The relation between pre-operative parameters and patient satisfaction after Total Knee Arthroplasty

Published: 27-07-2020 Last updated: 09-04-2024

The primary objective of this study is to identify correlations between pre-operative, i.e. biomechanical and planning, parameters and patient satisfaction after TKA surgery.

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

Summary

ID

NL-OMON49439

Source ToetsingOnline

Brief title THERAPIST

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym Total Knee Arthroplasty, Total Knee Replacement

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum **Source(s) of monetary or material Support:** Materialise NV,sponsor;zijnde Materialise NV

1 - The relation between pre-operative parameters and patient satisfaction after Tot ... 13-05-2025

Intervention

Keyword: Patient satisfaction, Pre-operative planning, Total Knee Arthroplasty

Outcome measures

Primary outcome

Main endpoint is to identify correlations between pre-operative, i.e.

biomechanical and planning, parameters and patient satisfaction after TKA

surgery.

Secondary outcome

Alignment of the implant components

Intra-operative soft tissue release

Study description

Background summary

Up to a fifth of primary implant Total Knee Arthroplasty (TKA) patients remains unsatisfied. Patient satisfaction is typically measured using patient reported outcome measures (PROMs). However, these scores are only snapshots and subjective measures of pain and function, and might therefore not fully represent the functional abilities of the patient. More detailed and objective information, such as physical activity and functional range of motion, might be more representative for the abilities of a patient.

Pre-operative parameters, i.e. planning and biomechanical variables, can have a crucial impact on TKA outcome. Specifically knee kinematics, ligament strains and knee loading were determined as important biomechanical variables. To predict post-operative biomechanical parameters based on pre-operative information, biomechanical models can be used. However, it is still unknown how these biomechanical parameters, together with planning parameters, such as geometrical dimensions and implant position, relate to post-operative functional outcome.

Study objective

The primary objective of this study is to identify correlations between pre-operative, i.e. biomechanical and planning, parameters and patient

satisfaction after TKA surgery.

Study design

A prospective cohort study design.

Study burden and risks

Instead of the standard physical therapy sessions, the patients will follow a tele-rehabilitation program using moveUP. TKA surgery will be performed following the standard of care, using patient-specific instruments. Pre- and post-operative CT scans are required to be able to reconstruct the exact implant position after surgery. This will result in an additional exposure to radiation for the patient (radiation dose for single CT scan: 5.69 mSv).

Contacts

Public

Zuyderland Medisch Centrum

dr h vd Hoffplein 1 Sittard-Geleen 6162 BG NL Scientific Zuyderland Medisch Centrum

dr h vd Hoffplein 1 Sittard-Geleen 6162 BG NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

3 - The relation between pre-operative parameters and patient satisfaction after Tot ... 13-05-2025

Inclusion criteria

- Painful and disabled knee joint resulting from osteoarthritis, rheumatoid
- arthritis, or traumatic arthritis where one or more compartments are involved
- Body-mass-index (BMI) below 35 kg/m2
- High need to obtain pain relief and improve function
- Ability and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations
- Ability to work with a mobile device for tele-rehabilitation
- Consent form read, understood and signed by patient

Exclusion criteria

- · Correction or revision of previous knee joint replacement procedure
- Patients selected for a posterior stabilized implant type
- Failure of previous joint replacement
- Patients with severe pre-operative varus or valgus deformity greater than or equal to 15 degrees
- BMI greater than or equal to 35 kg/m2
- Not able or willing to undergo MRI and CT scan
- Metal near knee joint (MRI-scan not possible)
- Non-correctable varus axis
- Uncooperative patient or patient with neurological disorders who is incapable of following directions

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Treatment	

Recruitment

NL Recruitment status:

Pending

Start date (anticipated):	01-08-2020
Enrollment:	50
Туре:	Anticipated

Medical products/devices used

Generic name:	telerehabiliation platform moveUP
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-07-2020
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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 CCMO **ID** NL74117.096.20