Clinical evaluation of the *spacer technique* as a simple PCL-balancing tool for implantation of a PCL-retaining total knee replacement.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON35866

Source
ToetsingOnline

Brief title
Clinical evaluation "spacer technique".

Condition

- Bone and joint therapeutic procedures

Synonym
osteoartritis, primary total knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Smith & Nephew,Smith&Nephew, Inc

Intervention

Keyword: femorotibial contact point, posterior cruciate ligament balancing, total knee replacement

Outcome measures

Primary outcome

The postoperative medial tibiofemoral contact point of the knee in 90 degrees

of flexion.

Secondary outcome

Antero-posterior stability of the knee, clinical and functional outcomes (Knee

Society Score (KSS), KOOS, patellofemoral score), active and passive ROM, VAS

pain and satisfaction.

Study description

Background summary

Measuring the step off during surgery (spacer technique) is a newly developed operative strategy to determine the ideal contact point of the femur with the tibia postoperative and to balance the posterior cruciate ligament (PCL). Engineers have calculated the ideal step off for every size of the total knee replacement (TKR), with which the tibiofemoral contact point in 90* will be at the designed position. For this specific implant (PCL-retaining Genesis II TKR) this will be at 66% (+/- 5%) of the anterior/posterior distance.
If the PCL is balanced well, the postoperative anteroposterior stress X-ray will show that there will be less than 4 mm posterior translation of the medial contact point compared with the *not stressed* X-ray.

Study objective

The primary objective of the study is to investigate whether the postoperative tibiofemoral contact point in 90 degrees of flexion will be at the designed position for this specific implant (PCL-retaining Genesis II TKR).

The secondary objective of this study is to measure the anteroposterior laxity in 90 degrees of flexion.

Study design

The study has designed as a mono-centre cohort study. A total of 42 consecutive patients will receive the PCL-retaining Genesis II total knee replacement. Two surgeons will perform the spacer technique during the surgeries.
In all patients the contact point will be determined on X-rays with 3D software. Additionally, AP-stress X-rays will be performed to test the PCL function. AP laxity will also be measured and several clinical and functional socres (KSS, patella score, LEFS, KOOS, and VAS pain and satisfaction) will be administered.

Study burden and risks

There is no additional risk with regard to the investigated "spacer technique". This technique will only confirm and quantify the ususal protocol for total knee replacement during the surgery. In order to determine the exact postoperative effect on stability and contact point extra radiographs are necessary. These extra radiographs have a lower radiation dose than regular X-rays, however, they cannot replace the regular X-rays. The total amount of radiation is only slightly higher than during regular follow-up. Patients will visit the clinic at 2 years follow-up. This follow-up moment is extra for the study and therefore travel reimbursement will be available for all patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient presenting with non-inflammatory osteoarthritis (radiologically confirmed), requiring total knee replacement
- Patient has an intact PCL and patient has indication for a PCL-retaining Genesis II TKR
- Patient is 40 to 70 years of age, inclusive
- Patient plans to be available for follow up through 2 years postoperative.
- Patient is in a stable health and is free of, or treated for, cardiac, pulmonary, haematological, or other conditions that would pose excessive operative risk.

Exclusion criteria

- Patient is known to have insufficient femoral or tibial bone stock
- Patient has shown to have insufficient posterior cruciate ligament during surgery
- Patient has a BMI > 35
- Patient's expected physical activity after surgery is 2 or less on the UCLA Activity Scale
- Patient has had previous hip or knee replacement surgery in the last 6 months, or is planned to have a (second) hip or knee replacement in the next 6-12 months
- Patient has had major, non-arthroscopic surgery to the study knee, including HTO.
- Patient has an active, local infection or systemic infection
- Patient has physical, emotional or neurological conditions that would compromise compliance with postoperative rehabilitation and follow up
- Patient has grade 3 collateral ligament insufficiency
- Patient has knee flexion < 90 degrees
- Patient has fixed flexion deformity >10 degrees (passive extension lag)
- Patient has > 30 degrees extension deficit (active restraint to extension)
- Patient has varus or valgus deformity >10 degrees
- Patient has rheumatoid arthritis, any autoimmune disorder or immunosuppressive disorder
- Patient is pregnant or plans to become pregnant during course of study

- Patient has a known sensitivity to materials in the device

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2012
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL36576.072.11