The search for objective determinants to assess the outcome of Total Knee Arthroplasty

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44728

Source
ToetsingOnline

Brief title
Objective assessment of the outcome of Total Knee Arthroplasty

Condition

- Joint disorders

Synonym
gonarthrosis, knee-osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Orthopedie
Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: gait analysis, knee adduction moment, knee-osteoarthritis, total knee arthroplasty

Outcome measures

Primary outcome

The magnitude of the knee adduction moment (KAM) is generally considered as a surrogate for medial compartment loading and a proxy for knee osteoarthritis. There have been studies linking the magnitude of the KAM, sometimes in combination with alterations in the knee flexion moment (KFM), to the outcome of TKA. However it can not (yet) be correlated to a dissatisfied/bad outcome of TKA, since patients haven't been selected based on their outcome. We hypothesize that the magnitude of the KAM in patients who are dissatisfied with the outcome of their TKP is greater than in patients who are satisfied with the outcome of their TKP.

Secondary outcome

Loss of cartilage can lead to knee instability, as a consequence of compensating for instability muscular co-contractions become present. Muscular co-contractions around the knee increase the compressive force on the knee joint. Together with the knee adduction moment (KAM) and knee flexion moment (KFM) represents this the load on the knee joint. The knee range of motion is of significant importance regarding the magnitude of the KAM and KFM, since it determines the size of the lever-arm on the Ground Reaction Force. Therefore these parameters will be analyzed as secondary parameters.

Study description

Background summary

Generally, a Total Knee Arthroplasty (TKA) is an effective treatment for patients suffering from severe knee osteoarthritis (KOA). On average 80-90% of the patients undergoing TKA are satisfied with the outcome. However, at least 10% suffers from persisting pain in the knee and/or a decrease in Range of Motion (ROM). Studies regarding the outcome of TKA generally focus on outcome measurements using PROMs (Patient reported outcome measures), which lack sensitivity, limiting their application to individual-level. These questionnaires are important in evaluating the overall outcome following knee arthroplasty; however they offer no objective clinical data concerning the patients* specific functional abilities as they primarily reflect reduction in pain. Additionally most of these questionnaires are influenced by the subjectivity of the research participant. This study aims to evaluate the kinematics and kinetics of the knee after TKA and to define objective measurement parameters to evaluate the outcome. We aim to identify mechanical and neuromuscular parameters that significantly differ between patients who are satisfied with their total knee prosthesis (TKP) and patients who are dissatisfied, according to the PROMs. Gaining insight in how these parameters behave after TKA will not only provide an objective outcome measurement, but will also help evaluate how patients mechanically benefit from TKA. This study will also help in generating hypotheses for further prospective studies regarding outcome-predictive factors for TKA.

Study objective

The main objective is to identify objective, neuromuscular and/or mechanic parameters through movement analysis, which are closely correlated to the subjective outcome of TKA. Secondary objective is to generate parameter specific hypotheses for our future prospective observational study regarding patients with severe knee osteoarthritis who will undergo TKA.

Study design

This is a cross sectional observational study between two groups selected based on the outcome of their TKA as measured with various PROMs and validated satisfaction scales for TKA.

Study burden and risks

The risks and burden of the experiments may be related to walking on the GRAIL (dual-belt instrumented treadmill) while receiving real-time feedback. All participants will wear a safety harness while walking on the GRAIL. From

previous experiments, we know that a 2-minute familiarization period on the treadmill is sufficient in most of the persons. Measurements will not start before research subjects indicate that they are comfortable with walking on the treadmill.
Experiences with subjects to walk in a VR-environment, is that most patients consider it fun to walk in this kind of *real world computer game*.
Patients will have to visit the VUmc only once for this study. Additional questionnaires can be filled in during their visit. The visit will take about 1,5 - 2 hours in total.

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

One total knee prosthesis placed >1 year ago, age ranging from 40 to 70 years old, able to

walk at least 20 minutes without stopping.

Exclusion criteria

Other prosthesis lower extremities; instable contra-lateral knee; instability, malposition, loosening, or current infection of the prosthesis; neuromuscular disorder(s); history of stroke; gout; other hip/knee or ankle disorders which affect the gait pattern; general diseases which affect the gait pattern; BMI > 35.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	11-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL51829.029.14