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An in-vivo gait analysis of the effect of different femoral tunnel positions in anterior cruciate ligament (ACL) reconstruction on knee rotational movement

Submission date
02/02/2009

Recruitment status
No longer recruiting

Registration date
13/03/2009

Overall study status
Completed

Last Edited
13/03/2009

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
An in-vivo gait analysis of the effect of different femoral tunnel positions in anterior cruciate ligament (ACL) reconstruction on tibial rotation: a prospective case-series

Study objectives
We hypothesised that a more horizontal placement of the anterior cruciate ligament (ACL) substitute graft (at the 10 o'clock position in the femur) can address abnormal rotational knee movement after an ACL reconstruction, as compared to the standard 11 o'clock femoral position.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Committee of the University Hospital of Ioannina, approved on 26/05/2008

Study design
Observational prospective comparative case-series, single-centre

Primary study design
Observational

Secondary study design
Other

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Anterior cruciate ligament (ACL) rupture and reconstruction, knee injury

Interventions
Twenty ACL reconstructed subjects (mean age: 28 +/- 8 years) and ten healthy subjects (mean age: 29 +/- 5 years) were enrolled in this study. The ACL reconstructed subjects were tested as follows (on average) 2 years after the surgery.

1. Knee muscle strength measured with BIODEX System-3® (Biodex Corp., USA) isokinetic dynamometer
2. Clinical evaluation:

2.1. Patient's level of activity measured with the Tegner test
2.2. Patient's knee functional scale measured with the Lysholm test
3. Anterior tibial translation was evaluated using the KT-1000™ Arthrometer® (MEDmetric Corp., USA) for both ACL reconstructed subjects and the healthy controls.
4. An eight camera optoelectronic system (Vicon-Peak Performance Technologies, Inc., UK/USA) was used to capture the movements of fifteen reflective markers placed on the selected bony landmarks of the lower limbs and the pelvis of the examined subjects. The subjects were asked to perform two different activities: 1) descending from a stair and subsequent pivoting, and 2) landing from a platform and subsequent pivoting. We also placed inline foot switches (Noraxon Inc., USA) with two sensors on each, on the plantar surface of the shoes in the toe and heel positions. Foot-switch data collection was time-synchronized with the kinematic data through the Vicon-Peak® digital transceiver. The signals provided from the foot-switches were used to determine the exact time occurrences of the start and the end of the pivoting period that was under evaluation. Based on our hypothesis, the dependent variable examined in the present study was the range of motion of tibial rotation during the pivoting period for the two examined tasks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The following were assessed at 2 years after ACL reconstruction:
1. Tibial rotation (kinematics) measured with the gait analysis system
2. Tibial translation measured with KT-1000™ Arthrometer®
3. Patient's level of activity measured with the Tegner test
4. Patient's knee functional scale measured with the Lysholm test

Secondary outcome measures
The following were assessed at 2 years after ACL reconstruction:
1. Knee muscle strength measured with BIODEX isokinetic dynamometer
2. Knee joint stability measured with static tests (Lachman, anterior-drawer, pivot-shift)

Overall study start date
10/08/2005

Completion date
10/05/2008

Eligibility

Key inclusion criteria
1. Males
2. Patients with ACL reconstruction with a bone patellar tendon bone (BPTB) graft
3. Healthy subjects

Note: Participants with similar anthropometric features and age group were selected for this study in order to minimise bias

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
30

Key exclusion criteria
1. Patients with concomitant injuries (e.g., chondral lesions, lateral collateral ligament injuries or meniscal injuries in which a meniscectomy or a suture of the meniscus was performed)
2. Patients with symptomatic anterior knee pain or objective instability at the latest follow-up examination (positive pivot-shift test results, positive Lachman-test results and arthrometer side-to-side differences of more than 3 mm)

Date of first enrolment
10/08/2005

Date of final enrolment
10/05/2008

Locations

Countries of recruitment
Greece

Study participating centre
University of Ioannina
Ioannina
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Sponsor information

Organisation
University of Ioannina (Greece)

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University/education

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https://ror.org/01qg3j183

Funder(s)

Funder type
University/education

Funder Name
University of Ioannina (Greece)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration