Pre-operative templating by use of MRI in primary total knee replacement

Published: 27-10-2009
Last updated: 04-05-2024

The purpose of this study is to evaluate the accuracy and the reliability of the new template system in total knee replacement by use of MRI in comparison with the conventional template method by use of radiographs.

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

Summary

ID

NL-OMON32957

Source
ToetsingOnline

Brief title
Templating total knie replacement by MRI

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
cartilage damage, Knee arthrosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MRI, Signature, Template, Total knee replacement

Outcome measures

Primary outcome

The primary outcome measures are the overall reliability and accuracy of the pre-operative template size of the MRI template method and the conventional method by use of radiographs, compared with the actually implanted prosthesis.

Secondary outcome

Secondary outcome measures are intra- and interobserver reliability of both methods.

Study description

Background summary

Templating is generally recommended prior to total knee replacement. The aim is to predict the bone stock; and the size and mechanical axis of the implant, which theoretically would reduce the operation time and complication rate. Several studies confirmed that there is a lack of reliability of the current pre-operative template system, by use of radiographics, with a relatively low percentage correlating with the exact size of the implanted prosthesis.

Because of the incapacity to predict the exact size of the implanted prosthesis with the present templating method, a new template system has been developed: the Signature* Personalized Patient Care (Biomet, Warshaw, IN). This system utilizes patient specific femoral and tibial positioning guides, developed from Magnetic Resonance Imaging (MRI). In combination with this template system, the Signature* Personalized Patient Care contains a new developed jig, using rapid prototyping, which could be used per-operatively in a total knee replacement procedure using the Vanguard® Complete Knee System.

Study objective

The purpose of this study is to evaluate the accuracy and the reliability of the new template system in total knee replacement by use of MRI in comparison

with the conventional template method by use of radiographs.

Study design

A pilot study of 10 patients is undertaken. If the pilot shows acceptable results, a new study protocol will be written. In that future study, we want to include more patients that will undergo the complete Signature* Personalized Patient Care protocol consisting of the MRI-template method combined with rapid prototyping to produce extramedullary alignment jigs for guidance during the operation. This new protocol will be compared with the conventional preplanning and operative protocol.

Eligible patients will be asked to sign an informed consent. The patients will be contacted through the following procedure: A research form is presented to the patient by mail, one week before pre-operative consultation. This pre-operative consultation will be approximately two or three weeks before surgery (so called *knee-carrousel*). During this consultation, patients will get the chance to obtain more information about the study. If informed consent is obtained, an appointment for a pre-operative MRI will be arranged. Radiographs of the knee have already been performed during the standard protocol.

The knee replacement will be done by an independent surgeon. The surgeon will be blinded for the study participation of the patient. Patient data will be coded on radiographs and MRI-scans to prevent observer bias. Two independent observers will template the pre-operative MRI and use the conventional templating method for the first time after randomization of these data. They are blinded for surgical technique and per-operative results. Two weeks after the first templating, the observers will repeat both templating methods. When the target of included patients is reached, the researcher will evaluate the template data of both observers by the operation records and post-operative radiographs. The post-operative score consist of the femoral and tibial size, by use of the following three-scale score: too small (undersized), correct, or too big (oversized).

Study burden and risks

The patient will undergo one MRI-scan pre-operative. No disadvantages for the patients are expected, because patients with a contra-indication for a MRI-scan will be excluded from the study.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
1100 DD
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1100 DD
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with knee osteoarthritis undergoing a total knee replacement.

Exclusion criteria

Systemic disease (e.g. rheumatoid arthritis, lupus erythemadosus), tibia plateau fracture or high tibial osteotomy in history, anterior cruciate ligament rupture in history, inability to understand the patient information (e.g. mental retardation, language barrier), patients with a contra-indication for MRI (e.g. pacemaker).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL27927.018.09