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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON26001

**Source**
Nationaal Trial Register

**Brief title**
Simpliciti RSA

**Health condition**

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

### Sponsors and support

**Primary sponsor:** Department of orthopaedic surgery, Reinier de Graaf Groep
**Source(s) of monetary or material Support:** Tornier, France

### Intervention

### Outcome measures

**Primary outcome**

The primary outcome is:

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

**Secondary outcome**

The secondary parameters are:

- To evaluate the mid and long term clinical results in an on-going follow-up, and correlate the clinical results to the RSA migration data. The clinical results will be measured by: NRS for pain, Range of Motion, Constant Score, SF-12, DASH, Oxford Schoulder Score and radiographs.

# Study description

**Background summary**

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.

**Study objective**

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

**Study design**

- Preoperative

- During hospital stay

- 6 weeks postoperative

- 6 months postoperative

- 1 year postoperative

- 2 years postoperative

**Intervention**

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

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

### Exclusion criteria

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.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |

**Control:** N/A , unknown

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2014 |
| Enrollment: | 25 |
| Type: | Actual |

### IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

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|---|---|
| Date: | 10-11-2017 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL6632 |
| NTR-old | NTR6809 |
| Other | METC Zuidwest Holland : 13-092 |

# Study results