Patient specific MRI protocol enhancement and Post-operative (imaging-based) evaluation of patient specific Total Knee Arthroplasty

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Primary Objective: - Improvement of MRI image quality and reduction of failure rate/rescan percentage- Evaluation of prosthesis placement accuracy and comparison to the planningSecondary Objective(s): - Alternative scan protocol- Reduce scan time...

Ethical review	Not approved
Status	Will not start
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38682

Source
ToetsingOnline

Brief title
MRI protocol enhancement and evaluation of patient specific TKA

Condition

- Joint disorders

Synonym
cuttingblocks, Total knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: custom-made, cuttingblocks, patient-specific, TKA

Outcome measures

Primary outcome

- The main study parameter is scan failure-rate. Our goal is to reduce failure rate by minimizing the scan sensitivity for distortions and reduce scan time to prevent movement artefacts.

- Validation tool/protocol for placement goals in post-operative scans

Secondary outcome

N/A

Study description

Background summary

Total knee arthroplasty is the standard treatment for advanced knee arthritis, resulting in pain relief, restoration of basic function, and it has acceptable clinical longevity. In the Netherlands about 18.000 knee prostheses are placed every year [1]. Over the past decade the number of procedures has greatly increased and because of an aging population it is expected this number will increase even more [2].
Fehring et al. analyzed the mechanisms of failure in patients who had revision surgery within 5 years of their TKA. Of the 440 patients with TKA, 279 had revision surgery (63%). The most important reason for early failure was infection (105, 38%) and the second leading cause of early failure was instability (74, 27%) [3]. Instability of the prosthesis is due to suboptimal placement of the implant.
To optimize implant positioning and therefore reducing the instability, proper rotational alignment of the femoral and tibial components is needed. Currently, a mechanically aligned patient-matched system VISIONAIRE (VIS) is used to help in placing the prosthesis with high accuracy. VISIONAIRE uses MRI scans to

create patient specific 3D cutting blocks which help in placing the prosthesis with high accuracy.
There only a few articles published which investigated the results of patient matched instrumentation. These articles all concentrate on the postoperative outcome/accuracy of this method. The results are divergent and vary from high and improved accuracy to unsatisfactory accuracy, according to these articles [4, 5, 6]. Also, no publications can be found about the effects of the pre-operative MRI scan concerning the number of rescans and the scan failure-rate.
At the UMC Utrecht, it is known that there is more than 20% scan failure in patients for VISIONAIRE due to sub-optimal MRI scans. There is a clear need to improve the current MRI protocol to decrease MRI failure rates and rescan needs. Our aim is to identify and modify key parameter to improve scan quality and reduce patient exclusion for the VISIONAIRE procedure due to sub-optimal MRI scans.
In addition, there is a need to establish the effectiveness of this method and expand its use in clinic. Post-operative imaging and image processing will enable us to validate the use of this technology and further asses its accuracy. This will open the possibility of providing clinical equivalents to the current FDA lab 30 yr. life time claim.
It should be emphasized that TKA using the VISIONNAIRE protocol is part of the standard procedure in this hospital. Also, the investigation is non-invasive, without radiation and no contrast agents are used. We only aim to improve this method by enhancing the pre-operative imaging and evaluate the accuracy to improve and insure overall quality and patient comfort/satisfaction, while retaining manufacturing standards (and 3D print parameters). This will allow better/further implementation of this procedure in the hospital by reducing MRI scan failure.

Study objective

Primary Objective:
- Improvement of MRI image quality and reduction of failure rate/rescan percentage
- Evaluation of prosthesis placement accuracy and comparison to the planning

Secondary Objective(s):
- Alternative scan protocol
- Reduce scan time --> Increased patient comfort/satisfaction
- Quality assurance

Study design

Single centre prospective (and restrospective) study, designed and coordinated at UMC Utrecht.

Study burden and risks

no risk, max 15min additional scanning time, and a post operative scan. Max 30 min

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

Men and women who are planned to undergo a total knee arthroplasty at UMC Utrecht

Exclusion criteria

- Patients with previous total knee arthroplasty
- Patients with other prostheses or metal objects/hardware in the field of view (FOV) of the MRI knee coil
- Incapacitated persons
- All contra-indications for MR-imaging

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	12
Type:	Anticipated

Ethics review

Not approved

Date:	30-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL44141.041.13