Signature* Personalized Patient Care in Total Knee Arthroplasty;Comparing preoperatively planned alignment with postoperative achieved alignment;A prospective shape-matching study

Published: 28-03-2011
Last updated: 27-04-2024

Clinical, prospective, non-randomized trial Orbis Medsich Centre, Sittard-Geleen

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

Summary

ID

NL-OMON36146

Source
ToetsingOnline

Brief title
Grating postoperative alignment TKA

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
gonarthrosis, knee wear

Research involving
Human

Sponsors and support

Primary sponsor: Orbis Medisch Centrum
Source(s) of monetary or material Support: Maatschap orthopedie Orbis MC/normale Nederlandse DBC systeem

Intervention

Keyword: postoperative alignment, preoperative planning, shape matching, total knee arthroplasty

Outcome measures

Primary outcome

To compare the preoperatively planned, computer-based Signature* alignment plan

with the actual achieved alignment in the frontal, coronal and sagittal plane

in vivo postoperatively of both the femur and tibia components of the total

knee arthroplasty.

Secondary outcome

To determine the occurrence (and percentage) of outliers in alignment in the

frontal, sagittal and horizontal plane of femoral and tibial components.

To determine the occurrence (and percentage) of outliers in alignment of the

mechanical axis of the leg.

Verify the fit, form and practical use of the Signature* alignment guides.

Verify to what extend the thickness of the in vivo inserted polyethylene

corresponds with the pre-operatively calculated thickness of this insert.

Study description

Background summary

So far, there were basically two types of operation methods on total knee

arthroplasty, namely one that uses intramedullary alignment, the conventional method, and the perioperative computernavigaded placement of a TKA. At Orbis Medical Center, we have experience with the Signature system developed by Biomet.

Signature uses patient-specific templates for femoral and tibial component of the TKP-standard system locations. The production of the molds starts 5 weeks before surgery with an MRI scan of the hip, knee and ankle of the leg of the patient. Software is used to calculate the most suitable size and position of a set of existing prosthetic components, such that a neutral mechanical leg axis postoperatively is created. The software uses bony reference points.
The overview of the proposed placement is summarized in a digital map. This plan is sent to the orthopedic surgeon who will perform the surgery. If necessary, adjustments for placement of the prosthesis can be made.
The patient-specific templates fit only one way to the femur (Figure 2) and tibia (Figure 3). Using these molds, pins are drilled in the femur and tibia to determine the position of the cutting blocks.

Study objective

Clinical, prospective, non-randomized trial
Orbis Medsich Centre, Sittard-Geleen

Study design

Comparison of the preoperatively planned adjustment of the prosthesis, as determined by the software and based on the MRI scan with the actual postoperative alignment of the prosthesis on Signature * Personalized Patient Care in the frontal, transverse and sagittal plane.

Study burden and risks

The main potential risks of a knee prosthesis infection, loosening, fracture, thrombosis or continuous pain. Moreover, the Signature * guides allergic reactions to materials used in the guides. However, the guides are only for adjusting the prosthesis and will be removed after the surgery.
The usual risks of performing a CT scan apply.

Contacts

Public
Orbis Medisch Centrum

Dr. H. van der Hoffplein 1

6162 BG Sittard-Geleen
NL
Scientific
Orbis Medisch Centrum

Dr. H. van der Hoffplein 1
6162 BG Sittard-Geleen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients scheduled to undergo primary total knee replacement with any of the following indications
Painful and disabled knee joint resulting from osteoarthritis.
One or more compartments are involved, as assessed by X-ray.
High need to obtain pain relief and improve function,
Above 18 years old (full skeletal maturity)
Body-mass-index (BMI) <38
Ability and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations.
Consent form read, understood and signed by patient.

Exclusion criteria

* Active infection in knee
* General infection
* Distant foci of infections which may spread to the implant site
* Failure of previous joint replacement
* Pregnancy

* Previous major knee surgery, except for arthroscopic meniscectomy.
* Metal near knee joint (MRI-scan not possible)
* Not able or willing to undergo MRI-scan and CT-scan

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-06-2011
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL35440.096.11