Comparison of Zimmer Maxera Acetabular System to the Allofit Cup with Roentgen Stereophotogrammetric Analysis (RSA) in Total Hip Arthroplasty

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The clinical results, radiographic outcomes, implant survival, overall pain and functional performances of the Maxera Cup are equal to the Allofit Cup, up to ten years of follow-up.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON26837

Source
NTR

Brief title
Maxera RSA

Condition

- Joint disorders

Health condition

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

Research involving
Human

Sponsors and support

Primary sponsor: Department of orthopaedics, Reinier de Graaf Groep
Source(s) of monetary or material Support: Zimmer Biomet

Intervention

- Surigical procedure

Explanation

Outcome measures

Primary outcome

Cup migration, measured with RSA, is the primary outcome of this study.

Secondary outcome

Outcome will be clinically measured using Harris Hip Score (HHS), Oxford Hip Score (OHS) and EQ-5D, whilst radiographic outcomes will be evaluated through standard radiographic parameters which include qualitative femoral and acetabular findings as well as position of the stem and cup.

Study description

Background summary

Rationale:

The Maxera Cup provides a large-head, ceramic-on-ceramic option for the younger and more active patient. The cup is an established hemispherical design. It is a cup system that offers high range of motion and a low-wear bearing to better enable the restoration of a patient¡¯s active lifestyle. The wear rates for Biolox delta material have been confirmed in vitro by hip simulator tests.

By mixing Zirconia and other oxide additives into the Alumina matrix, a composite is created that results in a significant reduction of the ceramic femoral head fracture rate. Nowadays the risk of poor performing survival over time should be limited to the max. The only clinical test that can provide data to predict long survival is stability testing with RSA. As a result, the risk of implanting potentially inferior prostheses in patients will be reduced, resulting in less suffering for patients and a reduction in healthcare expenses.

It is hypothesized that the clinical results, radiographic outcomes, implant survival, overall

pain and functional performances of the Maxera Cup are equal to the Allofit Cup, up to ten years of follow-up.

Objective:

To perform a comparative assessment between the clinical and radiographic outcomes (as measured with RSA) of the Maxera Ceramic cup versus the standard uncemented polyethylene Allofit Cup all combined with the ML Taper stem in patients undergoing primary uncemented THA over a period of 10 years (primary objective is stability over 2 years). All complications will be documented.

Study design:

A prospective randomised clinical trial in which 50 cases (25 vs. 25) will be enrolled over one hospital. The primary components to be implanted are an uncemented ML Taper stem combined with the uncemented Maxera or Allofit cup cup. All patients will have a Ceramic head. Patients will be evaluated preoperatively and postoperatively at discharge (from operation date to date of discharge), at 6 weeks, 3 months, 6 months,1 year, 2 years, 5 years, 7 years and 10 years. The 7 years follow up will be without RSA.

Study population:

The study population consists of active male or non-pregnant female 18-75 years of age, with a QI <35. The subjects have no clinical relevant disorders of the hip and they undergo a primary total hip replacement by dr. Bloem, after diagnosis of osteoarthritis or avascular necrosis.

Intervention (if applicable):

Placement of an uncemented Maxera® or Allofit® cup in combination with an uncemented ML Taper stem®.

Main study parameters/endpoints:

Outcome will be clinically measured using the Harris Hip Score (HHS), Oxford Hip score (OHS) and EQ5-D, whilst radiographic outcomes will be evaluated through standard radiographic parameters which include qualitative femoral and acetabular findings as well as position of

the stem and cup. RSA will be used to measure cup migration.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Subjects participating in the study have the same risks and benefits when not participating in the study. All components used in the study have CE mark and are already in use. Follow-up times are standard protocol evaluations of prosthesis in our clinic. Besides standard radiological follow-up, RSA x-rays will be made to measure the fixation of the cup.

Study objective

The clinical results, radiographic outcomes, implant survival, overall pain and functional performances of the Maxera Cup are equal to the Allofit Cup, up to ten years of follow-up.

Study design

- Preoperative

- Postoperative before discharge

- 6 weeks postoperative

- 3 months postoperative

- 6 months postoperative

- 1 year postoperative

- 2 years postoperative

- 5 years postoperative

- 10 years postoperative

Intervention

Placement of an uncemented Maxera or Allofit cup in combination with an uncemented ML Taper stem.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

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

- Male and non-pregnant females: ≤ 75 years

- Patients with a Quetelet index (QI=weight (kilogram)/square length (meters)) < 35.

- Patients requiring primary THR, suitable for the use of the Maxera Cup and Allofit Cup.

- The patient is diagnosed with osteoarthritis (OA) or avascular necrosis.

- The individual is physically and mentally willing and able to comply with postoperative functional evaluation and able to participate in an appropriate rehabilitation schedule.

- ASA classification score I-III.

- Patients who signed the Ethics Committee approved specific Informed Consent Form prior to surgery.

Exclusion criteria

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

- Patients who had a THA on contralateral side more than 6 months ago and the rehabilitation period outcome is considered unstatisfactory or not good. (Patients with contralateral THA > 6 months ago with good outcome (Harris Hip Score > 85) can be included in the study).

- Patients who had a THA on contralateral side less than 6 months ago.

- Patients with a major surgical procedure during the 12 weeks before the study related operation.

- Dutch language not mastered.

- The patient is unwilling to cooperate with the study.

- The patient is pregnant or desired to be pregnant after surgery or is using inadequate birth control.

- Recent Myocardial infarct or CVA (< 3 months).

- Mentally disabled patients.

- Patients with a Quetelet index (QI=weight (kilogram)/square length (meters)) > 35.

- Any active infection.

- Current malignancy.

- Uncontrolled hypertension.

- Known history of alcohol or drug abuse.

- ASA IV-V

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2015
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Approved WMO

Date:	14-10-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 53013
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6594
NTR-old	NTR6811
CCMO	NL47440.098.14
OMON	NL-OMON53013

Study results