Femoral component rotation in patellofemoral joint replacement.

No registrations found.

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

Summary

ID

NL-OMON22282

Source Nationaal Trial Register

Health condition

Isolated patellofemoral osteoarthritis.

Sponsors and support

Primary sponsor: Department of Orthopedic surgery Deventer Ziekenhuis Postbus 5001 7400 GC Deventer THE NETHERLANDS

Intervention

Outcome measures

Primary outcome

CT-based femoral component rotation expressed in degrees of rotation relative to the transepicondylar axis (where a positive value denotes external rotation).

Secondary outcome

Clinical outcomes at 1-year follow-up as assessed with the patient reported KOOS questionnaire (Knee injury and Osteoarthritis Outcome Score).

Study description

Background summary

Patellofemoral joint replacement is a successful treatment option for isolated patellofemoral osteoarthritis. The short and mid-term outcomes are related to malposition and unexplained pain.

The 'Zimmer Gender-Solutions Patello-Femoral Joint (PFJ) System' is a third generation, asymmetrical patellofemoral joint prosthesis. The surgical technique is highly reproducible although assessment of correct rotational alignment remains difficult. The 'Surgical Technique' brochure suggests using Whiteside's line or the transepicondylar axis. In practice the lower leg axis as described by Clark et al. is used (Clark et al. 2012).

At present, no studies have been performed that demonstrate the actual amount of rotation achieved with the Zimmer prosthesis or other prosthetic designs. Considering the importance of avoiding malposition, further study is needed.

We hypothesize that the CT-based (actual) femoral component rotation is 3 to 6 degrees external relative to the transepicondylar axis. Furthermore, we hypothesize that the short-term (less than 2 years) clinical outcomes of the Zimmer patellofemoral prosthesis are related to the actual amount of femoral component rotation.

Study objective

(1) When using the lower leg axis as a reference, the CT-based femoral component rotation with Zimmer Gender-Solutions patellofemoral joint replacement is 3 to 6 degrees external relative to the transepicondylar axis.

(2) The short-term (less than 2 years) clinical outcomes of Zimmer patellofemoral joint replacement are related to the actual amount of femoral component rotation.

Study design

(1) Preoperative: clinical (KOOS) and radiological assessment, screening, informed consent;

- (2) Patellofemoral joint replacement;
- (3) 1-3 days post-surgery: CT assessment of femoral component rotation;
- (4) 1 year post-surgery: clinical (KOOS) and radiological assessment.

Intervention

Zimmer Gender-Solutions patellofemoral joint replacement.

Contacts

Public

Department of Orthopaedic surgery Deventer Ziekenhuis Postbus 5001

Hans-Peter W. Jonbergen, van Deventer 7400 GC The Netherlands **Scientific** Department of Orthopaedic surgery Deventer Ziekenhuis Postbus 5001

Hans-Peter W. Jonbergen, van Deventer 7400 GC The Netherlands

Eligibility criteria

Inclusion criteria

- (1) Isolated patellofemoral osteoarthritis;
- (2) Informed consent for the surgical procedure;
- (3) Signed informed consent for the study.

Exclusion criteria

(1) Contra-indication for joint replacement surgery in general (pregnancy, active infection, severe cardiac and respiratory comorbidities);

(2) Previous distal femoral fracture resulting in an altered anatomy.

3 - Femoral component rotation in patellofemoral joint replacement. 14-05-2025

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2013
Enrollment:	40
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	22-09-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39527 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4003
NTR-old	NTR4175
ССМО	NL42639.075.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39527

Study results

Summary results

N/A