Prospective randomized controlled trial of 3 types of tibial intereference screws for ACL reconstruction

Short title: SharkACL

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Background and rationale:

Anterior cruciate ligament (ACL) reconstruction is a well-established procedure for restoring knee stability; however, optimal graft fixation—particularly on the tibial side—remains a subject of ongoing investigation. Interference screw fixation is widely used due to its ability to provide immediate graft stability and facilitate early rehabilitation. Despite its routine use, the choice of screw material may influence both biological and mechanical outcomes, including graft incorporation and bone tunnel changes over time [1].

One of the most frequently reported radiographic phenomena following ACL reconstruction is tunnel widening, particularly on the tibial side. The etiology of tunnel widening is multifactorial, involving mechanical factors such as micromotion and stress shielding, as well as biological factors including inflammatory responses and graft integration processes. While tunnel widening does not consistently correlate with short-term clinical outcomes, it may have implications for graft longevity, revision surgery, and overall structural integrity [2].

Different screw materials have been developed to address these concerns. Polyetheretherketone (PEEK) screws are biologically inert, radiolucent, and maintain long-term structural integrity, but they lack osteoconductive properties and do not integrate with surrounding bone. In contrast, biocomposite screws, typically composed of biodegradable polymers combined with osteoconductive ceramics, are designed to gradually resorb and promote bone ingrowth, potentially improving biological fixation. However, their degradation process may provoke local reactions and has been variably associated with tunnel widening.

More recently, allograft bone screws have been introduced as a fully biological alternative. These screws aim to provide immediate mechanical fixation while allowing for complete biological incorporation and remodeling into native bone. Theoretically, this may reduce tunnel widening and improve long-term integration, but clinical evidence remains limited [2,3].

To date, comparative data directly evaluating these three fixation strategies—biocomposite, PEEK, and allograft screws—are scarce, particularly with respect to tunnel widening and its clinical relevance. A better understanding of how screw material influences both radiographic and functional outcomes is essential for optimizing ACL reconstruction techniques and improving patient outcomes.

Objectives and hypothesis

The primary objective is to compare tibial tunnel widening after 1 year on CT. Secondary objectives are clinical outcomes (Lysholm, Tegner, KOOS and ACL-RSI) as well as graft integration in MRI after Putnis et al. [4]

We hypothesize a 1.5 mm reduced tunnel widening for the allograft screw, compared to both PEEK and biocomposite screws.

Methods

The study will be conducted across in the AUVA UKH Steiermark Hospital, Graz. All patients will have surgery, inpatient stays and follow-up at the sites.

Eligibility criteria

Inclusion criteria:

- Male and non-pregnant female patients aged 18–70 years
- MRI-confirmed rupture of the anterior cruciate ligament (ACL)
- Clinically positive anterior drawer test and Lachman test
- Subjective instability
- Clinically and MRI-confirmed intact posterior cruciate ligament (PCL), medial collateral ligament (MCL), and posterolateral corner
- Written informed consent obtained
- Patient is able and willing to participate in the study

Exclusion criteria:

- Previous surgery on the affected knee joint (ACL reconstruction, fracture fixation, osteotomy, or partial joint replacement)
- Body mass index (BMI) > 40
- Coronal instability due to injury of the medial collateral ligament or posterolateral corner
- Meniscal injury requiring postoperative restriction of weight-bearing (e.g., root tears, radial tears)
- The patient is unable to speak German
- The patient is pregnant

All patients will be screened by the orthopaedic surgeon and research coordinator based on the criteria. Patients that meet these criteria and express an interest in participating will be provided an ethics approved patient information sheet following initial consultation with their treating doctor. This sheet provides more detail about the study, potential risks and requirements for follow-up. Pre-operative visits include the collection of consent, MRI if not available, x-rays and completion of patient reported outcomes.

Intervention

ACL reconstruction will be performed using the SAMBBA[5] technique. All cases will be performed using the quad autograft ipsilateral tendon. Femoral fixation will be performed using the Arthrex (Naples, FL, U.S.) FiberTag RT and tibial fixation will be performed using either of the three screws. Both femoral and tibial tunnel are drilled line-to-line to the graft diameter. The screw diameter is either line-to-line, or, in case of 0.5 values, one size up (9 for 8.5). A lateral extraarticular tenodesis will not be performed.

Sample size

With equal allocation per group, to detect a 1.5 mm difference, assuming a standard deviation of 1.2 mm, 10 patients per group are required, plus 1 additional patient to account for loss to follow-up.

Randomization

Upon schedule of the surgery, each patient's records will receive one out of 33 pre-prepared and sealed envelopes, that will be open during the case, determining the screw.

Blinding

The participants, physiotherapists and assessors will be blinded to the treatment allocation. The participant identification list will be archived at the site on a secure network in a password-protected file, with the research team having access to the file. The investigators and research team are unable to be blinded to the allocation due to their role in the allocation of treatment and execution of surgery. Participants will be unblinded to the intervention at the end of the trial, unless there is a medical reason to do so prior to the end of the study.

Data collection

Outcomes will be primarily captured on paper, transferred to an excel table manually and stored using a password-protected electronic platform on the internal server of the healthcare facility.

For the purposes of group comparisons, we will collect age, gender, BMI and ASA score.

Preop	**In-hospital stay**	**6 weeks**	**3 months**	**6 months**	**12 months**
x-ray	x-ray	x-ray		x-ray	x-ray
Lysholm		Lysholm		Lysholm	Lysholm
Tegner		Tegner		Tegner	Tegner
					ACL-RSI
					CT
MRI				MRI	MRI

Table 1 – Overview of timepoints for data collection

Data management

The International Council for Harmonisation guidelines for Good Clinical Practice (ICH GCP) will be followed throughout the study. The sponsor will conduct routine monitoring visits for data verification against source material, as defined by participant entered data or medical records. Data collected by the sponsor will be stored electronically in a password-protected folder with restricted user access. Periodic surgeon investigator meetings will also be held to review participants where treatment has deviated from the protocol. The chief investigator will be responsible for the training and sign- off of all staff working on the study.

Confidentiality

All research staff and investigators will be employed by the AUVA and will comply with its confidentiality practices. All participants will be allocated a unique non-identifiable study

number and any information disseminated in journals or conferences will ensure patient anonymity is maintained.

Statistical methods

The primary and secondary outcome data gathered from patients in each study group will be pooled and summarised. The mean, standard deviation and 95% confidence intervals will be calculated for each measure in each group. All outcome measures will be assessed on their distribution and homogeneity to confirm the appropriate statistical model. Adjustments will be made for multiple testing over time. Pairwise comparisons will be examined using a paired t-test if normally distributed or non-parametric test for skewed distribution. Categorical data will be evaluated using frequency and percent distributions, with significance testing performed using Fisher exact test or chi-squared test. Statistical significance is defined as a p-value < 0.05.

Data assessment

Interim analysis will be conducted at 6-month follow-up for dissemination of results. Periodic analysis will also be conducted for patient safety. Sub-group analysis based on patient phenotype will be dependent on sufficient post hoc sample size calculations. A per-protocol and intention to treat analysis will be performed. In the event of randomisation errors, the participant will be converted to the study arm that represents the received treatment. The statistical model will be corrected in the event of missing data and to avoid type I error when performing multiple comparisons.

Oversight and monitoring

The principal investigator will be responsible for execution of GCP, delegation of authority to research staff and will review adverse events and protocol deviations. The principal investigator will review all adverse event forms for safety assessment. Any device or treatment related adverse events will be reviewed regularly by the Investigator team and a midpoint assessment of patient report outcomes will be conducted. An adverse event (AE) is defined as any undesirable clinical occurrence in a participant, whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

A serious adverse event (SAE) is an adverse event that results in hospitalisation or prolongation of existing hospitalisation, persistent or significant disability or incapacity, life-threatening or death. All will be reported to the principal investigator. All series adverse events will be periodically examined using an alert in the participants electronic medical records and will be reviewed periodically in-line with the evaluation schedule.

Referenzen:

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2. Coppola C, Krost S, Runer A, Raas C, Glodny B, Mayr R. PEEK Interference Screws Show Significant Tunnel Enlargement After ACL Reconstruction and is Comparable to Adjustable-Length Loop Cortical Button Fixation. Indian Journal of Orthopaedics. 2023 Nov 19;58(1):40. doi:10.1007/s43465-023-01029-8 PubMed PMID: 38161404.

3. Arzu U, Atasoy İT, Kızılkurt T, Pata DC, Erdil M, Polat G. Tibial tunnel widening in patients undergoing primary anterior cruciate ligament reconstruction: hydroxyapatite-coated vs. uncoated interference screws. Arch Orthop Trauma Surg. 2025 Sep 5;145(1):436. doi:10.1007/s00402-025-06056-8 PubMed PMID: 40911044.

4. Putnis SE, Oshima T, Klasan A, Grasso S, Neri T, Fritsch BA, et al. Magnetic Resonance Imaging 1 Year After Hamstring Autograft Anterior Cruciate Ligament Reconstruction Can Identify Those at Higher Risk of Graft Failure: An Analysis of 250 Cases. Am J Sports Med. 2021 Feb 25;363546521995512. doi:10.1177/0363546521995512 PubMed PMID: 33630656.

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