Optimizing Anterior Cruciate Ligament Replacement by using Numerical Musculoskeletal Model

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Primary Objective: The primary goal of this research project is to provide input data for a biomechanical simulation model of the knee and to determine the variation among subjects. With the simulation model ACL reconstruction can be optimised....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36009

Source
ToetsingOnline

Brief title
Optimizing ACL replacement by using numerical Musculoskeletal model

Condition

- Other condition

Synonym
We study healthy subjects

Health condition

Healthy subjects

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ACL reconstruction, ACL replacement, Anterior Cruciate Ligament / ACL, Musculoskeletal model

Outcome measures

Primary outcome

From MRI measurement:

a. The length and the elongation of all 4 ligaments during several flexion

position and maximal tibial rotation while the knee is in 90o flexion

b. The contact points of both femoral condyles and tibia plateau

c. The attachment position of every ligament (origin and insertion)

d. The geometric data of the knee bone, such as the widht of femoral condyle,

tibia plateau, varus valgus knee angle, the orientation of contact point

between articular cartilage and meniscus.

From Vicon measurement:

a. Kinematics of relevant body segments

b. EMG analog data of muscle activity, onset and off set of muscle activity and

muscle activity pattern.

Secondary outcome

From MRI measurement:

a. The relationship of the length of ACL, PCL, MCL and LCL in different angle

position during flexion and maximal tibia rotation at 90o knee flexion

Study description

Background summary

ACL-reconstructions are often performed in the Netherlands. The surgical techniques used depend on the instrumentation and those are developed for an average patient. However, patients differ in knee geometry and knee biomechanics. As a result in several cases complications occur after surgery, the anatomical reconstruction is not always optimal and rotational stability is not repaired completely. Due to those reasons, a patient-specific musculoskeletal model will be built in order to study and optimize patient-tailored ACL reconstruction.

The musculoskeletal model will be built using Anybody software from Aalborg University, Denmark. The model will consist of bones, muscles and ligaments. MRI scanning will be used to get the geometrical data of the knee. Scanning will be done in several different knee flexions. Kinematics of the model will be derived from the registration (via optical markers on bony landmarks) of active movements that will be recorded under 8 optical cameras of the Vicon system in the UMCG Gait Laboratory. Normal walking, forward hopping and side jumping will be choosen as the activities, as those activities are the standard procedure in the rehabilitation program of ACL reconstructed-patients. During this experiment also muscle activity will be registered with non-invasive EMG surface electrodes. These data will be used to validate the numerical model.

Geometrical data from MRI scanning is composed of:
a. the length of 4 ligaments (the most significant ligaments in the knee) - Anterior Cruciate Ligament (ACL), Posterior Cruciate Ligament (PCL), Medial Collateral Ligament (MCL) and Lateral Collateral Ligament (LCL) in several position of knee flexion (0o, 30o, 60o, 90o, full flexion, maximum internal and external tibia rotation in 90o).
b. Attachment position of all four ligaments
c. Contact points between the two femoral condyles and the tibia plateaus at several flexion positions as mentioned above. (knee flexion and maximum tibial rotation)
d. Bone geometry (including articular surfaces, width and length of the femoral condyles and tibial plateau)
e. The twisting behaviour of four ligaments as a function of the flexion angle and maximal tibial rotation
Ìn order to fix the leg during scanning, a polymer (MRI compatible) leg fixator will be used

Study objective

Primary Objective: The primary goal of this research project is to provide input data for a biomechanical simulation model of the knee and to determine the variation among subjects. With the simulation model ACL reconstruction can be optimised.

Primary questions:
1. From the MRI measurements: What is the geometry of all relevant knee structures (bones, ligaments and articular cartilages)? And how are the variations among different subjects?
2. From the Vicon measurements: What are the kinematics of body segments during normal walking, forward hopping and sidewards jumping? And how are the variations among different subjects?
3. From the Vicon measurements: Muscle activity, duration of muscle activity, onset and offset of relevant muscles (3 Hamstring, Quadriceps Medialis and Lateralis, 2 Gastrocnemius, Tibialis Anterior), muscle recruitment pattern during movement? And how are the variations among different subjects?

Secondary Objective(s): As secondary goals, we will investigate:
1) From the MRI measurements: how is the relationship of all 4 ligaments properties (elongating, twisting) and femoral-tibial contact points during several knee flexion positions and maximum tibial rotation? And how are the variations among different subjects?

Study design

Experimental pilot study

Study burden and risks

a) For MRI scanning, the subject will be lying inside the MRI tube, with the right knee flexed at 0o, 30o, 60o, 90o, full flexion, maximum internal and external tibia rotation under 90o knee flexion using the leg fixator. For every angle of flexion/tibia rotation, the subject will be scanned for 7 minutes, so in total with 3 minutes break after every scanning time will be 7 minutes x 7 positions = 49 minutes + (3 minutes x 6 times break = 18 minutes), approximately 1 hours. There is no risk associated with this experiment.
b) For the Vicon Measurements, the subject will get markers and EMG surface electrodes attached to certain positions of the leg, then normal walking will be performed at the first measurement, continued by forward hopping over 1 m. The third measurment will be side jumping for 10 seconds, with a distance between each step of 60 cm, and a jumping height of 20 cm. During all those tasks, a force plate is applied to calculate the ground reaction force of the subject. Every task will be performed 3 times. Every subject will need about 15 minutes for these experiments; attaching the markers and EMG surface electrodes

will take about 30 minutes, so in total the measurements will take approximately 45 min.
The risk associated with this experiment is twisting the ankle

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The healthy subjects should be able to do the walking hopping task without any help or trouble. Age range should be between 18- 55 years.

Exclusion criteria

Subject is not eligible if she/he meets one or more of the following criteria: ;(a) Claustrophobic subject will be erased from the list (for MRI scanning)
(b) Current pain in the knee or other lower limb parts that can cause abnormal walking, hopping and side jumping.
(c) Past lower limb trauma that has caused current imbalance in walking and hopping
(d) Current neurological and metabolic disorders that have effect on lower limb function (diagnosed by sports physician)
(e) Current inflammatory arthritis of foot, ankle, knee, hip and back (diagnosed by sports physician)
(f) Lack of normal lower extremity function that interferes with normal walking, hopping and side jumping (diagnosed by sports physician)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL36663.042.11