Mechanical Analysis of function and Gait In total Knee replacements

Published: 07-03-2024
Last updated: 02-12-2024

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Ethical review	Approved WMO
Status	Completed
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON56638

Source
ToetsingOnline

Brief title
MAGIK

Condition

- Bone and joint therapeutic procedures

Synonym
joint replacement, total knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Orthopaedic Innovation Technology Center
Source(s) of monetary or material Support: self-funding and Orthopaedic Innovation Technology Center

Intervention

Keyword: Fluoroscopy, Gait, Kinematics, Knee replacement

Outcome measures

Primary outcome

The weight-bearing kinematics will be assessed using traditional 3D-to-2D registration techniques. Raw data consists of the fluoroscopy video, and using registration techniques, we are able to extract the 3D position of the components and then analyze various parameters-of-interest, such as medial condyle contact position.

Specific femorotibial parameters of interest will include maximum flexion, anterior/posterior motion of the medial and lateral condyles, axial rotation throughout each activity, and cam/post engagement angles (if applicable). In other words, researchers will determine the relative motion of the femoral component atop the tibial component as patients flex their knee. Patellofemoral kinematics will include in vivo patellofemoral contact pattern in the sagittal plane, in vivo patellar tilt in the sagittal plane with respect to tibia bone, patellofemoral separation, and patella ligament rotation in the sagittal plane. All parameters of interest will be measured directly from the fluoroscopy images.

Secondary outcome

VAG signals will be correlated to cam-post engagement times. Specifically, when the posterior cam/post engage (determined from the fluoroscopy overlays), we will observe the filtered VAG signals to determine if there is a spike in

the signal data. Additionally, signals will be evaluated for noisy versus quiet signals, based on signal amplitude, and this will be correlated to weight-bearing kinematics as well as outcome scores.

Patient-reported Outcome Measures will be collected by the Forgotten Joint Score, the Oxford Knee Score, KOOS-PS, NRS for pain and satisfaction. All surveys have been previously validated.

Functional outcome parameters will be assessed by two mobility tasks, including gait and sit-to-stand transfers. Specifically, patients will walk for 2 minutes back and forth a 10m trajectory making 180* turns. This task will be repeated while performing a secondary, cognitive task to evaluate the level of attention they need for this task. Subsequently, the participants will be instructed to rise from a chair at their comfortable speed. During these tasks, inertial measurement units will be used to record the tasks and obtain spatiotemporal outcome measures.

Study description

Background summary

Although total knee arthroplasty (TKA) is a successful orthopedic procedure of today, many patients are unsatisfied with their implanted knee when having to perform higher flexion activities such as a squat. Patients often feel anterior knee pain, tightness, or a loss of range of motion in their implanted knees. To improve the performance of total knee replacement systems, implant manufacturing companies rely on in-vivo fluoroscopic testing and patient reported outcome measures to determine to provide feedback. Unfortunately, most of the research conducted today focuses primarily on well-performing

implants, using outcome scores as inclusion criteria to ensure satisfied patients, and therefore does not provide insight into patients who may not be as satisfied with their implanted knee. Additionally, scores self-reports by patients measure a different construct of physical function - related to perceived abilities - compared to the actual performance of a task, and self-reported scores are highly subjective and are strongly dominated by pain.

To specifically improve the performance of a bi-cruciate substituting TKA system, we want to conduct a fluoroscopic evaluation of this TKA system without using *success* or *scores* as inclusion criteria. This will help us better understand how this system will perform across a broad spectrum of patients and will provide further insight into areas of improvement that total knee replacement systems may have, to ultimately reduce the number of postoperative complications or unsatisfied patients in the future.

Study objective

The primary objective of this study is to determine the femorotibial and patellofemoral weight bearing in vivo kinematics of Journey II BCS TKA patients and to determine correlations that the kinematics may have with patient-reported outcome measures (patient-reported, clinical reported, and functional outcome). Secondary objectives include correlations between vibroarthrography (VAG) signals, in vivo kinematics, and outcome scores.

It is hypothesized that the participants with higher scores will have a better weight bearing kinematics (larger range-of-motion, more condylar rollback, better patellar tracking) than participants with lower scores. More specifically, we are hypothesizing that an increase in PROMs will correlate with more condylar rollback, more normal patellar height classifications (alta, norma, baja), improved functional outcomes, less attention during gait, and less VAG noise. These evaluations will provide insight into potential areas of improvement for total knee replacement systems, to ultimately reduce the number of postoperative complications in the future.

Study design

This is a cohort study. Patients will not undergo assigned treatments or interventions but will undergo new assessments. Data will be collected for participants on a single day, and there will be no follow-up.

Study burden and risks

This study will require the use of X-Rays to collect data. Thus, participants will be exposed to radiation beyond their normal standard of care. However, the doses of radiation exposure received by participants in this study will be much lower than those known to produce detectable health effects. The

measurement used to monitor the amount of radiation a patient receives is the millisieverts (mSv).

For this study, participants will be limited to a maximum of 2 minutes of fluoroscopy time. A previous fluoroscopy TKA study conducted at another hospital with a 2 minute limit showed that the average fluoroscopy time was 16 seconds with a maximum of 37 seconds. Additionally, average radiation exposure amount was 0.018 mSv with a maximum dose of 0.050 mSv. At these dose levels, no harmful effects of radiation have been demonstrated and any effect is too small to measure. Therefore, the risk associated with this study is believed to be minimal.

Since the fluoroscopy data will be collected in one session, there will only be one day in which the participants will be exposed to this amount of radiation. Fluoroscopic parameters will be recorded for each participant on their CRF, including on-time, kV, mA, and any other dose report data from the fluoroscopy unit. Data collection will stop if the 2-minute time limit is approached. To keep radiation time as low as reasonably achievable (ALARA), the participant will practice the activity before the fluoroscopy system is turned on, to ensure they can comfortably and painlessly complete the motion.

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

1. Subjects will have the appropriate TKA system: a Smith & Nephew Journey II BCS TKA.
2. Patients in the age range of 18 years to 85 years (both inclusive)
3. Patients who do not have previous surgery on either knee that might restrict their movement
4. Patient who are at least 6 months post-operative
5. Patients will be less than 11 years post-operative.
6. Patients who can perform the requested activity safely
7. Patients who are willing to participate in this study and are willing to sign appropriate informed consent forms

Exclusion criteria

1. Female patients who are pregnant, trying to become pregnant, or lactating.
2. Patients who have enrolled in a fluoroscopic kinematic study within the past year.
3. Patients with neurological or musculoskeletal disorders that might adversely affect weight-bearing motion ability.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-06-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2024
Application type:	First submission
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	NL85398.091.23