Stability of the Journey II XR total knee system, measured with RSA

Published: 26-03-2020
Last updated: 05-10-2024

The main objective is to investigate the fixation of the Journey II XR BCR TKA in terms of micromotion of the femoral and tibial components over time measured by RSA. Secondary, this study aims to assess the effect of this BCR TKA on daily life...

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

Summary

ID

NL-OMON50159

Source
ToetsingOnline

Brief title
Journey II XR

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
degenerative joint disease, Knee osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Smith & Nephew

Intervention

Keyword: Bi-cruciate retaining, Fixation, RSA, Total knee arthroplasty

Outcome measures

Primary outcome

The main study parameters are the 3D translation (in mm) and rotation (in degrees) of the components of the Journey II XR over time, in reference to the (markers in the) bone.

Secondary outcome

The secondary study parameters are the contact point of the femur on tibia in 90 degrees flexion and extension, gait speed and quantity measured at home using wearable sensors, knee joint kinematics and moments during walking tasks in the lab with and without perturbations and CROMs/PROMs and additional questionnaires.

Study description

Background summary

Bicruciate Retaining (BCR) Total Knee Arthroplasty (TKA) is thought to maintain a closer resemblance to the normal knee function and feel compared to cruciate retaining or cruciate substituting techniques. With this technique both cruciate ligaments are preserved which is thought to lead to enlarged proprioception and stability in the knee. However, because of the difficult surgical technique due to retaining both cruciate ligaments, initial stability of this type of prosthesis in terms of fixation is unclear Therefore this study aims to investigate the fixation of the Journey II XR BCR TKA over time measured by radiostereometric analysis (RSA). Secondly, gait quality assessed in daily life and challenging lab-based skills tasks is compared to healthy controls. It is expected that the prosthesis might show some early micromotion until 6 months post-operatively followed by stabilization, showing a fixation pattern comparable to other TKAs. Gait quality is expected to improve from pre-

to post surgery for all patients, resembling the gait of healthy controls.

Study objective

The main objective is to investigate the fixation of the Journey II XR BCR TKA in terms of micromotion of the femoral and tibial components over time measured by RSA. Secondary, this study aims to assess the effect of this BCR TKA on daily life functioning and to investigate whether the patients have natural knee kinematics and physiological motion compared to a healthy cohort.

Study design

This is a prospective study comparing the fixation of the implant during hospitalization, 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively. For the secondary objectives a healthy cohort is recruited to compare the gait quality pre-operatively, 1 year and 2 years post-operatively.

Study burden and risks

The burden of participation consists of 9 additional (stereometric) radiological assessments, but the total amount of radiation that participants will receive provides only a low chance of extra risk. Participants will take part in 3 gait assessments at the Sint Maartenskliniek (Pre-operatively, 1 year and 2 years post-operatively, 2-3 hours each) and around these time points are also asked to wear inertial sensors at home for 5 days. Risks of the gait assessment in the clinic are minimal as the subjects will be wearing a harness to prevent falls. Additionally, questionnaires and CROMs/PROMs will be assessed during their visits to the clinic. The risks related to the surgery are minimal and are not higher than the conventional knee prosthesis placed in our hospital.

Contacts

Public
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574 NA
NL
Scientific
Sint Maartenskliniek

Hengstdal 3
Ubbergen 6574 NA

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients:
Age between 40-80 years old
Non-inflammatory knee osteoarthritis, confirmed by radiology
Set to receive a primary total knee arthroplasty
Stable health
Intact anterior and posterior cruciate ligaments

Healthy controls:
40-80 years old
In stable health

Exclusion criteria

Patients:
Patient has BMI > 35
Patient has an active, local infection or systemic infection
Operation to the study knee

Healthy controls:
Moderate to severe pain in one or both knees, hip or ankle (>4 on items 3-6 form Brief Pain Inventory)
Previous replacement surgery to knee, hip or ankle or planned for future replacement surgery

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Bi-cruciate retaining total knee arthroplasty
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-07-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-10-2020
Application type:	Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL71885.091.19