Fluoroscopic evaluation of the Duracon 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-OMON31983

Source
ToetsingOnline

Brief title
Dura

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: DeSSOS IST- 2004-27252

Intervention

Keyword: Fluoroscopy, Kinematics, Total knee prosthesis

Outcome measures

Primary outcome

Kinematic patterns: segment angels

EMG: muscle activation and coordination

Secondary outcome

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Study description

Background summary

Three-dimensional (3D) fluoroscopic analysis is the most accurate measurement technique to examine the in vivo kinematics of TKR (Banks et al., 1997; Dennis et al., 1996; Dennis et al., 1998a; Garling et al., 2005; Stiehl et al., 1999).
The position and orientation of 3D computer models of total knee components are manipulated so that their projections on the image match those captured during the in vivo knee motion (Garling et al., 2002; Kaptein et al., 2006).

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).

The kinematics are determined by the design of the implant, particularly the geometry of the articulating surfaces, the alignment of the components with respect to the bone and to each other, and of the surrounding soft tissue (Dennis et al., 1998b; Karrholm et al., 1994). Because of the influences of the prosthesis design, it is important to asses the in vivo characteristics and functional adaptations of the design following TKR (Banks and Hodge, 2004;

Banks et al., 1997; Taylor et al., 2003).

Study objective

The goal of this study is to perform a kinematic evaluation of the Duracon knee prosthesis (Stryker, USA), by means of fluoroscopy and EMG. The findings of this study will contribute to improve total knee designs and improve rehabilitation strategies.

Study design

1 year post-operative patients will be evaluated with fluoroscopy and EMG. Also, patients are asked to fill in several questionnaires.

Study burden and risks

For fluoroscopy the cumulative effective dose will be 0.02 mSv (3 trials × 2 tasks × 3 seconds of 15 fps imaging). 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.

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

•Patient has already an implanted fixed bearing Duracon knee prosthesis (1 year postoperative)
•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).
•No symptoms / complaints from the other lower extremity joints which might interfer with ambulation.

Exclusion criteria

•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 15° and more
•Patient has a varus/valgus contracture of 15° and more
•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

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	10
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	NL19737.058.07