Difference in patellar tracking before and after Journey II BCS total knee arthroplasty, evaluated with 4D CT imaging.

No registrations found.

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

Summary

ID

NL-OMON24890

Source
Nationaal Trial Register

Brief title
4DCT tracking TKA

Health condition

Patients with primary osteoarthritis of the knee and overall varus or neutral alignment of the leg.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Difference in patellar tracking between pre-operative and one year post-operative measured with 4D CT imaging.

Secondary outcome

Implant positioning:
By using the CORI, we will collect implant position, perioperative ligament laxities, alignment and tibiofemoral kinematics.
Patient Reported Outcome Measures (PROMs):
The following PROMs will be collected; FJS, KOOS and Kujala knee score to assess the patient experienced outcomes in pain and movement before and after the TKA.

Study description

Background summary

Rationale: Pain at the anterior side of the knee after total knee arthroplasty is still a common phenomenon with an incidence reported to be as high as 49%. The aetiology is poorly understood and several mechanisms have been postulated. Next to the influence of alignment on retinacular stresses, overstuffing of the patellofemoral joint and instability also lead to higher retinacular stresses and are shown to lead to anterior knee pain. These mechanisms are all related to surgical technique and implant positioning. There are also mechanisms related to prosthesis design, like the sagittal curve, trochlear depth and trochlea shape.
New implant designs like the Journey II prothesis are designed to replicate optimal geometry and optimal tibiofemoral and patellofemoral kinematics. Therefore, the Journey II BCS seems the optimal implant to reduce anterior knee pain. However, large registry studies show that a higher revision rate is seen when no patellar button is used in case of the Journey II BCS. The use of a patellar button is still under debate, but using an onlay patella button has clear influence on the patella tracking. Therefore, there might be a relation between the use of an onlay patella button and the retinacular balance and thus clinical results.
With current surgical instrumentation the positioning of the prosthesis based on the kinematics of the natural knee is challenging, and a small error can completely counteract the normal motion defined by the implant design/geometry. Therefore, comparative studies are only leading to new evidence when the surgical technique is including objective and accurate tools, like the CORI robotic platform. With the CORI, component positioning can be set based on constitutional alignment and ligament functioning. Furthermore, the patellofemoral compartment can be taken into account during the surgery to enable optimal geometry replication of the trochlea in the sagittal plane. This enables the surgeon to position the components accurately within the envelop of motion of a specific joint.
With new emerging imaging techniques we are able to investigate in vivo patella tracking. One of these promising techniques is the 4D CT imaging. This technique is proven to be accurate within 1 mm and 1° and therefore useful to investigate the patellofemoral compartment.

The current proposal aims to investigate the patellar tracking in patients receiving Journey II BCS total knee arthroplasty before and one year after surgery, positioned with the CORI instrumentation. The hypothesis is that less change in patella tracking before and after surgery will lead to less anterior knee pain complaints. Patella tracking is investigated using 4D CT imaging.
Objective: Primary Objective: Difference in patellar tracking between pre-operative and one year post-operative measured with 4D CT imaging.
Secondary Objective(s):
Implant positioning:
By using the CORI, we will collect implant position, perioperative ligament laxities, alignment and tibiofemoral kinematics.
Patient Reported Outcome Measures (PROMs):
The following PROMs will be collected; FJS, KOOS and Kujala knee score to assess the patient experienced outcomes in pain and movement before and after the TKA.
Study design: Randomized controlled trial with two arms. Randomization for Journey II BCS implant with the use of an onlay patella button or not.
Study population: Patients, between 50 and 75 years of age, with primary osteoarthritis of the knee and overall varus or neutral alignment of the leg, who are patients with the Radboudumc and scheduled for a TKA performed by the Radboudumc orthopaedic surgeons.
Main study parameters/endpoints: the main study parameter is the between group differences between changes in patellar tracking (i.e., implant position, perioperative ligament laxities, alignment and tibiofemoral kinematics measured before and after 12 months after surgery).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will be asked to fill in a digital questionnaire before their TKA and to undergo a 4DCT of their knees. Where possible, patients will not have to come to the hospital separately for the CT scan. The questionnaires can be filled in at home. At 3, 6, and 12 months the same questionnaire will be filled in, this will take approximately 15 minutes. At one year post-operation, the patient will be asked to come in for the second and final 4dCT scan of the knees.
The CT scans add to the level of radiation experienced by a person. For this study this level is set at an intermediate risk. No additional risks are associated with this study as all materials used are CE-marked and used within intended use.
Potential burden for the patient is predominantly time and additional radiation exposure. No direct personal health benefit is expected, however the knowledge generated with this study is expected to benefit future patients who need to undergo a TKA.

Study objective

The hypothesis is that less change in patella tracking before and after surgery will lead to less anterior knee pain complaints. Patella tracking is investigated using 4D CT imaging.

Study design

Patients will be asked to fill in a digital questionnaire before their TKA and to undergo a 4DCT of their knees. At 3, 6, and 12 months the same questionnaire will be filled in. At one year

post-operation, the patient will be asked to come in for the second and final 4DCT scan of the knees.

Intervention

Undergoing total knee arthroplasty with or without the addition of a kneecap.

Contacts

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Eligibility criteria

Inclusion criteria

• Non-inflammatory knee osteoarthritis, which is confirmed by radiology.
• Osteoarthritis is unilateral or bilateral with the contralateral knee functioning properly, not operated on in the last 6 months.
• Set to receive a primary cemented total knee arthroplasty.
• Aged between 50 and 80 years, inclusive, on the day of the operation.
• In stable health (ASA-score ≤ 3) and is free of or treated for cardiac, pulmonary, haematological, or other conditions that would pose excessive operative risk.
• Patient has a correctable or <10° rigid (non-correctable) varus deformity of the knee.
• Participants must be able to give informed consent.
• Patient plans to be available for follow-up until two years post-operative.
• Ability to walk for 2 minutes without walking aid

Exclusion criteria

Exclusion:
• Valgus deformity

• BMI > 35.
• Previous hip /knee/ankle replacement surgery in the last 12 months, or is planned to have a hip 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
• Incomplete or insufficient tissue surrounding the knee.
• Severe damage to the medial or collateral knee ligaments and popliteal tendon
• Documented osteoporosis with patient in active medical treatment.
• Patient has physical, emotional or neurological conditions that impacts gait or balance, or would compromise compliance with post-operative rehabilitation and follow-up.
• Bone quality compromised by disease or infection which cannot provide adequate support and/or fixation to the prosthesis
• Knee flexion < 90 degrees
• > 30 degrees extension deficit (active restraint to extension)
• Patient does not have a proper functioning patella tendon on the affected side; measured as inability of active extension of the knee
• Patient has rheumatoid arthritis, any auto-immune disorder, immunosuppressive disorder or a terminal illness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-12-2021
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 15-09-2021
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54338
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9733
CCMO	NL77819.091.21
OMON	NL-OMON54338

Study results