Migration in a Cruciate Retaining and a Condylar Stabilizing Insert of a robot-assisted Uncemented Total Knee Prosthesis using Model-based RSA: a Mono-Center Randomized Controlled Trial with 10 years follow-up

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON53414

Source
ToetsingOnline

Brief title
CS vs CR TKA RSA study

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
degenerative joint disease, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Reinier Haga Orthopedisch Centrum

Intervention

Keyword: Insert, Migration, Total knee arthroplasty, Wear

Outcome measures

Primary outcome

Main study parameters are migration of the femoral and tibial components

measured with model-based RSA software till 10 years postoperatively.

Furthermore, the stability of the markers will be determined and the

complications due to the markers and/or the marker inserter will be registered.

Secondary outcome

The secondary parameters are wear, inducible displacement, survival, clinical

outcomes and complications up to 10 years postoperatively.

Study description

Background summary

The choice whether or not to preserve the posterior cruciate ligament (PCL) in total knee arthroplasty (TKA) is coupled to the use of a PCL-retaining (CR) or a condylar stabilizing (CS) insert. The CS insert is anterior-lipped (AL) to prevent anterior translation of the femur on the tibia with flexion and compensate the function of the PCL. Currently both the CR and CS insert are made of highly cross-linked polyethylene (HXPLE) to theoretically reduce wear related osteolysis. However, this also might diminish the fracture toughness and crack propagation of the insert. We expect that due to the high contact

forces on the anterior lip of the CS insert during flexion, especially in younger and more active patients, and the lower fracture toughness of HXPLE, the CS insert might show more migration, wear or other damage compared to the CR insert in the long-term, which might lead to more revisions in the CS insert compared to the CR insert.

To measure the migration and wear, during surgery tantalum markers will be inserted in the host bone using a marker inserter. The displacement of the prosthesis with reference to the host bone will be measured using model-based RSA. Both the tantalum markers and the inserter are already used for study purposes. However, the safety and usability are not registered before.

Study objective

The primary objective is to compare the migration of both the femoral and tibial component by the use of a CS insert or CR insert both made of HXPLE using model-based roentgen stereophotogrammetric analysis (mRSA). Furthermore, the safety and usability of the tantalum markers and the marker inserter will be determined. The secondary objective is to determine the influence of the type of insert on the wear, inducible displacement, survival and clinical outcomes.

Study design

A randomized controlled trial

Intervention

One group receives an uncemented total knee prosthesis with a CS insert, while the other group receives an uncemented total knee prosthesis with a CR insert. Both will be placed using the MAKO-robotic arm using a kinematic balancing technique.

Study burden and risks

There are no additional risks expected for the CS or CR insert used in the uncemented total knee prosthesis as compared to risks for other prostheses, as these prostheses are used for standard care in clinical practice. Also the MAKO-robotic arm is already used in clinical practice. Also the markers and marker inserter are used before without any problems in comparable studies. Patients are asked to spend time to fill in the questionnaires and to have extra visits to the hospital consisting of an examination and radiographs, next to the standard visits. The possible benefit from participation in this study might be that patients have more follow up visits, which has as advantage that possible complications might be noticed earlier compared to normal follow up.

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

• Patients scheduled to undergo primary total knee replacement with the MAKO-robotic arm, with one of the following indications:
o Painful, disabling joint disease of the knee resulting from: non-inflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis.
o One or more compartments are involved;
o Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability (meaning a varus, valgus or flexion deformity < 15 degrees);
• Age between 18 and 70 years;
• ASA score I or II;
• A good nutritional state of the patient;

• Patients with a completely intact PCL at the time of surgery;
• Patient is able to understand the study and is willing to participate and to sign the Informed Consent;
• Patient is able to speak and write Dutch.

Exclusion criteria

• Contraindications of the manufacturer;
• Metal in the operative or non-operative leg which lead to the creation of accuracy-reducing artefacts in the CT scan;
• Body Mass Index (BMI) of > 35 kg/m2;
• Flexion contracture of 15 degrees and more;
• Varus/valgus contracture of 15 degrees and more;
• History of total or unicompartmental reconstruction of the affected joint;
• Bilateral operation;
• A Total Hip Arthroplasty (THA) on contralateral and/or ipsilateral side within the last year that is considered to have an unsatisfactory outcome (Patients with contralateral and/or ipsilateral THA > 1 year ago with good outcome can be included in the study);
• A Total Knee Arthroplasty (TKA) on contralateral side within the last 6 months that is considered to have an unsatisfactory outcome. (Patients with contralateral TKA > 6 months ago with good outcome can be included in the study);
• Patients who will need lower limb joint replacement for another joint within one year.
• Active or suspected latent infection in or about the knee joint;
• Osteomyelitis;
• Sepsis;
• A systemic or metabolic disorder leading to progressive bone deterioration, excluding rheumatoid arthritis;
• Vascular insufficiency, muscular atrophy;
• Neuromuscular or neurosensory deficiency, which would limit the ability to assess the performance of the device;
• Female patients planning a pregnancy during the course of the study;
• The patient is immunologically suppressed or receiving steroids in excess of normal physiological requirements.
• Patients bone stock is compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis;
• A knee fusion to the affected joint;
• Patient has a known or suspected sensitivity or allergy to one or more of the implant materials;
• Insufficient bone stock to provide adequate support and/or fixation to the prosthesis;
• Unable or unwilling to sign the Informed Consent specific to this study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2023
Enrollment:	44
Type:	Actual

Medical products/devices used

Generic name:	Triathlon Total Knee System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-06-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL80554.058.23