In vivo analysis of tibial rotation after anatomical versus trans-tibial anterior cruciate ligament reconstruction surgery

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Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39154

Source
ToetsingOnline

Brief title
Validation study on Gait analysis after ACL reconstruction

Condition

- Tendon, ligament and cartilage disorders

Synonym
Anterior Cruciate Ligament, movement analysis

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Er is geen financiele ondersteuning hiervoor. Eigen initiatief in samenwerking met de universiteit

Intervention

Keyword: anterior cruciate ligament, Gait analysis, tibial rotation, VICON

Outcome measures

Primary outcome

Primary Objective/endpoint

Our first outcome of interest will be the tibial rotation excursion. This is the graph which we can draw from our gait analysis system which measures the position of the tibia in relation to that of the femur and allows us to see the angle of rotation.

Secondary outcome

Secondary Objective/endpoint

Additionally we keep track of our patients well being and satisfaction with the procedure through several questionnaires. We will use the following questionnaires that have been recommended by the NOV (Nederlandse Orthopeden Vereniging, 2011)

* International Knee Documentation Committee (IKDC) (0-100)

* Knee Injury and Osteoarthritis Outcome Score (KOOS) (0-100)

* Tegner Score (0-10)

We will perform several clinical tests to assess stability.

* Lachman (mild-moderate-severe)

* Anterior drawer (mild-moderate-severe)

* Pivot shift (positive-negative)

Study description

Background summary

The knee accounts for 40% of all injuries acquired through sports. (Majewski M, 2006) Ligament instability is a commonly seen result of these injuries. One of these ligaments is the anterior cruciate ligament (ACL). ACL-ruptures mostly result from abrupt deceleration, hyperextension or pivoting on a fixed foot. (Boden BP, 2000) (Noyes FR M. D., 1983)
Sometimes they result from contact injuries, typically a blow to the lateral side of the knee when the foot is planted. These injuries are often associated with medial instability and patients sometimes report feeling or hearing a *pop*. Patients are mostly unable to continue their current activity, and often develop acute effusion. (Cummings JR, 2005)
With chronic ACL insufficiency patients frequently perceive their knee as unstable and often complain about activity related swelling, difficulty walking downhill and problems with acutely stopping. (Losee, 1985) (Noyes FR M. D., 1983)

The anterior cruciate ligaments primary function is to prevent excessive anterior tibial translation in relation to the femur. Abnormal anterior tibial translation is tested through clinical tests like the Lachman and anterior drawer tests or through mechanic testing using the KT-1000 or KT-2000 arthrometer. Cadaveric studies have shown that the ACL is the primary restraint to anterior tibial translation and the ligaments greatest contribution to this restraint was at 30° flexion. (Butler DL, 1980) Sectioning of the medial collateral ligament increased anterior translation at 90° flexion but not at 30°, thereby giving the Lachmans* test a specificity advantage over the anterior drawers test. (Beynnon BD, 1992)

An important secondary function of the ACL is the prevention of rotational instability through preventing excessive internal rotation of the tibia. Most often ACL-rupture results in a specific form of rotational instability called Anterolateral Rotational Instability (ALRI), which typically results from acute internal rotation and varus-stress on a weight bearing knee such as losing balance after landing off a jump. (Hughston JC, 1976) Several tests can be used to assess the presence and degree of ALRI, like the pivot-shift test, the flexion-rotation drawer test, the Losee test and the Jerk test of Hughston. (Hughston JC, 1976) (Losee RE, 1978) (Noyes FR B. R., 1980)
However, most of these tests have either low sensitivity or specificity. The sensitivity of the Pivot-shift test varies between 0.18 and 0.48 and a specificity varying between 0.97 and 0.99 (Scholten, 2003)
Flexion-rotation drawer for partial or complete ruptures reported sensitivity of respectively 0.62 and 0.89 while under anesthesia, but only 8% and 38% while not anaesthetized. (Noyes FR B. R., 1980)

After tearing of the ACL, initial treatment is conservative. In case of persistent instability after conservative treatment, surgical reconstruction of the ACL is advisable. Currently a few ACL-reconstruction techniques are used. The most commonly used is the transtibial reconstruction. In this technique the orientation of the femoral tunnel depends on the orientation of the tibial tunnel, because the femoral tunnel is created through the tibial tunnel. In this way a non-anatomical reconstruction of the ACL can be made, because the ACL is not exactly oriented as is the native ACL. (E.F.P.A. Fievez, 2011) The anatomical reconstruction aims to better restore this rotational stability by placing an extra anteromedial arthroscopy portal through which the femoral tunnel can be reamed more laterally and more diagonally oriented, hereby placing the graft in a more anatomical orientation similar to the native ACL.
In 30° of flexion both anatomical and transtibial reconstruction techniques cannot prevent tibial anterotranslation as is in a normal knee, but both significantly improve stability compared to ACL deficient knees. In full extension the anterior stability is also improved through both techniques, but only the anatomical reconstruction seems capable of restoring ACL stability back to the original native ACL state. (Sim, 2011)
Theoretically, the anatomical ACL reconstruction might be superior to the non-anatomical reconstruction in respect to stability and patient*s satisfaction. Clinical results are however comparable with high satisfaction rates in both anatomical or transtibial surgery techniques and no significant differences exist between patient satisfaction rates or functionality (Alentorn-Geli, 2010)

Experiments dealing with the rotational stability after an ACL reconstruction have not been performed in vivo or were performed under static conditions. Although static rotational stability testing is currently the standard, many studies have shown that static stability tests are often incapable of correlating with functional outcome following anterior cruciate ligament-reconstruction-surgery. (Tashman S, 2008) (Barber SD, 1990) Through in vivo testing in dynamic weight bearing knees we expect to get a better view of the actual rotational pivoting forces in the knee.

Study objective

Theoretically the anatomical reconstruction technique should give better results in rotational stability due to a more anatomical placement of the ACL-graft. Though it is difficult to test this correlating to functional outcome, because in current literature there seems to be no significant difference between both surgical techniques and because statically performed anterolateral rotational instability tests do not reproduce the forces loaded onto an in vivo anterior cruciate ligament (Noyes, 1980)
Through in vivo kinematic 3D- gait analysis, we aim to measure statistically and clinically significant differences in tibial rotational excursion when patients perform several motor tasks

Study design

Prospective non randomized pilot study

Study burden and risks

All possible, participating subjects will have three times contact.

The first time they will be informed by telephone about the study. The information will be sent by post. (+ / - 15 minutes)
The second time the possible participant will be asked to participate and informed consent will be signed (+ / - 15 minutes)
The third time, all measurements including physical examination by a physician will be done. Also the questionnaires will be obtained. (+ / - 60 minutes)

total time 90 minutes

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

Universal Inclusion criteria;* Age 18-40 years
* Able to understand and speak the Dutch or English language ;Healthy Control group
Specific inclusion criteria
* No history of knee ligament or meniscal injury

ACL Deficient Group
Patients with a unilateral ACL rupture, verified by the patients* history, a positive Lachman test and MRI or arthroscopy, are candidates to participate in the ACL deficient group this study
Specific inclusion criteria
* Diagnosed ACL rupture with MRI or surgical knee arthroscopy
* Primary ACL rupture
Transtibial Reconstruction group
We will recruit patients that have received transtibial ACL reconstruction from Orbis Medisch Centrum and Atrium MC
Inclusion criteria
* Received transtibial ACL reconstruction minimally one year ago. We*ve chosen this cut-off point due to the risks of graft loosening or re-rupture in patients that have not fully completed their rehabilitation program which takes about 9 to 12 months.

Anatomical Reconstruction group
We will recruit patients that have received anatomical ACL reconstruction from Maastricht University Medical Centre (MUMC) and Atrium MC
Inclusion criteria
* Received anatomical ACL reconstruction minimally one year ago. The cut off points was chosen for the same reason as in the transtibial group.

Exclusion criteria

Universal Exclusion criteria
* Not able and willing to sign informed consent
* BMI > 30;ACL deficient group
Specific exclusion criteria
* Ligament injury to the contralateral knee ;Transtibial Reconstruction group
Exclusion criteria
* Ligament injury to the contralateral knee ;Anatomical Reconstruction group
Ligament injury to the contralateral knee

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	20-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-07-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27173
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40420.068.12
OMON	NL-OMON27173