Challenge CR

No registrations found.

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

Summary

ID

NL-OMON27446

Source
NTR

Health condition

Knee Osteoarthritis

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Daily-life gait speed*

*Note: we will need to explore further analysis options to take gait bout length into account when evaluating daily-life gait speed given their semi-linear relationship.

Secondary outcome

Perturbations (both anteroposterior and mediolateral):
- xCoM excursion (during perturbed and subsequent steps)
- Margin of stability

- Foot placement
- Spatiotemporal gait parameters (step width, step length, step time)

Up/downhill walking:
- Sagittal knee angles
- Trunk motion
- Spatiotemporal gait parameters

Study description

Background summary

BACKGROUND:
The main goal of total knee arthroplasty (TKA) with cruciate retaining (CR) is to reduce pain and improve mobility in individuals with end-stage osteoarhtritis (OA) of the knee. However, whether patients after TKA recover up to the level of healthy subjects is still under debate. It is therefore important to objectively capture mobility of these patiens, such as during gait analaysis. These objective gait assessments have mostly been limited to simple, lab-based tasks that may not fully capture the locomotor challenges individuals with TKA encounter during daily life. This study therefore aims to 1) compare gait during daily-life and challenging situations between individuals that received a CR-TKA and healthy controls, and 2) to investigate improvement in gait after CR-TKA.

METHODS:
Objective monitoring during daily life
Participants will take three lightweight sensors home and wear it on their back and two feet during 7 days. The sensors will only be worn during daytime. The data will be stored locally on the sensor and analyzed offline after return. From accelerometer and gyroscope signals, gait bouts and turns will be identified using validated algorithms. Number of gait bout and turns, and the durations of these activities will be outputted. To calculate measures reflecting quality of gait and turns, step characteristics and motion of the trunk can be calculated.

Challenging gait tasks
Subjects will complete three tasks while walking on an instrumented treadmill (GRAIL). First, uphill walking will be recorded on a treadmill slope of 9 degrees. A trial will last 1 minute. Second, downhill walking will be at 9-degree slope for the same duration. Thirdly, perturbations will be delivered by sudden movement of the treadmill in medio-lateral directions (left to right, right to left) and belt decelerations to induce trips. Whole-body movement will be recorded using a 3D motion analysis system (Vicon Motion Systems). Three-dimensional motion analysis using the Vicon Plug-In-Gait model will be used together with Nexus software to calculate spatiotemporal gait parameters, the center of mass trajectory, and joint kinematics.

Study objective

Gait quality improves after cruciate-retaining TKA, but will still be abberant compared to healthy, age-matched controls. We will quantify the quality of gait using different metrics related to the specific testing condition. As a primary hypothesis, we expect that daily-life gait speed will be lower in individuals one year after TKA compared to healthy participants.

Study design

Baseline, 1 and 2 year post-operative

Intervention

Cruciate retaining total knee arthroplasty

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for patients undergoing CR TKA:
• Non-inflammatory knee osteoarthritis, which is confirmed by radiology (Kellgren & Lawrence ≥ 2).
• Set to receive a primary cemented total knee arthroplasty.
• Age between 40 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 or valgus deformity of the knee.
• Participants must be able to give informed consent.

Inclusion criteria for healthy controls:
• Age between 40 and 80 years, inclusive, on the day of the baseline measurement.
• In stable health (ASA-score ≤ 3)
• Participants must be able to give informed consent.

Exclusion criteria

Exclusion criteria for patients undergoing CR TKA:
• BMI > 35.
• Patient has had major, non-arthroscopic surgery to the study knee, including high tibial osteotomy.
• Patient has an active, local infection or systemic infection • Prior high-energy trauma to the affected knee or prior history of posterior cruciate ligament rupture.
• Suspicion of posterior cruciate ligament rupture at clinical examination.
• Incomplete or insufficient tissue surrounding the knee.
• Severe damage to any knee ligament other than the anterior cruciate ligament
• Documented osteoporosis with patient in active medical treatment.
• Patient has physical, emotional or neurological conditions that 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 • Fixed flexion deformity >10 degrees (passive extension lag)
• > 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
• Impaired extensor strength defined as MRC Grade < 4.
• Undergone patellectomy in the knee receiving CR-TKA
• Moderate to severe knee pain in the contralateral knee defined as an average score of >4 on items 3-6 of the Short Brief Pain Inventory
• Moderate to severe hip or ankle pain defined as an average score of >4 on items 3-6 of the Short Brief Pain Inventory
• Previous knee, hip or ankle replacement surgery, or is planned to have a knee (contralateral), hip or ankle replacement in the next 12 months.
• Any musculoskeletal or neurological disease, or uncorrected visual impairment other than osteoarthritis that impairs gait or balance.

Exclusion criteria for healthy control subjects:
• Moderate to severe knee pain in one or both knees defined as an average score of >4 on items 3-6 of the Short Brief Pain Inventory
• Moderate to severe hip or ankle pain defined as an average score of >4 on items 3-6 of the Short Brief Pain Inventory
• Previous knee, hip or ankle replacement surgery, or is planned to have a knee, hip or ankle replacement in the next 24 months.
• Any musculoskeletal or neurological disease, or uncorrected visual impairment other than osteoarthritis that impairs gait or balance.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	32
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49702
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9610
CCMO	NL71606.091.19
OMON	NL-OMON49702

Study results