

Vergelijken van het Zimmer Maxera Acetabulair Systeem met de Allofit Cup met RoentgenStereophotogrammetric Analysis (RSA) in Totale Heup Arthroplastiek

Gepubliceerd: 10-11-2017 Laatste bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Gewrichtsaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26837

Bron

NTR

Verkorte titel

Maxera RSA

Aandoening

- Gewrichtsaandoeningen

Aandoening

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

Betreft onderzoek met

Mensen

Ondersteuning

Primaire sponsor: Department of orthopaedics, Reinier de Graaf Groep

Overige ondersteuning: Zimmer Biomet

Onderzoeksproduct en/of interventie

- Chirurgische ingreep

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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. 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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

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Contactpersonen

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Deelname eisen

Leeftijd

Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

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:

- Male and non-pregnant females: ≤ 75 years
- Patients with a Quetelet index ($QI = \text{weight (kilogram)} / \text{square length (meters)}^2$) < 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.

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 who had a THA on contralateral side more than 6 months ago and the rehabilitation period outcome is considered unsatisfactory 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 ($QI = \text{weight (kilogram)} / \text{square length (meters)}^2$) > 35.
- Any active infection.
- Current malignancy.
- Uncontrolled hypertension.
- Known history of alcohol or drug abuse.
- ASA IV-V

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Behandeling / therapie

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	12-05-2015
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Goedgekeurd WMO	
Datum:	14-10-2014
Soort:	Eerste indiening
Toetsingscommissie:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53013

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten