Migration of the Restoris MultiCompartmental Knee Implant System in robotic-assisted unicompartmental knee arthroplasty: a 5 year follow up RSA study

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

Summary

ID

NL-OMON54033

Source
ToetsingOnline

Brief title
RSA Restoris MCK 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: robot-assisted, roentgen stereophotogrammetric analysis, unicompartmental knee arthroplasty

Outcome measures

Primary outcome

The migration of the Restoris MCK of both the tibial and femoral component

calculated as translation (mm) and rotation (degrees) measured with mRSA.

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

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

Secondary outcome

Survival of the Restoris MCK, short and long term clinical scores of pain

(NRS), function (Knee Society Score (KSS), Range of Motion, ROM) and the Knee

injury and Osteoarthritis Outcome Score (KOOS-PS), Oxford Knee Score (OKS),

EuroQoL-5D (EQ-5D-5L), Forgotten Joint Score (FJS), satisfaction and

radiographic aspects (both x-ray and CT scan).

Study description

Background summary

Patients with isolated medial compartment arthritis of the knee are commonly treated with unicompartmental knee arthroplasty (UKA). In contrast with total knee arthroplasty (TKA), UKA shows a higher revision rate, which might be due to implant malpositioning and postoperative malalignment of the lower limb and

incorrect soft tissue balancing. Nowadays, robotic-assisted UKA is used to improve accurate positioning, optimize soft-tissue balancing, optimize radiographic alignment of the implant, which also might improve functional outcome and survivorship in long-term.

As there is a lack in long-term results, more research is needed to the long-term results of robotic-assisted UKA. As long-term results are related to early migration of the implant, investigating the early migration will have additional value to predict the long-term results of robotic-assisted UKA. In this study, we will investigate the early migration of a unicompartmental knee implant (Restoris MultiCompartmental Knee Implant System (Restoris MCK)) used in robotic-assisted UKA and we will relate the migration of this implant to the long-term results of the implant. The migration will be measured using model-based roentgen stereophotogrammetric analysis (mRSA), which is a very accurate, 3-dimensional method to measure the migration relative to the bone.

To measure the migration, 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 assess the fixation and migration patterns of the Restoris MutliCompartmental Knee Implant System (Stryker) in vivo, using mRSA, over 5 years. Furthermore, the safety and usability of the tantalum markers and the marker inserter will be determined. Secondary objectives are to analyse alignment, survival, clinical scores and radiographic aspects of the Restoris MultiCompartmental Knee Implant System (Stryker) and to relate these to the migration patterns over 5 years.

Study design

A prospective cohort study in the Reinier Haga Orthopedisch Centrum, Zoetermeer, the Netherlands. Patients will be asked to participate and will be followed during 5 years. Patients will be evaluated preoperatively, at 6 weeks, 6 months, 1 year, 2 years and 5 years postoperatively.

Study burden and risks

Patients participating in the study will have the same risks when not participating in the study. Patients are asked to spend time to fill in the questionnaires and to have 2 extra visits to the hospital, next to the standard visits.Participating patients have more follow up visits, which has as advantage that possible complications might be noticed earlier compared to

normal follow up.

The markers and marker inserter are used before without any problems in comparable studies.

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

- Indication for medial unicompartmental knee replacement mainly as a result of moderately disabling joint disease because of: Painful osteo- or post-traumatic arthitis or as an alternative to tibial osteotomy. - Patient qualified for UKP based on physical exam and medical history - Patient is able to speak and write Dutch - Patient is willing to participate and able to provide written informed

consent - Age > 18 years

Exclusion criteria

- contraindication as described by the manufacturer
- patient has a known or suspected sensitivity or allergy to one or more of the implant materials
- revision UKP surgery of the same compartment

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-05-2024
Enrollment:	33
Type:	Actual

Medical products/devices used

Generic name:	Restoris MCK MultiCompartmental Knee System (Medial Unicondylar)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-05-2022
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	17-07-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	05-01-2024
Application type:	Amendment
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	NL79250.058.21