TLEMsafe: Improving safety and predictability of complex musculo-skeletal surgery using a patient-specifc navigation system. Part IIb: validation with hip patients pre and post OR.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON37914

Source
ToetsingOnline

Brief title
TLEMsafe part IIb: hip patients.

Condition

- Joint disorders

Synonym
1) Congenital hip dysplasia, and 2) hip revision., dislocation of the hip

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Europese Commissie.

Intervention

Keyword: musculo-skeletal modelling, orthopaedic surgery, patient-specific, surgical navigation

Outcome measures

Primary outcome

The main study parameters are 1) changes in anatomical musculo-skeletal parameters pre- and post-OR, and 2) the amount of difference in spatiotemporal, kinematic and kinetic parameters during basic ADL between model outcome and actual measurement (6-9 months post-OR). The anatomical parameters consist of the hip centre of rotation, femoral shortening length, muscle attachment points, muscle wrapping contours, muscle volumes, bony landmarks, tendon lengths and physiological cross-sectional areas of muscles. The spatiotemporal, kinematic and kinetic parameters include walking speed, stride length, cadence, hip range of motion, maximal hip flexion/extension, hip power generation/absorption, and hip flexion moment during various ADL.

Secondary outcome

not applicable.

Study description

Background summary

Two of the most challenging surgical interventions on patients with hip disorders are 1) total hip arthroplasty (THA) for developmental dysplasia of the hips (DDH), and 2) major revision of a previously implanted total hip replacement (THR).
In the case of THA for DDH, the centre of rotation (COR) of the hip has gradually migrated cranially over the years because of lack of acetabular coverage, and the proximal femur is in varus anteversion position. The largest difficulties lie in the placement of the COR at the correct anatomical location and determining the optimal amount of femoral shortening. If these are not optimal, the ability of the patient to perform basic activities of daily living (ADL) after surgery may be compromised.
In the case of revision surgery, it is a fact that all total hip implants will fail in time (Schreurs 1994). The clinical outcome of revision surgery is not as good as that of primary THA. Revision surgery requires more operation time, there is more blood loss, the incidence of infection is doubled, there is increased incidence of dislocation, heterotopic ossifications, penetration and fractures of femur or acetabulum, there are more nerve lesions, and complications occur more often. Re-revision surgery has even worse outcome (Retpen, Varmarken et al. 1992). To make sure that a re-revision does not become necessary, it is essential that during the revision surgery, the COR is restored at the most anatomically correct location to avoid additional strain on the implanted acetabulum and femoral head during ADL.
In both DDH patients and patients that require a revision, a powerful computer model coupled with a surgical navigation system could be of great help, and this is exactly the challenge of the TLEMsafe project (TLEM - Twente Lower Extremity Model). The surgeon would benefit greatly from a pre-planning system that could show him the effects of several surgical scenarios on post-OR functionality. To this end, we will use a state-of-the-art musculo-skeletal (M-S) model of the lower limb which has recently been developed (Klein Horsman 2007). In this model, the ability to perform basic ADL after surgery can be simulated. In order to simulate ADL after surgery in an accurate manner, the model first has to be made patient-specific and undergo rigorous validation. In the first part of the project, healthy-subject-specific M-S models have been created, which are currently being validated. In the present phase of the project, we will create and validate patient-specific post-OR M-S models of hip patients. This is a crucial step towards the construction of a reliable surgical pre-planning and navigation system.

Study objective

To create and validate patient-specific post-OR M-S models of the lower limb of hip patients. The primary goal of this study is to see if the model can accurately predict how a patient walks after surgery given the pre-OR MRI scan and accurately recorded pre-OR activities of daily living.

Study design

Observational prospective cohort study.

Study burden and risks

The study procedures are split into identical pre-OR and post-OR parts. Both parts consist of an MRI scan of the lower limb and a session during which the patient performs basic ADL. The post-OR part takes place 6-9 months after the surgery.
Each MRI scan takes about 45 minutes. The scans are made exclusively of the lower limb. They are painless and not dangerous.
The ADL sessions that patients have to perform before and 6-9 months after surgery take place in the motion laboratory of the department of Rehabilitation. These sessions take three to four hours to complete. In these sessions, 3-D kinematics, ground reaction force measurements, and electromyography will be employed to measure the patient*s functionality during ADL such as walking, getting up from a chair, stepping over an obstacle, and maintaining balance while standing on a moveable platform. We will also perform maximum strength tests. All of the measurements in the motion laboratory are regularly performed in this laboratory and are non-invasive and painless. If a patient anticipates or experiences pain during any of the exercises, that exercise will be skipped.
Both the MRI scans and the ADL sessions will be scheduled as much as possible on days that the patient is already at the RUMC for other treatment-related visits.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 2
6525 CG Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Reinier Postlaan 2
6525 CG Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients must have developmental dysplasia of the hips or require a major revision of a previously implanted total hip replacement, be between 18-70 years of age, and have a body mass index between 17-30.

Exclusion criteria

- Substantial neurologic or musculo-skeletal disorders that would adversely affect ability to perform ADL;
- Use of medication that affects the functioning or the neurological control of the M-S system;
- Prior intraarticular infection of the hip;
- Osteoporosis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2013

Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL39992.091.12