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

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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…

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| **Ethical review** | Approved WMO |
| **Status** | Completed |
| **Health condition type** | Bone and joint therapeutic procedures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54338

**Source**
ToetsingOnline

**Brief title**
4DCT tracking TKA

### Condition

- Bone and joint therapeutic procedures

**Synonym**
patellofemoral instability / patella luxation-pain

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

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

## Intervention

**Keyword:** 4DCT, CORI, PROM, TKA

## 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

PROMs:

FJS, KOOS and Kujala knee score

# Study description

### Background summary

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% [1]. The aetiology is poorly understood and several mechanisms have been postulated. Several studies showed an internal rotation of the femoral component to be associated with AKP [2-4]. Classically, the optimal femoral component alignment is thought to be perpendicular to the mechanical axis in the coronal view and in approximately 3° external rotation relative to the posterior condylar line (in absence of significant condylar deficiencies) or in line with the femoral transepicondylar axis. This allows both for a balanced flexion gap and favorable patellar tracking [3,4]. Even with the ideal position of the femoral component, biomechanical studies show that the normal patella tracking is not fully restored [8,9]. Furthermore, the optimal femoral component position is

driven by a balanced flexion gap and therefore heavily depending on the alignment method. In classical mechanical alignment, the natural oblique jointline is cut to perpendicular to the mechanical axis, this leads to necessary external rotation of the femoral component to obtain a balanced flexion gap. While mechanical alignment is still the golden standard in the coronal plane, the concept of constitutional alignment is rapidly being accepted as the way forward. There are many techniques to regain constitutional alignment. One technique often used with good results is the restricted kinematic alignment technique [10]. With this technique the natural oblique jointline is recreated, resulting in internal rotation of the femoral component relative to the transepicondylar axis to obtain a balanced flexion gap. With this technique good clinical results are obtained and no increase in anterior knee pain is seen [11]. Moreover, biomechanical studies even suggest superior patellar kinematics in kinematically in comparison to mechanically aligned knee prosthesis [12]. This is likely the result of more natural tibiofemoral kinematics and a reduction of distal lateral femoral overstuffing, leading to less stresses in the lateral retinaculum. Anterior knee pain can occur from a variety of sources. A large number of free nerve endings and fibres exist, particularly in the quadriceps muscles, retinacula, patellar tendon and synovium. Anterior knee pain can result from any one of these sources, and clinicians typically have difficulty identifying the exact source. Previous studies showed that the state of the cartilage is not the only consideration. S.F. Dye [13] asked a colleague to perform knee arthroscopy on him using local anesthetic. His findings were instructive: he did not feel any pain in the PFJ, whereas the capsule and prepatellar fat pad were exceptionally painful. Therefore, it is most likely that retinacular stresses are the main reason for anterior knee pain. Next to the influence of alignment on retinacular stresses, as described above, overstuffing of the patellofemoral joint and instability also lead to higher retinacular stresses and are shown to lead to anterior knee pain [5,6,7]. 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. By replicating natural rollback, cruciate stability and the oblique jointline, the tibiofemoral kinematics of the Journey II resemble very closely the natural knee. Moreover, the Journey II knee has an anterior dwell point and 3° varus jointline which has been designed to restore the natural patellar tendon angle and improve patella tracking. 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.

A considerable number of cadaver studies and computer experiments have shown that slight alterations of the shape and position/rotation of the femoral component in TKA result in significant changes in patellar tracking and patellar contact forces [14,15,16]. While all of these studies thoroughly investigate the patellar tracking patterns and patella position, the correlation between changes in pre- and postoperative patella tracking and clinical results remain unknown. Since changes in retinacular stresses are very likely the most important source of anterior knee pain, comparison between pre- and postoperative tracking are mandatory to relate to clinical results.

With new emerging imaging techniques we are able to investigate in vivo patella tracking. One of these promising techniques is the 4D CT imaging. Within the Radboudumc we are the first in the world to use this technique actively in patellofemoral instability patient evaluation. In the past half year we optimized this technique with the use of the geometry files of the Journey II BCS and cadaver experiments to use this technique on total knee arthroplasty patients. This technique is proven to be accurate within 1 mm and 1° and therefore useful to investigate the patellofemoral compartment.

References:
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### Study objective

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.

### Study design

Randomized controlled trial with two arms. Randomization for the use of an onlay patella button or not with the Journey II prosthesis.

### Intervention

Group 1 will receive a total knee replacement surgery without the placement of a patella component.
Group 2 will receive a total knee replacement surgery with the placement of a patella component.

### Study burden and risks

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.

## 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

• 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

• 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 active rheumatoid arthritis, any auto-immune disorder, immunosuppressive disorder or a terminal illness.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

## Recruitment

NL

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| Recruitment status: | Completed |
| Start date (anticipated): | 08-04-2022 |
| Enrollment: | 100 |
| Type: | Actual |

### Medical products/devices used

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| Generic name: | Journey II BCS knee implant |
| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 23-03-2022 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 01-05-2023 |
| 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

ID: 24890
Source: NTR
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL77819.091.21 |
| Other | voorheen: NL9733. Gezien het NTR niet meer beschikbaar is zal dit onderzoek ook worden geregistreerd in ClinicalTrials.gov |

## Study results

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| Date completed: | 17-09-2024 |
| Results posted: | 06-04-2022 |

**First publication**
01-01-1900