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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28068

Source
Nationaal Trial Register

Brief title
THERAPIST

Health condition

Patients who require TKA as a result of arthritis

Sponsors and support

Primary sponsor: Materialise N.V.
Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to identify correlations between pre-operative parameters and patient satisfaction after TKA surgery. Pre-operative parameters consist of biomechanical parameters, i.e. kinematics, ligament elongations and contact forces over the

range of flexion motion, and planning parameters, i.e. bone geometrical dimensions and hip-knee-ankle angle. Patient satisfaction consists of patient reported outcome measures, i.e. KSS and daily pain scores, and objective measures, i.e. activity and video-based evaluation of range of motion and gait.

Secondary outcome

• To investigate whether the pre-operatively planned implant position corresponds to the post-operative implant position as measured on CT scan
• To investigate whether soft tissue releases are necessary during surgery, in which cases and to what extent

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

We hypothesize that a combination of parameters relate to patient satisfaction and are able to differentiate between satisfied and non-satisfied patients. In addition, we hypothesize that the detailed post-operative outcome, as measured using moveUP, results in a stronger correlation with pre-operative parameters than traditional PROM scores.

Study design

Pre-op, Inpatient, 6 W FU, 3 M FU, 6 M FU, 12 M FU

Intervention

moveUP (a CE certified medical device; www.moveup.care) is a digital platform which will be used to provide daily follow up and tele-rehabilitation for patients.

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-05-2020
Application type:	First submission

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
NTR-new	NL8619
Other	METC Z : Z2020117

Study results