Biomechanical analysis of the anterolateral rotatory instability in combined anterior cruciate ligament and lateral extra-articular soft tissue reconstruction.

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Ethical review	Not approved
Status	Will not start
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational invasive

Summary

ID

NL-OMON42454

Source
ToetsingOnline

Brief title
CR ALESA

Condition

- Tendon, ligament and cartilage disorders

Synonym
extra-articular soft-tissue reconstruction, knee instability

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie
Source(s) of monetary or material Support: Eigen vermogen;aangevraagde beurzen

Intervention

Keyword: anterolateral ligament, anterolateral rotatory instability, knie, lateral extra-articular soft tissue reconstruction

Outcome measures

Primary outcome

The primary objectives are to describe the anterior-posterior translation, medial-lateral translation, proximal-distal translation, internal-external rotation, varus-valgus rotation as a function of flexion and knee state (intact contralateral control, ACL and lateral soft tissue injured, ACL and LES reconstructed).

Secondary outcome

The secondary objectives are: to evaluate the integrity of the LES reconstruction; and determination of patient subjective outcomes using questionnaires (IKDC, KOOS and the Tegner questionnaire).

Study description

Background summary

Approximately 5% of ACL reconstructions will fail and require revision surgery. Traditionally, failure of the primary ACL reconstruction was believed to be technical, traumatic, biological or a combination of these. Recent interest has been given to the anterolateral extra-articular structures of the knee, which might be injured during the initial ACL injury. Failure to recognize and manage these concomitant injuries might result in persistent postoperative instability of the knee and lead to failure of the primary ACL reconstruction. It is believed that concomitant LES reconstruction to the ACL reconstruction might be

able to better restore the kinematics of the knee. However, no in vivo information on the LES reconstructions exists; and the optimal flexion angle for fixation and pre-tensioning of the graft are unknown.

Study objective

The purpose of this study is to determine whether the concomitant LES reconstruction of the knee in combination with standard revision ACL reconstruction results in restoration of normal in vivo tibiofemoral joint kinematics. By evaluating the in vivo kinematics using a combined dual fluoroscopic and magnetic resonance (MR) imaging technique, of revision ACL surgery accompanied by one of the two different LES reconstruction techniques used in this study.

Study design

Prospective, observational cohort study with 6 months follow-up,consisting of 20 patients in total.
Patients will receive the standard ACL revision surgery as given in our clinic. An additional anterolateral extra-articular soft tissue reconstruction will be done. Pre-operatively an extra MRI scan will be made of the healthy contralateral knee. Also, two additional 'dual fluoroscopic' films will be made to evaluate the in vivo kinematica of the knee. After the surgery, standard out clinic appointments will be scheduled. Preoperatively and postoperatively; knee and ACL specific questionnaires will be taken (KOOS, IKDC and Tegner).

Study burden and risks

Standard orthopaedic care will be given to all patients. As this is an observational study, there is no direct benefit for the patient. An additional MR scan of the contralateral knee will be made. Also, two observational tests to the regular treatment will be made by means of a dual fluoroscopic technique, exposing the patient to additional Rontgen rays. Future patients will benefit from this study as surgical techniques will be optimized based on these results.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age: 18-40 years
- Failure of primary ACL reconstruction with LES injury
- Scheduled for two-stage revision ACL surgery
- Written informed consent

Exclusion criteria

- Collateral ligaments injury that requires surgery
- Evident cartilage lesions
- Injury to underlying bone
- Adequate tunnel placement (so that one-stage rather than a two-stage revision could be performed)
- Injury or prior surgery to the contralateral knee
- Pregnant patients
- Patients with metal in-vivo (making it impossible to perform an MRI-scan)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	03-09-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL53951.098.15