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

Published: 21-02-2014
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Primary objective:Identifying the fixation and migration patterns of the Simplicity (Tornier, France) stem less humeral component in vivo, using model based radiostereophotogrammetric (mRSA) analysis.Secondary objective:To evaluate the mid and long…

Ethical review	Approved WMO
Status	Completed
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON50468

Source
ToetsingOnline

Brief title
Simpliciti study

Condition

- Bone and joint therapeutic procedures

Synonym
shoulder prosthesis, Shoulder wear/artritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Tornier,Tornier;France

Intervention

Keyword: RSA, Shoulder, Simplicity stemless humeral component

Outcome measures

Primary outcome

fixation and migration patterns of the Simplicity (Tornier, France) stemless humeral component in vivo using model based radiostereophotogrammetric (mRSA) analysis

Secondary outcome

To evaluate the mid and long term clinical results (NRS for pain, Range of motion, Constant score, SF-12, Dash, Oxford Shoulder score and radiographs) in an on-going follow-up, and correlate the clinical results to the RSA migration data.

Study description

Background summary

In shoulder arthroplasty the use of Roentgen Stereometric Analysis (RSA), a highly accurate three dimensional method to quantify the motion between an implant and the host bone (Selvik 1989), is rare. Shoulder arthroplasty has traditionally been designed as a stemmed device relying on intramedullary fixation for its stability. Unfortunately drawbacks in stemmed arthoplasty devices are caused by stress-shielding1, stress risers, fractures and the need for modularity due to variable anatomy. Therefore, in shoulder arthroplasty short stem devices are developed. These short stem devices have been proven that fixation of the humeral component is not compromised due to a shorter stem (2). However, a reduced area of fixation, like the stemless design, can hypothetically show compromised fixation in the initial or long term. To quantify if motion between a stemless design and the host bone occurs Roentgen Stereometric Analysis (RSA) can be used.
RSA is a highly accurate, three dimensional method to quantify the motion between an implant and the host bone (Selvik 1989). Since its introduction RSA have been widely used in the assessment of hip en knee joint replacements.

Using RSA the risk of implanting potentially inferior prostheses will be reduced, resulting in better implants used in patients that needs arthoplasty. In the assessment of RSA spherical tantalum markers are inserted into the bone. Two radiographs are taken simultaneously for precise 3D determination of the tantalum markers and the implant. The radiographs are then analysed by RSA software by computer. Using reference markers, relative translations, rotations and micromotion of the implant can be exactly measured.
In this study, we identify the fixation and migration patterns of the Simplicity (Tornier, France) stemless humeral component using RSA. The Simplicity stemless humeral design has already clinically been proven to be promising design. Using RSA we can accurately and quantitative evaluate this implant design and micromotion of the stemless component in patients that needs shoulder arthroplasty. We hypothesise that the simplicity stemless humeral component is a stable implant with minimal translation, rotation and micromotion.

Study objective

Primary objective:
Identifying the fixation and migration patterns of the Simplicity (Tornier, France) stem less humeral component in vivo, using model based radiostereophotogrammetric (mRSA) analysis.

Secondary objective:
To evaluate the mid and long term clinical results (NRS for pain, Range of motion, Constant score, SF-36, Dash and radiographs) in an on-going follow-up, and correlate the clinical results to the RSA migration data.

Study design

Monocenter Prospective Cohort study
Participating centers / groups:
- Reinier de Graaf gasthuis (Delft, the Netherlands

Intervention

The Simpliciti shoulder prosthesis used in primary total shoulder arthroplasty.

Study burden and risks

no risks nor burden associated with participation. Non applicable. see section 5.2 METC protocol.

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

• 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

Exclusion criteria

•Patients with osteonecrosis (except the necrosis of the humeral head),

fractures, (post-)septic arthritis, instability.
•Patients with BMI>35
•Any active infection

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	20-03-2014
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Simpliciti stemless humeral component
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-02-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	07-08-2015
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	26-08-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	24-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	13-06-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-11-2024
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL45412.098.13