Fixation of the Simpliciti stemless humeral component, a radio-steophotogrammatic analysis

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The Simpliciti stemless humeral component is a stable implant with minimal translation, rotation and micromotion.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26001

Bron
Nationaal Trial Register

Verkorte titel
Simpliciti RSA

Aandoening

Shoulder osteoarthritis, Arthroplasty, Prosthesis, implant technical complications, Radio Stereometric Analysis

Ondersteuning

Primaire sponsor: Department of orthopaedic surgery, Reinier de Graaf Groep
Overige ondersteuning: Tornier, France

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is:
- fixation and migration of the Simplicti (Tornier, France) stemless humeral component in vivo using model based radiostereophotogrammetric (mRSA) analysis.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Shoulder arthroplasty has traditionally been designed as a stemmed device relying on intramedullary fixation for its stability. Unfortunately drawbacks in stemmed arthroplasty devices are caused by stress-shielding, stress risers, fractures and the need for modularity due to variable anatomy. Therefore, in shoulder arthroplasty short stem devices are developed. It has been proven that the fixation of the humeral component is not compromised due to a shorter stem. However, a reduced area of fixation, like the stemless design, can hypothetically show compromised fixation in the initial or long term. To quantify motion of a stemless design Roentgen Stereometric Analysis (RSA) can be used. In this study, we will identify the fixation and migration patterns of the Simpliciti (Tornier, France) stemless humeral component using RSA.

Objective:

Identifying the fixation and migration patterns of the Simpliciti (Tornier, France) stem less humeral component in vivo, using model based radiostereophotogrammetric (mRSA) analysis.
Evaluating the short and midterm clinical results (NRS for pain, range of motion, Constant score, SF-12, Dash and radiographs).

Study design:

We will perform a prospective cohort study in which 25 patient from Reinier de Graaf Hospital, Delft, The Netherlands, will be enrolled. Patients will be evaluated preoperatively, during hospital stay within the first week postoperatively, at 6 weeks, 6 months, 1 year and after 2 years.

Study population:

The study population will consist of 25 patients aged 45
years and older, with a BMI<35. The subjects will have no clinical relevant disorders of the shoulder and they will undergo a primary shoulder replacement after diagnosis of osteoarthritis, traumatic osteoarthritis, rheumatoid arthritis or avascular necrosis of the humeral head.

Main study parameters/endpoints:

Outcome will be clinically measured using the NRS for pain, Constant score, Oxford shoulderscore,
SF-12 and DASH score, whilst radiographic outcomes will be evaluated through standard radiographic parameters. RSA will be used to measure stem migration.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Subjects participating in the study will have the same risks and benefits when not participating in the study. Follow-up times are standard protocol evaluations of the prosthesis. Besides standard follow-up, RSA x-rays will be made to measure the fixation.

Doel van het onderzoek

The Simpliciti stemless humeral component is a stable implant with minimal translation, rotation and micromotion.

Onderzoeksopzet

- Preoperative

- During hospital stay

- 6 weeks postoperative

- 6 months postoperative

- 1 year postoperative

- 2 years postoperative

Onderzoeksproduct en/of interventie

Placement of the Simpliciti stemless humeral component prosthesis, with insertion of tantalum beads for radiosteraophotogrammetric analysis (RSA).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Aged 45 years and older.

- Patients willing to participate.

- Speaking and writing Dutch language.

- Patients with either osteoarthritis, traumatic arthritis, rheumatoid arthritis of the glenohumeral joint or necrosis of the humeral head.

- Indication for shoulder replacement (Larsen grade 4 or 5, invalidating pain).

- Patients able to provide written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Patients with osteonecrosis (except the necrosis of the humeral head), fractures, (post-)septic arthritis, instability.

- Patients with BMI > 35.

- Any active infection.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	10-11-2017

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6632
NTR-old	NTR6809
Ander register	METC Zuidwest Holland : 13-092

Resultaten