Femoral component rotation in patellofemoral joint replacement.

Gepubliceerd: 22-09-2013 Laatst bijgewerkt: 15-05-2024

(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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22282

Bron
Nationaal Trial Register

Aandoening

Isolated patellofemoral osteoarthritis.

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

(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.

Onderzoeksopzet

(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.

Onderzoeksproduct en/of interventie

Zimmer Gender-Solutions patellofemoral joint replacement.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(1) Isolated patellofemoral osteoarthritis;

(2) Informed consent for the surgical procedure;

(3) Signed informed consent for the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

(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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2013
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-09-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39527
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A