kellgren-Lawrence grade II or higher osteoarthritis
5. Coagulopathy, systemic active infection, preoperative fever above 38.5°C
6. Pregnant, lactating females or women planning pregnancy within 6 months
7. Severe cognitive impairment or mental illness, unable to cooperate with follow-up and rehabilitation

Date of first enrolment
20/11/2025

Date of final enrolment
20/12/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Changji Hui Autonomous Prefecture Hospital of Traditional Chinese Medicine

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available