Inducible Displacement in Total Knee Prostheses

No registrations found.

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

Summary

ID

NL-OMON21288

Source
NTR

Brief title
TBA

Health condition

osteoarthritis; reumatoid arthritis for which TKA is performed

Sponsors and support

Primary sponsor: LUMC is the sponsor of the study
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Maximum Total Point Motion (MTPM) in the 6 different RSA acquisitions positions

Secondary outcome

Translation and Rotation along and about the 3 orthogonal axes in the 6 different RSA

acquisition positions

Study description

Background summary

Total Knee Replacement (TKR) is one ofthe most performed orthopedic procedures worldwide. If successful, TKR provides pain
reduction and restores the function ofthe joint. Migration of orthopaedic implants can be assessed with sub-millimetre accuracy
using radiostereometric analysis (RSA) and early migration can be used as a predictor of later aseptic loosening. In addition to
migration analysis, RSA could also give valuable results measuring "inducible displacement", which can be defined as the
reversible motion of the prosthesis with respect to the bone as a result of applying a force to the prosthesis. For individual patients,
measuring inducible displacement could potentially provide clinical evidence of a deteriorating bone-implant or bone-cement
interface and therefore a heightened risk of aseptic loosening

Study objective

TKR with large migration in the last 2 PO years show a larger inducible migration compared with TKR with little to no migration in the last 2 PO years

Study design

Single timepoint

Intervention

RSA acquisitions during 6 different positions of the operated knee to assess the induced migration

Contacts

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Eligibility criteria

Inclusion criteria

Patients will be included if
• they underwent TKR for primary as well as secondary gonarthrosis as long as the indication for surgery is
clearly specified
• a minimal set of patient characteristics (age, gender, BMI, co-morbidity) and disease characteristics
(radiological severity, knee function and alignment, status of other knee or hip joints, previous surgeries of the
affected knee) is available.
• they are at least `up to date' in terms of follow-up of their respective study (i.e. the most recent examination was
less than a year ago and patients have apost-operative examination)
• they participated for at least three years in their respective study and have a usable MTPM-value (i.e. >_ 3 bonemarkers
can be consistently matched with the reference-examination with a CN < 120 over the most recent iwo
years of fol low-u p
• their standard RSA data meets the criteria as mentioned in the ISO-standard
• they are willing to participate and able to perform the 4 pre-set tasks for the inducible displacement

Exclusion criteria

Patients will be excluded from participation if they do not meet the inclusion criteria, or if they already underwent
revision surgery of their TKR since the start of the study they were enrolled in.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2017
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	25-03-2020
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	NL8487
Other	METC-LDD, previously CME-LUMC : P16.156; ABR NL58105.058.16

Study results