Objectifying a patient*s perception of TKA instability using fluoroscopy during stair descent

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The objective of this study is to quantify the subjective feeling of knee (in)stability during a stair descent. This results in the following research question:*Is there a relation between the kinematics of the knee joint from people who suffer from…

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

Summary

ID

NL-OMON57102

Source
ToetsingOnline

Brief title
OBJECTIFY

Condition

- Bone and joint therapeutic procedures

Synonym
joint replacement, total knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Instability, Knee kinematics, Total knee arthroplasty

Outcome measures

Primary outcome

The main study parameters are the AP translation of the femoral condyles (in mm) and rotation of the femur component (in degrees) with respect to the tibia component during stair descent as measured on fluoroscopic images.

Secondary outcome

In addition, alignment, functional tests, objective laxity tests performed with radiographs, and PROMS are investigated to see if they have a relation with the perceived instability of the patient and/or the movement patterns of the femur component with respect to the tibia component during the stair descent activity.

Study description

Background summary

As the life expectancy of people rises due to advancements in healthcare, the number of total knee arthroplasties (TKAs) performed increases. This has led to a rise in the number of TKA revisions, which almost doubled between 2010 and 2022.
In 25% of revision cases, instability is at least one of the reasons to proceed to surgery. Unfortunately, instability is poorly understood as the subjective reports of the patient often do not correlate with objective diagnostic tests used by a clinician. Finding a measure that better correlates with the subjective complaints can help understand instability and how to treat it.

Study objective

The objective of this study is to quantify the subjective feeling of knee (in)stability during a stair descent. This results in the following research

question:
Is there a relation between the kinematics of the knee joint from people who suffer from knee instability during a stair descent activity and their self-perceived feelings of joint instability?
We hypothesize that patients who report having an unstable TKA have more translation of their femoral condyles with respect to the tibia component of their TKA during stair descent than patients who report having a stable TKA.

Study design

This is an observational study comparing knee kinematics of TKA-patients with instability complaints to TKA-patients without complaints using fluoroscopy. During the site visit, patients will perform a stair descent activity, which will be recorded using a fluoroscope. From these fluoroscopic images, the precise movements of the femoral condyles can be investigated throughout the range of motion during the stair descent activity. The movements of the femoral condyles will be related to the self-perceived instability of the subjects.

Study burden and risks

The tests done for this study will take about two hours per participant. For the cases-group, these tests will be planned, as much as possible, during their scheduled visits to the clinic. The patients in the control-group will need to visit the clinic once outside of their usual care to perform the tests. The additional radiological assessments have a total amount of radiation that leads to a very small extra risk, there are no additional risks to the tests. The questionnaires and physical examination of the knee do not bring much extra burden.

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

- Subjects who have a primary Genesis PS TKA system
- Subjects in the cases-group should be up for a revision with the main reason being instability. This is defined as the indication for the revision as determined by the surgeon. To establish this diagnosis, infection (according to the ICM 2018 criteria), loosening, and patellar problems have been excluded. Although no clear and absolute definitions for malposition exist, it could be the cause of instability. However, the treating surgeon will decide which of the two complications is the main reason for revision. Patients with malposition and major deviation in alignment will not be included in the study.
- Subjects in the cases-group should be self-reported unstable, as defined as scoring either 1 or 2 points
on questions 7, 10, and 12 of the Oxford knee score, which we deem important questions for people
suffering from instability issues with their TKA.
- Subjects falling in the control-group should have a good outcome of their TKA, as defined by having an
Oxford Knee Score of above 30 and score at least 3 points on questions 7, 10, and 12, which we deem
important questions for people suffering from instability issues with their TKA.
- Subjects who are in the age range of 40 to 85 years (both inclusive)
- Subjects who did not have had any previous surgery to their knee which could restrict their range of
motion
- Subjects who are at least two years post-operative
- Subjects who can perform the requested activities safely
- Subjects who are willing to participate in this study and are willing to sign appropriate informed consent

forms

Exclusion criteria

- Female patients who are pregnant, trying to become pregnant, or lactating
- Patients who have enrolled in a fluoroscopic kinematic study within the past year
- Patients with neurological or musculoskeletal disorders that might adversely affect weight-bearing motion ability
- Patients whose body size exceeds the limits that can be accommodated by the equipment

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2024
Enrollment:	36
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	14-11-2024
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	NL87109.091.24