Fluoroscopic and RSA evaluation of the ROCC total knee prosthesis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON30476

Source
ToetsingOnline

Brief title
ROCC

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
artificial knee, Total Knee arthroplasty

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: 6e kader;DESSOS IST-2004-27252

Intervention

Keyword: Fluoroscopy, Kinematics, Total Knee prosthesis

Outcome measures

Primary outcome

kinematic patterns: segment angles

Rotating bearing: degrees

micromotion of the prosthesis: mm

Secondary outcome

Compare the kinematic patterns found by fluoroscopy and external movement

registration: segment angels

EMG: Co-contraction

Kinetica

Study description

Background summary

Three-dimensional (3D) fluoroscopic analysis is the most accurate measurement technique to examine the in vivo kinematics of total knee replacement (TKR) (Banks et al., 1997; Dennis et al., 1996; Dennis et al., 1998a; Garling et al., 2005; Stiehl et al., 1999). Fluoroscopic analysis studies has shown that there is a broad range of kinematic patterns of the femur with respect to the tibia during dynamic activities and a significant proportion of implanted knees has abnormal kinematics (Callaghan et al., 2001; Dennis et al., 1998b; Stiehl et al., 1999). In the short term, poor kinematics may lead to a feeling of instability and limits the mobility of the patient. In the long term, abnormal kinematics may lead to accelerated wear of the articular surfaces (Banks and Hodge, 2004; Krichen et al., 2006) and excessive stresses in bone-implant interface leading to aseptic loosening (Taylor and Barrett, 2003). Because of the influences of the prosthesis design on the kinematics, it is important to asses the in vivo characteristics and functional adaptations of the design following TKR (Banks and Hodge, 2004; Taylor et al., 2003).

To decrease the excessive stresses and wear of the articular surface a mobile bearing design has been developed. The essential point of this design is that the polyethylene bearing can move with respect to the underlying tibial component. The broad range of kinematic patterns seen in mobile bearing knees could be explained by the absence of motion or occurrence of erratic motion of the polyethylene bearing. This will enhance wear of the polyethylene surface and could induce more aseptic loosening (Garling et al., 2005). For this reason, it is important to evaluate the motions of the polyethylene bearing over a substantial period of time.

Study objective

The primary objective is the assessment of the in vivo kinematic patterns of a mobile bearing knee prosthesis (ROCC, Biomet Europe BV, The Netherlands) over time by means of fluoroscopy and to evaluate if the polyethylene bearing is rotating.

The secondary objective will be to evaluate if there is micromotion of the prosthesis with respect to the bone and if it changes over time.

The last objective will be to compare the kinematic patterns found by fluoroscopy of the mobile bearing knee prosthesis with the kinematic patterns found by external movement registration.

Study design

Evaluations will be performed at 6, 12 and 24 months post-operative. At 0 months a RSA examination will be performed.

Post operative evaluation will consist of:
•Age, gender, length, weight, affection, side TKA
•RSA assessment
•Performing tasks (fluoroscopy, external movement registration, ground reaction forces and EMG)
•Questionnaires: Womac, Knee Society Score, Rand-36
•Post-operative procedure information (physiotherapy (how long and how much, when totally loaded)

Study burden and risks

Burden
•3 questionnaires (Knee Society Score, Womac, Rand-36)
•Fluoroscopic assessment
•RSA assessment
•EMG measurements will be performed for eight muscles. For this reason, two electrodes are placed on the subject for each muscle.

•External movement registration will be performed. For this reason, a cluster of three LED*s will be placed on several segments (foot, lower leg, upper leg, pelvis and trunk).

The subject is asked to perform two tasks (step-up task and lunge movement). During these tasks, EMG, ground reaction forces and segment angels are measured synchronised with fluoroscopic images. The burden for the subjects during this study will not be different with respect to normal daily activities.

Potential risks
The effective radiation dose per RSA-radiograph is 3 µSv. For fluoroscopy, a follow up consisting of three fluoroscopic sessions (involving each 3 trials × 2 tasks × 3 seconds of 15 fps imaging) the cumulative effective dose will be 0.06 mSv. The total effective radiation dose for this protocol is estimated on 0.07 mSv. The additional annual radiation dose is negligible if the natural annual exposure of 2 mSv is considered and will do the subject no harm.

The International Commission on Radiological Protection categorizes the corresponding level of risk qualitative due to radiation as *trivial* with a quantitative risk of about one in a million or less. The required level of benefit should be related to *only increase knowledge*. (http://ec.europa.eu/energy/nuclear/radioprotection/publication/099_en.htm)

Other potential risks are risks associated with normal knee replacements such as infection, migration, bone loss, pain, loosening of components, metal sensitivity reactions and tromboembolic complications.

Potential benefits
While the patients participating in this study may not directly derive any immediate benefits, the results of the study should improve the understanding of knee prostheses. This information will be extremely useful in optimizing total knee prosthesis implant designs and improve long-term results.

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

Patients:
•Patient is diagnosed with osteoarthritis and requiring primary arthroplasty
•Patient is capable of giving informed consent and expressing a willingness to comply with this study
•Patient has no major deformities
•The ability to perform a lunge and step-up motion without the help of bars or a cane.
•No or slight pain during activity according to the Knee Society Pain Score (Ewald, 1989; Insall et al., 1989);Control group:
•The subject has no functional impairment of a lower extremity joint
•Subject is capable of giving informed consent and expressing a willingness to comply with this study

Exclusion criteria

Patients:
•The patient is unable or unwilling to sign the Informed Consent specific to this study
•The individual has a functional impairment of any other lower extremity joint besides the operated knee
•Patient has a flexion contracture of more than 15°
•Patient has a varus/valgus contracture of more than 15°
•Patients requiring revision arthroplasty
•The patient does not understand the Dutch or English language good enough to participate.
•The use of walking aids

•The inability to walk more than 500 meters;Control group:
•The subject has a functional impairment of a lower extremity joint
•The subject is unable or unwilling to sign the Informed Consent specific to this study
•The subject does not understand the Dutch or English language good enough to participate

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL14060.058.07