Pre operatieve navigatie voor de plaatsing van een totale knie prothese. Wat doet de industrie?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29421

Source
Nationaal Trial Register

Health condition

consecutive patients with debilitating osteoarthritis of the knee joint
patient specific, TKA, industrie, alignment, cutting guide, pin guide,

Sponsors and support

Primary sponsor: NA/Orbis
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

Pre operative approved planning for the femur and tibia component were compared with the post operative achieved alignment of each component on radiographs.

Biomechanical limb alignment and implant position were measured with a calibrated protocol on digital images on a PACS system [Boonen et al 2012,Boonen et al 2013]. Biomechanical

axis (HKA: Hip-Knee-Ankle angle) was evaluated on standardized 1-year postoperative coronal full leg standing radiographs. Varus/ valgus position of the femur (FFC) and tibia (FTC) components perpendicular to the HKA angle were measured on the same coronal radiographs.

Secondary outcome

Flexion/ extension of the femur component (LFC), measured from the anterior femoral cortex and posterior or anterior slope of the tibia component (LTC) measured from the posterior cortex of the tibia, were evaluated on 1-year postoperative lateral radiographs. Deviations >3 degrees between pre-operative planned HKA (sum of FFC and FTC) and individual components (FFC, FTC, LFC and LTC) compared to post operative achieved alignment on radiographs, were considered as outliers.

Study description

Study objective

There is no difference between the different PSG systems if it becomes to outliers of the biomechanical axis

Study design

Pre-, 6 weeks and 12 monts post-operative

Intervention

PSG from the following manufaturer

TruMatch system

Visionaire system

Patient Specific Instrument system

Signature system

Contacts

Public

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Eligibility criteria

Inclusion criteria

- eligible for primary unilateral TKA

- able and willing to participate

- written consent

Exclusion criteria

Patients who were not eligible to undergo MRI due to metal artefacts around the knee joint from previous surgery, claustrophobia, movement artefacts during MRI scanning time, pigmented villonodular synovitis (PVNS), implanted electronic devices (e.g. pacemaker, neurostimulator for bladder control or cochlear implants).

Patients that refused to consent were excluded.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	105
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-08-2014
Application type:	First submission

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
NTR-new	NL4571
NTR-old	NTR4739
Other	13.007 : 13N09

Study results

Summary results

Schotanus, Martijn GM, Bert Boonen, and Nanne P. Kort. "Patient specific guides for total knee arthroplasty are ready for primetime." World Journal of Orthopedics 7.1 (2016): 61.