

■ **PROTOCOL**

Conventional versus 'all-inside' anterior cruciate ligament reconstruction: a randomized controlled trial comparing hamstring strength and functional outcome

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Introduction

Anterior cruciate ligament (ACL) reconstruction using the hamstring tendon autograft is a well-recognised and commonly performed procedure across the world. The 'all-inside' ACL reconstruction technique is a new development which is gaining popularity due to its unique features of using a single tendon autograft as compared to two tendon autograft used in the conventional technique. Theoretically, the spared hamstring tendon with the new 'all-inside' technique should leave the leg with a greater hamstring strength, thus an improved functional outcome. However, comparative studies,¹ systematic reviews, and meta-analysis²⁻⁴ have not been able to demonstrate a superior outcome with the 'all-inside' single tendon autograft.

Many studies have alluded to the good functional results of the all-inside technique,³ along with its other advantages, for example, its bone preserving nature,⁴ reduced postoperative pain,⁵ and smaller skin incision.⁶ Some technical problem with the new 'all-inside' technique has also been reported.⁷ A prospective multi-surgeon blinded randomized control trial is therefore required to study a difference in subjective and objective outcomes and technical problems between the two techniques. It is also worth studying whether the 'all-inside' technique allows the knee to regain its strength earlier than the conventional technique.

Aims

We aim to compare the conventional technique of reconstructing the ACL with semitendinosus and gracilis autografts, to the 'all-inside' technique of using a semitendinosus autograft alone. We plan to study the patient-reported outcome measure (Knee Injury and Osteoarthritis Score (KOOS), international knee documentation committee, and Lysholm score) at different stages of treatment. We plan to objectively assess the strength and stability of the operated knee by comparing it to the non-operated knee acting as a control.

We hypothesize that the 'all-inside' technique using a semi-tendinosis autograft alone is associated with better patient-reported subjective outcome scores and objectively measured strength and stability.

Methods

A prospective blinded randomized study from January 2021 to January 2024 is being set up. Skeletally-mature patients with isolated, unilateral primary ACL rupture will be recruited to the study. Those with associated or pre-existing meniscus, chondral injury, injury to other ligaments, or any injury to the opposite leg will not be selected. Patients will be randomized into two groups depending on the type of operation performed.

The conventional method of reconstructing the ACL is to use semitendinosus and gracilis tendon autografts from the same leg. Both these tendons are doubled up to

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create a four stranded graft. Femoral closed socket is drilled via the medial arthroscopic portal, and the tibia has an open tunnel drilled in from the outside. The graft is fixed to the femur using a suspensory fixation and secured in the tibia using interference screw fixation.

The 'all-inside' technique involves a quadrupled semitendinosus autograft alone with suspensory fixation on each end secured into the closed inside out drilled sockets of femur and tibia.

All operations will be performed in one of the two hospitals by senior consultant knee surgeons proficient in both types of reconstruction techniques. The postoperative care, physiotherapy, and follow-up assessment will be conducted at one centre using the same protocol.

Randomization, allocation, concealment, and blinding. Randomization in the two groups will be conducted with block randomization method. A randomization plan using mixed block size of two, four, and six patients will be made. A continuous numbered sealed envelop containing corresponding allocation will be used. These envelopes will only be opened at the time of surgery.

Patients selected after applying the inclusion criteria will undergo an informed consent process about the study and both types of reconstruction techniques. The allocation will not be disclosed to the patient until the end of the treatment and final follow-up of two years. The physiotherapist and outcome assessor will be blinded to the operation performed. The data analyst will be blinded to the details of the patients.

Outcome assessment

Before the operation all patients will undergo clinical assessment by the operating surgeon. Lysholm knee score and KOOS will be obtained. An objective assessment of laxity in the injured knee will be compared to the opposite knee.

At one year, 18 months, and two years after operation the same assessment will be repeated. At 18 months and two years of follow-up, we will also record the Return to Sports after Injury (RSI) scale.³ We also intend to record complications such as infection, deep vein thrombosis, and technical- or hardware-related problems.

Strength testing will take place at 18 months and two years after the operation. This will involve testing quadriceps and hamstring strength using an isokinetic dynamometer. The isokinetic dynamometer can measure muscle peak torque as a percentage to body weight, times to peak torque, and total work of extensors and flexors. The numerical value for each of the testing modality is obtained as raw data and as a comparison to the uninjured opposite leg. At the same time, we intend to undertake standard ACL functional assessment as a secondary strength measure.^{8,9}

Primary strength measure. The hamstring versus quadriceps strength ratio of the operated leg will be compared to the opposite (uninjured leg). The mean value of this in each group will be statistically compared.

Secondary strength measure. Hop testing, measuring single hop distance, triple hop distance, and cross over hop distance, and Limb Symmetry Index (LSI).

Statistical analysis. A power calculation by our medical statistics department has been performed. For a 5% level of significance, a sample size of 50 patients in each arm of the study is required. The patient-reported outcome and specific measurements will be expressed as mean with standard deviation. To determine the difference between the two sample means the *t*-test will be used. Statistical analysis will be conducted by the hospital medical statistic department.

Results

Two senior surgeons in the two collaborating hospitals have agreed to participate in the study. Each of the surgeons undertakes about 50 ACL reconstructions per year. We expect one-third of these patients will satisfy our inclusion criteria and will agree to participate in the study. Thus, we expect to recruit 100 patients between 2021 and 2024.

Discussion

This is a multi-surgeon prospective blinded randomized study comparing the subjective outcome scores, functional outcome, and knee strength in the conventional ACL reconstruction versus the 'all-inside' ACL reconstruction technique. The main difference between the two being that the conventional technique uses two autograft tendons (semitendinosus and gracilis), while the 'all-inside' technique uses the semitendinosus alone and spares the gracilis.

The 'all-inside' ACL reconstruction is meant to reduce surgical trauma and as the gracilis tendon is not used, the overall knee strength and function should be better and achieved earlier. In a recent single-surgeon comparative study, the strength of the knee with 'all-inside' ACL reconstruction was found to be superior but the functional outcome was similar.⁸ If a similar observation is seen in a multi-surgeon blinded randomized trial, the technique would be worth promoting.

Secondly, the assessments undertaken and strength testing in our study is at multiple intervals, unlike the other study,⁸ where assessments were at 24 months. Our study will also show if the difference in functional outcome and strength is achieved any earlier in the patients with 'all-inside' ACL reconstruction. These findings can influence physiotherapy and rehabilitation.⁸

Inclusion criteria

- All patients aged between 18 and 50 years.
- Isolated primary ACL complete rupture needing reconstruction surgery.

Exclusion criteria

- Previous injury to the knee.
- Concomitant meniscus cartilage or injury to other ligaments.
- Previous or recent injury to opposite leg.
- Significant medical comorbidity.

Subject withdrawal criteria

- If patients are lost to follow-up, or the patient decides on the choice of surgery.

Endpoints

- Target number of patients: 100 (50 in each group).
- Expected duration of the study: four years.

Publication policy. Results will be published in appropriate peer-review journals and presented at relevant scientific meetings. All participants shall receive a short report of the study findings if requested.

Archive plan. All essential study documentation will be archived in the trust archiving facility for a period of 15 years.

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- Y. Ashraf: Revised the manuscript, Wrote the new protocol.
- S. R. Senevirathna: Took initiative in setting up the research project, Wrote the initial protocol, Made the IRAS application for REC approval.
- T. Ashraf: Supervised the trial.

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